Hendrickson Gary E
Form 4
October 05, 2011

FORM 4

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

STATEMENT OF CHANGES IN BENEFICIAL OWNERSHIP OF SECURITIES

Filed pursuant to Section 16(a) of the Securities Exchange Act of 1934, Section 17(a) of the Public Utility Holding Company Act of 1935 or Section 30(h) of the Investment Company Act of 1940

OMB APPROVAL

OMB Number:	3235-0287
Expires:	January 31, 2005
Estimated average burden hours per response...	0.5

Check this box if no longer subject to Section 16. Form 4 or Form 5 obligations may continue. *See* Instruction 1(b).

(Print or Type Responses)

1. Name and Address of Reporting Person *
Hendrickson Gary E

(Last) (First) (Middle)

2100 HIGHWAY 55

(Street)

MEDINA, MN 55340

(City) (State) (Zip)

2. Issuer Name **and** Ticker or Trading Symbol
POLARIS INDUSTRIES INC/MN [PII]

3. Date of Earliest Transaction (Month/Day/Year)
10/03/2011

4. If Amendment, Date Original Filed(Month/Day/Year)

5. Relationship of Reporting Person(s) to Issuer
(Check all applicable)

__X__ Director _____ 10% Owner
_____ Officer (give title below) _____ Other (specify below)

6. Individual or Joint/Group Filing(Check Applicable Line)
_X_ Form filed by One Reporting Person
___ Form filed by More than One Reporting Person

Table I - Non-Derivative Securities Acquired, Disposed of, or Beneficially Owned

1.Title of Security (Instr. 3)	2. Transaction Date (Month/Day/Year)	2A. Deemed Execution Date, if any (Month/Day/Year)	3. Transaction Code (Instr. 8)		4. Securities Acquired (A) or Disposed of (D) (Instr. 3, 4 and 5)			5. Amount of Securities Beneficially Owned Following Reported Transaction(s) (Instr. 3 and 4)	6. Ownership Form: Direct (D) or Indirect (I) (Instr. 4)	7. Nature of Indirect Beneficial Ownership (Instr. 4)
			Code	V	Amount	(A) or (D)	Price			

Reminder: Report on a separate line for each class of securities beneficially owned directly or indirectly.

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SEC 1474 (9-02)

Table II - Derivative Securities Acquired, Disposed of, or Beneficially Owned
(*e.g.*, puts, calls, warrants, options, convertible securities)

1. Title of Derivative Security	2. Conversion or Exercise	3. Transaction Date (Month/Day/Year)	3A. Deemed Execution Date, if any	4. Transaction Code	5. Number of Derivative Securities	6. Date Exercisable and Expiration Date (Month/Day/Year)	7. Title and Amount of Underlying Securities (Instr. 3 and 4)	8. Pr Deriv Secu

(Instr. 3)	Price of Derivative Security	(Month/Day/Year)	(Instr. 8)	Acquired (A) or Disposed of (D) (Instr. 3, 4, and 5)							(Instr
			Code	V	(A)	(D)	Date Exercisable	Expiration Date	Title	Amount or Number of Shares	
CSE (1)	(2)	10/03/2011	A		293.33		(1)	(1)	Common Stock	293.33	$ 4

Reporting Owners

Reporting Owner Name / Address	Relationships			
	Director	10% Owner	Officer	Other
Hendrickson Gary E 2100 HIGHWAY 55 MEDINA, MN 55340	X			

Signatures

Jennifer Carbert, Attorney-in-Fact	10/05/2011
**Signature of Reporting Person	Date

Explanation of Responses:

***** If the form is filed by more than one reporting person, *see* Instruction 4(b)(v).

****** Intentional misstatements or omissions of facts constitute Federal Criminal Violations. *See* 18 U.S.C. 1001 and 15 U.S.C. 78ff(a).

(1) Common Stock Equivalents (CSE) are credited to director accounts under the Company's Deferred Compensation Plan for Non-Employee Directors. The Plan has been approved by a vote of shareholders. Upon termination of his/her services, a Director is entitled to receive one share of common stock for each CSE earned.

(2) 1 for 1 conversion

(3) Includes 1.98 CSEs acquired pursuant to a dividend reinvestment feature of the Plan.

(4) Amount has been adjusted pursuant to a two-for-one stock split effected on September 12, 2011.

Note: File three copies of this Form, one of which must be manually signed. If space is insufficient, *see* Instruction 6 for procedure.
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Emerging growth company o
If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 7(a)(2)(B) of the Securities Act.
Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ¨ No ý
The aggregate market value of the registrant’s common stock held by non-affiliates of the registrant was $22,262,043,858 as of June 29, 2018 based on the closing sale price of the registrant’s common stock on the NASDAQ Global Market on such date. Shares held by persons who may be deemed affiliates have been excluded. This

determination of affiliate status is not necessarily a conclusive determination for other purposes.
On February 22, 2019, 79,989,347 shares of the registrant's common stock were outstanding.
DOCUMENTS INCORPORATED BY REFERENCE
Portions of the registrant's definitive Proxy Statement relating to its 2019 Annual Stockholders' Meeting to be filed pursuant to Regulation 14A within 120 days after the registrant's fiscal year end of December 31, 2018 are incorporated by reference into Part III of this Annual Report on Form 10-K.

ALIGN TECHNOLOGY, INC.
FORM 10-K
For the Year Ended December 31, 2018
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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 regarding the anticipated impact of our new products and product enhancements will have on doctor utilization and our market share, our expectations regarding product mix and product adoption, our expectations regarding the existence and impact of seasonality, our expectations regarding the sales growth of our intra-oral scanner sales in international markets, our expectations regarding the financial and strategic benefits of establishing regional order acquisition, treatment planning and manufacturing facilities, our intention to hire more sales representatives in 2019 and their expected impact on our sales, our expectations regarding the continued expansion of our international markets, the anticipated impact of the Invisalign Experience program on demand creation, our expectation to incur additional costs related to the planned corporate structure reorganization, the level of our operating expenses and gross margins and other factors beyond our control, as well as other statements regarding our future operations, financial condition and prospects and business strategies. These statements may contain words such as “expects,” “anticipates,” “intends,” “plans,” “believes,” “estimates,” or other words indicating future res These forward-looking statements are subject to certain risks and uncertainties that could cause actual results to differ materially from those reflected in the forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in Item 2 “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 engaged in the design, manufacture and marketing of Invisalign® clear aligners and iTero® intraoral scanners and services for orthodontics, and restorative and aesthetic dentistry. Align’s products are intended primarily for the treatment of malocclusion or the misalignment of teeth and are designed to help dental professionals achieve the clinical outcomes that they expect. Align Technology was founded in March 1997 and incorporated in Delaware in April 1997. Our corporate headquarters is located at 2820 Orchard Parkway, San Jose, California, U.S.A., 95134, and our telephone number is 408-470-1000. Our internet address is www.aligntech.com. Our Americas regional headquarters is located in Raleigh, North Carolina; our European regional headquarters is located in Amsterdam, the Netherlands; and our Asia Pacific regional headquarters is located in Singapore.

We have two operating segments: (1) Clear Aligner and (2) Scanners and Services ("Scanner"). For the year ended December 31, 2018, Clear Aligner net revenues represent approximately 86% of worldwide net revenues, while Scanner net revenues represent the remaining 14% of worldwide net revenues. We sell the vast majority of our products directly to our customers: orthodontists and general practitioner dentists ("GPs"), as well as to restorative and aesthetic dentists, including prosthodontists, periodontists, and oral surgeons. 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 directly to dental laboratories who manufacture or customize a variety of products to assist in the provision of oral health care by a licensed dentist. Our Clear Aligner operating segment includes revenues from non-Invisalign aligners supplied to SmileDirectClub, LLC ("SDC"). Refer to "Supply Agreement with SmileDirectClub, LLC" section.

We received 510(k) clearance from the United States Food and Drug Administration (“FDA”) to market the Invisalign System in 1998. The Invisalign System is regulated by the FDA as a Class II medical device. In order to provide Invisalign treatment to their patients, orthodontists and GPs must initially complete an Invisalign training course. The

Invisalign System is sold primarily through a direct sales force in North America, Asia Pacific ("APAC"), Europe, Middle East and Africa (EMEA) and Latin America. To date, over 6.1 million people worldwide have been treated with our Invisalign System.

Our iTero scanner is used by dental professionals and/or labs and service providers for restorative and orthodontic digital procedures as well as Invisalign case submission. We received 510(k) clearance from the FDA to market iTero software for expanded indications in 2013. Scanners and computer-aided design/computer-aided manufacturing ("CAD/CAM") services are primarily sold through our direct sales force and a few distributors in North America, Europe and certain Asia Pacific countries, and through distribution partners in smaller non-core international country markets.

Clear Aligner Segment

Malocclusion and Traditional Orthodontic Treatment

Malocclusion, or the misalignment of teeth, is one of the most prevalent clinical dental conditions, affecting billions of people, or approximately 60% to 75% of the population. Annually, approximately 12 million people in major developed countries elect treatment by orthodontists worldwide. Most orthodontic patients are treated with the use of traditional methods such as metal arch wires and brackets, referred to as braces, and may be augmented with elastics, metal expanders, headgear or functional appliances, and other ancillary devices as needed. Upon completion of the treatment, the dental professional may, at his or her discretion, have the patient use a retainer appliance. Of the 12 million annual orthodontic cases started, approximately 75% or 8.4 million are applicable to Invisalign treatment our served market. In addition, approximately 300 million people with malocclusion could benefit from straightening their teeth but are unlikely to seek treatment through a doctor’s office. This represents an incremental opportunity for us as we expand the market for orthodontics by educating more consumers about the benefits of straighter teeth using Invisalign clear aligners and connect them with an Invisalign 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 plastic, removable aligners. The Invisalign System offers a range of treatment options, specialized services, and proprietary software for treatment visualization and is comprised of the following phases:

Orthodontic diagnosis and transmission of treatment data to us. The Invisalign-trained dental professional prepares and sends us a patient’s treatment data package which consists of a prescription form, a digital scan or a polyvinyl-siloxane (or "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 either Align's iTero scanner or a few qualified third-party scanners. See "Third Party Scanners and Digital scans for Invisalign treatment submission." More than 63% of Invisalign case submissions are submitted via digital scan instead of a physical PVS impression.

Preparation of computer-simulated treatment plan. Using propriety software which we do not sell, we generate a proposed custom, three-dimensional treatment plan, called a ClinCheck treatment plan. The ClinCheck treatment plan simulates appropriate tooth movement in stages and details timing and placement of any features or attachments that will 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 effect 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 the Invisalign Doctor Site which enables the dental professional to project tooth movement with a level of accuracy not previously possible with metal arch wires and brackets. By reviewing, modifying as needed and approving the treatment plan, the dental professional retains control over the treatment plan.

Manufacture of custom aligners. Upon the dental professional’s approval of the ClinCheck treatment plan, we use the data underlying the simulation, in conjunction with 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 plastic, removable dental appliances that are custom manufactured in a series to correspond to each stage of the ClinCheck treatment plan.

Shipment to the dental professional and patient aligner wear. All the aligners for a patient are shipped directly to the dental professional, who then dispenses them to the patient at regular check-up intervals throughout the treatment. Aligners are generally worn for a period of time which correspond to the stages of the approved ClinCheck treatment plan. The patient replaces the aligners with the next pair in the series when prescribed, advancing tooth movement with each aligner stage. Throughout treatment, the doctor may place attachments or use other auxiliaries to achieve desired tooth movements, per the doctor's original prescription and resulting ClinCheck treatment plan. In October 2016, we introduced one-week aligner wear. At the treating doctor's discretion, weekly aligner changes are recommended for all Invisalign treatments for Invisalign Comprehensive, Invisalign First Comprehensive, Invisalign Lite, Invisalign Assist and Invisalign Go packages, thereby reducing treatment time by up to 50% compared to two week aligner wear.

Additional aligners. Should the dental professional determine that the treatment is not tracking for various reasons, such as patient compliance, certain teeth movement not tracking to plan, or they need to extend the treatment a few stages further to

achieve their treatment goals, the dental professional can request additional aligners at any point during the treatment, subject to certain requirements in our terms and conditions.

Clear Aligner Products

Comprehensive Products - Invisalign Treatment Options:

Invisalign Comprehensive. Invisalign Comprehensive Package replaces both Invisalign Full and Invisalign Teen treatments and includes the Mandibular Advancement feature launched in March 2017. Used for a wide range of malocclusion, the Invisalign Comprehensive treatment plans each consist of the number of aligners necessary to achieve the doctor's treatment goals. The Invisalign Comprehensive treatment includes all the features of Invisalign treatment, plus additional features that address the orthodontic needs of teenage patients such as compliance indicators, compensation for tooth eruption. Aligners for Invisalign Comprehensive treatments are manufactured and then delivered to the dental professionals in a single shipment. Invisalign Comprehensive Package is sold in the U.S., Canada and select international countries.

Invisalign Assist. Used for anterior alignment and aesthetically-oriented cases, the Invisalign Assist treatment offers added support to our dental practitioners throughout the treatment process, including progress tracking that allows the dental professional to submit new impressions every nine stages. When the progress tracking feature is selected, aligners are shipped to the dental professional after every nine stages thereby helping to achieve successful treatment outcomes. Predominantly marketed to GPs, Invisalign Assist is intended to make it easier to select appropriate cases for their experience level or treatment approach, submit cases more efficiently and manage appointments with suggested tasks. Invisalign Assist is sold in the U.S. and Canada.

Invisalign First Phase 1 and Invisalign First Comprehensive Phase 2 Package. Designed with features specifically for younger patients with early mixed dentition with a mixture of primary/baby and permanent teeth. Phase 1 treatment is early interceptive orthodontic treatment for young patients, traditionally done through arch expanders, or partial metal braces, before all permanent teeth have erupted - typically at ages 7 through 10 years. Invisalign First clear aligners are designed specifically to address a broad range of younger patients' malocclusions, including shorter clinical crowns, management of erupting dentition, and predictable dental arch expansion. Invisalign First clear aligners became commercially available to Invisalign-trained doctors in the U.S., Canada, Australia, New Zealand, Japan, and certain countries in the EMEA region as of July 1, 2018, and became available in Brazil in January 2019.

Non-Comprehensive Products - Invisalign Treatment Options:

Invisalign Express 10, Invisalign Express 5, Express Package and Lite Package. Lower-cost solutions are used for less complex orthodontic cases, non-comprehensive treatment relapse cases, or straightening prior to restorative or cosmetic treatments such as veneers. Invisalign Express 10, Invisalign Express 5 and Express Package use up to 10 sets, 5 sets and 7 sets of aligners, respectively. Invisalign Lite use up to 14 sets of aligners. Non-comprehensive products are available in select country markets and delivered to the dental professionals in a single shipment.

Invisalign Go. A simplified and streamlined solution designed for GPs to more easily identify and treat patients with mild malocclusion. Invisalign Go combines case assessment support, a simplified ClinCheck treatment plan and a progress assessment feature for case monitoring. Invisalign Go is available in select country markets.

Non-Case Products:

Clear Aligner non-case products include retention products, Invisalign training fees and sales of ancillary products, such as cleaning material and adjusting tools used by dental professionals during the course of treatment.

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. Vivera Retainers are available to both Invisalign and non-Invisalign patients. In select markets, we also offer single arch retainers.

Feature Enhancements

We have consistently introduced enhanced features across the Invisalign System over the past several years to improve treatment outcomes or address broader clinical indications.

Invisalign Comprehensive with Mandibular Advancement (launched in March 2017) is the first clear aligner solution for Class II correction in growing tween and teen patients. This new offering combines the benefits of our clear aligner system with

features for moving the lower jaw forward while simultaneously aligning the teeth without the need for elastics typically used to treat teen Class II patients. In 2017, it was available in Canada, core country markets in EMEA and certain country markets in APAC and Latin America. In October 2018, Invisalign Treatment with mandibular advancement was approved by the FDA and became commercially available in the U.S. in November 2018.

In November 2018, we introduced enhancements designed to improve clinical outcomes and user experience including: wing overlap and engagement in deep bite cases with anterior intrusion, new options to set up mandibular advancement cases beyond edge-to-edge, an option to prescribe symmetrical advancement of the left and right side, new default protocol of 2 mm incremental advancement, and improvements to support leveling the curve of Spee in deep bite cases.

SmartTrack™ Aligner Material

SmartTrack 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 energy in the initial days of aligner wear, but SmartTrack maintains more constant force over the period of time the patient wears the aligners. The flexible SmartTrack material also more precisely conforms to tooth morphology, attachments and interproximal spaces to improve control of tooth movement throughout treatment.

Non-Invisalign Aligners Supplied to SmileDirectClub, LLC:

SmileDirectClub Aligners. On July 25, 2016, we entered into a supply agreement with SmileDirectClub, LLC ("SDC") to manufacture non-Invisalign clear aligners for SDC's doctor-led, at-home program for simple teeth straightening. In October 2016, we became SDC's exclusive third-party supplier and began supplying aligners directly to SDC. SDC aligners include up to 20 stages without attachments or interproximal reduction ("IPR"). Align manufactures the aligners per SDC’s specifications for minor tooth movement using EX-30, a non-proprietary aligner material used prior to the introduction of SmartTrack aligner material. Align does not market or sell SDC products and ships supply of aligners directly to SDC when requested. While we are SDC's only third-party supplier, SDC also manufactures their own aligners. The supply agreement terminates by its terms December 31, 2019 and we do not intend on renewing it (Refer to Note 8 "Legal Proceedings" of the Notes to Consolidated Financial Statements for details on SDC dispute).

Scanner Segment

Intraoral scanning is an emerging technology that we believe will have substantial impact on the future of dentistry. By enabling the dental practitioner to create a 3D image of the patient's teeth (digital scan) using a handheld intraoral scanner inside the mouth, digital scanning is more efficient and precise and more comfortable for patients, compared to the discomfort and subjective nature of taking physical impressions. The digitally scanned model is more accurate than a physical impression and substantially reduces the rate of restoration "remakes" so patients are recalled less often and the appointment time for the restoration is shorter because of fewer adjustments which results in greater overall patient satisfaction. 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; orthodontic diagnosis; orthodontic retainers and appliances; and Invisalign digital impression submission.

iTero Scanner. The iTero Element scanner (launched in September 2015) is available as a single hardware platform with software options for restorative or orthodontic procedures. The expanded portfolio (launched in May 2018) includes the iTero Element 2 and the iTero element Flex scanners. These additions build on the existing high precision, full-color imaging and fast scan times of the iTero Element portfolio. The next-generation iTero Element 2

is designed for greater performance with 2X faster start-up and 25% faster scan processing time compared to the iTero Element. The iTero Element Flex is a wand-only device that transforms compatible laptop computers into a highly portable scanner that works anywhere - it's ideal for practices with multiple locations who need a scanner that is convenient and easy to transport. We market and sell the iTero Element in North America and in select international markets. iTero Element 2 and iTero Element Flex scanners are available in the U.S., Canada, the majority of European countries, including France, Germany, Italy, Spain, and the United Kingdom as well as select Asia Pacific markets. The iTero scanner is interoperable with our Invisalign treatment such that a full arch digital scan can be submitted as part of the Invisalign case submission process. In addition, the Invisalign Outcome Simulator and Invisalign Assessment tool are exclusive to the iTero scanner. Prior to the launch of iTero Element 2 and iTero Element Flex, we sold and continue to sell iTero Element and, prior to that, we sold the iTero 2.9 scanner. On February 18, 2019, we launched the iTero Element 5D Imaging system which provides a new comprehensive approach to clinical applications, workflows and user experience that expands the suite of existing high-precision, full-color imagining and fast scan times of the iTero Element portfolio. In addition to offering all of the features and functionality that doctors have come to expect and rely on with the iTero Element 2 scanner, the iTero

Element 5D scanner is the first integrated dental imaging system that simultaneously records 3D, intra-oral color and near-infrared ("NIRI") imaging and enables comparison over time using iTero TimeLapse. NIRI technology of the iTero Element 5D Imaging System aids in detection and monitoring of interproximal caries lesions above the gingiva without using harmful radiation. The iTero Element 5D Imaging System is commercially available now in Canada, European Union countries accepting CE-Marking (excluding Greece), Switzerland, Norway, Australia, New Zealand, Hong Kong and Thailand. It is not available in the U.S. or Latin America.

Restorative software for iTero. Software designed for GPs, prosthodontists, periodontists, and oral surgeons which includes restorative workflows providing them with the ability to send digital impressions to the lab of choice and communicate seamlessly with external treatment planning, custom implant abutment, chairside milling, and laboratory CAD/CAM systems.

Orthodontic software for iTero. Software designed for orthodontists for digital records storage, orthodontic diagnosis, and for the fabrication of printed models and retainers.

CAD/CAM Services and Ancillary Products

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 conducts then completes the ceramic buildup or staining and glazing and delivers the end result - a precisely fitting restoration. iTero prosthetics have a near-zero remake rate.

OrthoCAD iCast. iCast provides a digital alternative to traditional stone cast models which allows for simplified storage and digital record retrieval. The iCast digital model contains a full American Board of Orthodontics ("ABO") base and is available from an iTero scan or from a traditional alginate impression.

OrthoCAD iRecord. iRecord scans provide a digital alternative to traditional stone cast models which allows for simplified storage and digital record retrieval. iRecord scan data may also be exported to orthodontic laboratories for the fabrication of retainers, orthodontic appliances, and hard model fabrication.

Ancillary Products. We also sell other ancillary products for the iTero scanner, such as disposable sleeves for the wand.

Third Party Scanners and Digital scans for Invisalign treatment submission. We support an open systems approach to digital scans and other intraoral scanning companies interested in qualifying their scanners to submit a digital impression in place of a traditional PVS impression as part of the Invisalign case submission process. We have qualified third party scanners for digital scan submission including 3M™ True Definition scanner and the Sirona CEREC Omnicam scanner. Information regarding legal proceedings associated with the scanner may be found in Item 3 of this Annual Report on Form 10-K under the heading “Legal Proceedings.”

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 through a dual view layout that shows a prospective patient an image of his/her own current dentition next to his/her simulated final position after Invisalign treatment.

Invisalign 3D 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 to visually assess and communicate Invisalign treatment progress with an easy to read, color-coded tooth movement report that allows the doctor to know how each tooth is tracking.

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

Our iTero Element, iTero Element 2 and iTero Element Flex scanners include the Invisalign Outcome Simulator, Invisalign 3D Assessment tool and Timelapse as well as the orthodontic software and/or restorative software. The orthodontic or restorative software may also be purchased subsequently for an upgrade fee. Additional applications such as the Invisalign Outcome Simulator are not available for sale separately.

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

Business Strategy

Our goal is to establish the Invisalign System as the standard method for treating malocclusion and our intraoral scanning platform as the preferred scanning protocol for digital scans. Our technology and innovations are designed to meet the demands of today's patients with treatment options that are convenient, comfortable, affordable, while helping to improve overall oral health. We strive to help our doctors move their practices forward by connecting them with new patients, providing digital solutions to help increase practice efficiency and helping them deliver the best possible treatment outcomes and experiences to millions of people around the world.

We achieve this by continued focus and execution of our strategic growth drivers:

1. International Expansion. In order to provide the millions of consumers access to a better smile, we continue increasing our presence globally by making our products available in more countries. We expect to continue to grow and expand our business by investing in resources, infrastructure, and initiatives that will drive Invisalign treatment growth in our current and new international markets. As our core countries within the EMEA and APAC regions continue to grow in both number of new Invisalign trained doctors and customer utilization, we strive to make sure we can support that growth through investments such as headcount, clinical support, education and advertising. We have transitioned most of our smaller country markets from an indirect to a direct sales model, and, while we do not expect a material impact from these countries for some time, in the near term we will leverage our existing infrastructure in adjacent country markets as we build local sales organizations to drive long-term market penetration. In addition, we are scaling and expanding our operations and facilities to better support our customers across the globe. In 2018, we opened new treatment planning facilities in Madrid, Spain to support our customers within this region and we expanded our facilities in Costa Rica to support our growth.

2. Orthodontist Utilization. We continue to innovate and increase the product applicability and predictability to address a wide range of cases, from simple to complex, thereby enabling doctors to confidently treat teenagers and adults with the Invisalign System. Over the last several years, we launched clinical innovations such as Invisalign G6 and Invisalign G7. In March 2017, we launched Invisalign Comprehensive with Mandibular Advancement, the first clear aligner solution for Class II correction in growing tween and teen patients in Canada and certain country markets in EMEA and APAC. This offering combines the benefits of our clear aligner system with features for moving the lower jaw forward while simultaneously aligning the teeth. Approximately 30% to 45% of teen cases need Class II correction. In October 2018 we received 510(k) approval for Invisalign with Mandibular Advancement in the U.S. and began its commercial launch in November 2018. We also continue to make improvements to our Invisalign treatment software, ClinCheck Pro, designed to deliver an exceptional user experience and increase treatment control to help our doctors achieve their treatment goals.

3. GP Dentist Treat & Refer. We want to enable GPs, who have access to a large patient base, to more easily identify Invisalign cases they can treat, monitor patient progress or, if needed, help refer cases to an orthodontist while providing high-quality restorative, orthodontic, and dental hygiene care. In 2018, we continued to commercialize Invisalign Go, a simplified and streamlined solution designed for GPs and trained over 3,000 new iGo doctors primarily in EMEA. In the EMEA region, we segmented sales and marketing for certain country markets into two separate organizations to serve each customer segment, orthodontists and GP dentists separately, thereby increasing our focus and effectiveness on GP dentists. In the first quarter of 2019, we plan to add 50 new sales representatives in EMEA to cover the GP dentist channel. The iTero scanner is an important component to that customer experience

and is central to a digital approach as well as overall customer utilization of Invisalign treatment. The iTero scanner is optimized for Invisalign treatment with the Invisalign Outcome Simulator and Progress Assessment tool. In June 2017, we launched TimeLapse technology that allows doctors or practitioners to compare a patient's 3D historic scans to the present-day scan, enabling clinicians to identify and measure orthodontic movement, tooth wear, and gingival recession. This highlights areas of diagnostic interest to dental professionals and helps foster a proactive conversation with the patient regarding potential restorative or orthodontic solutions. In 2018, we announced multi-year agreements with Heartland Dental and Aspen Dental, two large dental support organizations, to extend iTero Element intraoral scanners to their supported dentists and teams nationwide.

Patient Demand & Conversion. Our goal is to make Invisalign a highly recognized name brand worldwide by creating awareness for Invisalign treatment among consumers and motivating potential patients to seek Invisalign treatment. We accomplish this objective through an integrated consumer marketing strategy that includes television, media, social networking and event marketing as well as educating patients on treatment options and directing them to high volume Invisalign doctors. In January 2017, we launched a new Smile Concierge program with the objective to help more U.S. consumers start Invisalign treatment and improve their overall experience by shortening their research cycles and utilizing consumer insights to help our doctors better engage with consumers. Our Smile Concierge program educates consumers on the benefits of Invisalign treatment, answers their questions, and helps them schedule an appointment with an Invisalign doctor. In addition, the Invisalign Experience program reflects the Company’s overarching approach to engaging consumers through brand experiences in consumer-based settings and environments. Through the Invisalign Experience program we’re learning more than ever about reducing barriers to treatment for potential patients so that they are excited about getting a better smile with an Invisalign doctor. In 2018, we expanded the interactive brand experience that was piloted in 2017 and finished the year with twelve

4. Invisalign Experience locations in major U.S. cities. The program expansion is designed to address the rapidly evolving consumer market for clear aligners and connects consumers interested in Invisalign treatment with Invisalign doctors in their communities. We also partnered with a few Invisalign doctors in select U.S. cities piloting doctor-owned Invisalign Experience centers to test new ways to reach consumers and connect them directly with doctors to start Invisalign treatment. This pilot is intended to help doctors integrate consumer-friendly design and consultation workflow into their practices and test the new Invisalign Experience branding and a consumer-focused approach to consultations and Invisalign treatment starts. It includes an initial digital scan and smile visualization with a scanner and immediate appointments for walk-ins. In addition to providing potential leads to participating Invisalign practices, we are seeing a positive halo effect and increased growth rates for all of the Invisalign practices in the surrounding area whether they participate in the location network or not. While we are still early in the development of our Invisalign Experience locations and the overarching Invisalign Experience program, we believe it will have a positive impact on demand creation for Invisalign practices by engaging directly with consumers (Refer to Note 8 "Legal Proceedings" of the Notes to Consolidated Financial Statements for a communication received from SDC on the Invisalign Experience program).

Manufacturing and Suppliers

Our manufacturing facilities are located in Juarez, Mexico, and Ziyang, China, where we conduct our aligner fabrication, distribute and repair our scanners and perform our CAD/CAM services, and in Or Yehuda, Israel where we produce our handheld intraoral scanner wand and perform the final assembly of our iTero scanner. Our Invisalign digital treatment planning and interpretation for iTero restorative cases are conducted at our facilities located in San Jose, Costa Rica, Chengdu, China, Cologne, Germany and Madrid, Spain. Information regarding risks associated with our manufacturing process and foreign operations may be found in Item 1A of this Annual Report on Form 10-K under the heading “Risk Factors.”

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 EN ISO 13485:2003, an internationally recognized standard for medical device manufacturing. 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 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 supply 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 suppliers. We are also committed to purchasing all of our resin and polymer, the primary raw

materials used in our manufacturing process for clear aligners, from a single source. The need to replace one of our single source suppliers could cause a disruption in our ability to timely deliver certain of our products or increase costs. See Item 1A Risk Factors — “We maintain single supply relationships for certain of our key machines and materials technologies, 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.”

Sales and Marketing

Our sales efforts are focused primarily on the Invisalign System and continuing to increase adoption and utilization by orthodontists and GPs worldwide. In North America, Europe, certain Asia Pacific country markets, and, more recently in Brazil and certain countries in the Middle East and Africa, we have direct sales and support organizations, which includes quota carrying sales representatives, sales management and sales administration. We also have distribution partners that sell the Invisalign System in smaller non-core international country markets. We continued to expand in our existing markets through targeted investments in sales resources, professional marketing and education programs, along with consumer marketing in select country markets.

For the iTero scanner, we have a small team of direct sales representatives and a few distributors in North America who leverage leads generated by our Invisalign sales and marketing resources, including customer events and industry trade-shows. We sell the iTero scanner in select country markets internationally and will expand to additional markets over time to grow the scanner business.

We provide training, marketing and clinical support to orthodontists and GPs. As of December 31, 2018, we had approximately 69,940 active Invisalign trained doctors, which is defined as having submitted at least one case in the prior 12 month period.

Research and Development

We are committed to investing in world-class technology development, which we believe is critical to achieving our goal of establishing the Invisalign System as the standard method for treating malocclusion and our intraoral scanning platform as the preferred scanning protocol for digital scans.

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

In an effort to demonstrate Invisalign’s broad treatment capabilities, various clinical case studies and articles have been published that highlight the clinical applicability of Invisalign to malocclusion cases, including those of severe complexity. We undertake pre-commercialization trials and testing of our technological improvements to the product and manufacturing process.

Intellectual Property

We believe our intellectual property position represents a substantial business advantage. As of December 31, 2018, we had 449 active U.S. patents, 423 active foreign patents, and 486 pending global patent applications.

Our active U.S. patents expire between 2019 and 2037. When patents expire, we lose the protection and competitive advantages they provided to us, which could negatively impact our operating results; however, we continue to pursue further intellectual property protection 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 cannot be certain that patents will be issued as a result of any patent application or that patents that have been issued to us or that may be issued in the future will be found to be valid and enforceable and sufficient to protect our technology or products. Our intellectual property rights may not be successfully asserted in the future or may be invalidated, circumvented or challenged. In addition, the laws of various foreign countries do not protect our intellectual property rights to the same extent as U.S. laws. Our inability to protect our proprietary information could harm our business. Information regarding risks associated with failing to protect 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 experience seasonal trends within our two operating segments, customer channels and the geographic locations that we serve. Sales of Invisalign treatments are often weaker in Europe during the summer months due to our customers and their patients being on holiday. Similarly, other international holidays like Chinese New Year can also negatively impact our sales. 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 Scanner 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.

Backlog

All Invisalign treatments are individually unique and prescribed by a doctor so, no two cases are alike. The period from which a treatment data package (or a "case") is received until the acceptance of the digital ClinCheck treatment plan is dependent on the dental professional's discretion to modify, accept or cancel the treatment plan. Therefore, we consider the case a firm order to manufacture aligners once the dental professional has approved the ClinCheck treatment plan. Our Invisalign backlog consists of ClinCheck treatment plans that have been accepted but not yet shipped. Because aligners are shipped shortly after the ClinCheck treatment plan has been accepted, we believe that backlog is not a good indicator of future Invisalign revenues. Our quarterly Invisalign revenues can be impacted by the timing of the ClinCheck treatment plan acceptances and our ability to ship those cases in the same quarter. We define our intraoral scanner backlog as orders where credit and financing is approved and payment is reasonably assured but the scanner has not yet shipped. Our intraoral scanner backlog as of December 31, 2018 was not material to the business as a whole.

Competition

Currently, our products compete directly against products manufactured and distributed by various companies, both within and outside the U.S. Although the number of competitors varies by segment, geography and customer, we encounter a wide variety of competitors, including 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 key patents owned by us beginning in 2017, we are facing increased competition in the clear aligner market markets as a result of the entry of new, large companies into certain markets who have the ability to leverage their existing channels in the dental market to compete directly with us. In addition, corresponding foreign patents started to expire in 2018 and will likely result in increased competition in some of the markets outside the U.S. Furthermore, we also face competition from companies that now offer clear aligners directly to the consumer and do not require the consumer to see a doctor before or during orthodontic treatment. Unlike these direct to consumer competitors, we are committed to a doctor in the core of everything we do, and Invisalign Treatment requires a doctor's prescription and an in person physical examination of the patients dentition before treatment can begin. 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."

Key competitive factors include:
- effectiveness of treatment;
- price;
- software features;
- aesthetic appeal of the treatment method;

- customer support;
- customer online interface;
- brand awareness;
- innovation;
- distribution network;
- comfort associated with the treatment method;
- oral hygiene;

- ease of use; and
- dental professionals' chair time.

We believe that our products compare favorably with our competitors' products with respect to each of these factors.

Government Regulation

In order for us to market our products, we must obtain regulatory authorization and comply with extensive product and quality system regulations both within and outside the U.S. These regulations, including the requirements for approvals or clearance and the time required for regulatory review, vary from country to country. Failure to obtain regulatory approval and to meet all local requirements including language and specific safety standards in any country in which we currently market or plan to market our products could prevent us from marketing products in such countries or subject us to sanctions and fines. The approval by government authorities is unpredictable and uncertain and may not be granted on a timely basis, if at all. Delays in receipt of, or a failure to receive, such approvals or clearances, or the loss of any previously received approvals or clearances, could have a material adverse effect on our business, financial condition, and results of operations.

Certain of our products are classified as medical devices under the U.S. Food, Drug, and Cosmetic Act ("FD&CA"). The FD&CA requires these products, when sold in the U.S., to be safe and effective for their intended use and to comply with the regulations administered by the FDA. Our products may also be regulated by comparable agencies in non-U.S. countries in which they are produced or sold. In the European Union ("EU"), our products are subject to the medical devices laws of the various member states, which are based on a Directive of the European Commission which was updated in April 2017 to the Medical Device Regulation. Such laws generally regulate the safety of the products in a similar way to the FDA regulations.

We believe we are in compliance with all FDA, federal and state laws and international regulatory requirements that are applicable to our products and manufacturing operations.

We are also subject to various laws inside and outside the U.S. concerning our relationships with healthcare professionals and government officials, price reporting and regulation, the promotion, sales and marketing of our products and services, the importation and exportation of our products, the operation of our facilities and distribution of our products. As a global company, we are subject to varying degrees of government regulation in the various countries in which we do business, 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 federal funded programs such as Medicaid or a foreign national healthcare program, each of which may offer some degree of oversight. 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 defense 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 requirements that span from individual state and national laws in the U.S. to multinational requirements in the EU. In the U.S., final regulations implementing amendments to the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") became effective in the latter part of 2013 with the HIPAA Omnibus Rule. Align is also preparing for compliance with the recently passed California Consumer Privacy Act ("CCPA"), scheduled to take effect in January 2020. In the EU, Align must comply with the General Data Protection Regulation ("GDPR"), which serves as a harmonization of European data-privacy laws. The GDPR went into

effect May 25, 2018. Further expansion into Latin American markets require Align to prepare for Brazil's Lei Geral de Proteção de Dados ("LGPD"), scheduled to take effect in August 2020. Meanwhile, the Asia Pacific region has also seen rapid development of privacy laws including Russia, China, South Korea, Singapore, Hong Kong, and Australia.

We believe we have designed our product and service offerings to be compliant with the requirements of applicable data protection laws and regulations. Maintaining systems that are compliant 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 in managing data protection requirements.

Employees

As of December 31, 2018, we had approximately 11,660 employees, including 7,580 in manufacturing and operations, 2,320 in sales and marketing which includes customer care, 700 in research and development and 1,060 in general and administrative functions.

Available Information

Our website is www.aligntech.com, and our investor relations website is http://investor.aligntech.com. The information on or accessible through our websites is not part of this Annual Report on Form 10-K. Our Annual Reports 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.

Executive Officers of the Registrant

The following table sets forth certain information regarding our executive officers as of February 28, 2019:

Name	Age	Position
Joseph M. Hogan	61	President and Chief Executive Officer
John F. Morici	52	Chief Financial Officer and Senior Vice President, Global Finance
Simon Beard	52	Senior Vice President and Managing Director, EMEA
Roger E. George	53	Senior Vice President, Chief Legal and Regulatory Officer
Stuart Hockridge	47	Senior Vice President, Global Human Resources
Sreelakshmi Kolli	44	Senior Vice President, Global Information Technology
Jennifer Olson	41	Senior Vice President and Managing Director, Doctor-Directed Consumer Channel
Raphael S. Pascaud	47	Senior Vice President, Business Development and Strategy
Raj Pudipeddi	46	Senior Vice President and Chief Marketing Officer
Zelko Relic	54	Chief Technology Officer and Senior Vice President, Global Research & Development
Yuval Shaked	45	Senior Vice President and Managing Director, iTero Scanner and Services Business
Julie Tay	52	Senior Vice President and Managing Director, Asia Pacific
Emory M. Wright	49	Senior 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 in 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 has served as our Chief Financial Officer since November 2016, whose title was changed to Chief Financial Officer and Senior Vice President, Global Finance in February 2018. 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.

Simon Beard has served as our Vice President and Managing Director, EMEA since October 2015, whose title was changed to Senior Vice President and Managing Director, EMEA in February 2018. Prior to joining us, from 2012 to

2014, Mr. Beard was Regional Director for the South East Asia business of Smith & Nephew, a multinational medical equipment manufacturing company. From 2006 to 2012, Mr. Beard was Director & General Manager for UK and Ireland for Smith & Nephew's Advanced Woundcare business. Prior to Smith & Nephew, Mr. Beard held multiple commercial, strategic, and general management positions in companies such as DePuy International (Johnson & Johnson), Sankyo Pharmaceutical and Sanofi Aventis.

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Roger E. George has served as our Vice President, Corporate and Legal Affairs and General Counsel since July 2002, whose title was changed to Senior Vice President, Chief Legal and Regulatory Officer in February 2018. Prior to joining us, Mr. George was the Chief Financial Officer, Vice President of Finance and Legal Affairs and General Counsel of SkyStream Networks, a privately held broadband and broadcast network equipment company. Prior to SkyStream, Mr. George was a partner at Wilson Sonsini Goodrich & Rosati, P.C. in Palo Alto, California.

Stuart Hockridge has served as our Vice President, Global Human Resources since May 2016, whose title was changed to Senior Vice President, Global Human Resources in February 2018. Prior to joining us, Mr. Hockridge was Senior Vice President of Talent at Visa Inc. from 2013 to 2016 where he led all aspects of talent delivery for the company including executive development, succession planning, employee engagement, learning and development, and talent acquisition. 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.

Sreelakshmi Kolli has served as our Vice President, Information Technology since December 2012, whose title was changed to Senior Vice President, Global Information Technology in February 2018. Ms. Kolli joined us in June 2003 and has held positions leading business operations and engineering for customer-facing applications. Before joining us, she held technical lead positions with Sword CT Space and Accenture.

Jennifer Olson has served as our Vice President and Managing Director, Doctor-Directed Consumer Channel since August 2016, whose title was changed to Senior Vice President and Managing Director, Doctor-Directed Consumer Channel in February 2018. Ms. Olson joined us in 2002 and has held multiple roles in sales, marketing, and business development. Most recently, she was Area Sales Director for the North America region where she led all sales activities in Western Canada and the Western region of the U.S. Prior to joining Align, Ms. Olson was with technology companies including Extreme Networks and PWI Technologies.

Raphael S. Pascaud is our Senior Vice President, Business Development and Strategy. He joined Align in 2010 as Vice President and Managing Director for EMEA and was promoted in January 2014 to Vice President, International. Over his tenure, Mr. Pascaud increased his regional responsibilities and was promoted to Vice President, International in January 2014. In July 2015, he was promoted to Chief Marketing, Portfolio and Business Development Officer assuming global marketing responsibility for the Company’s Invisalign product portfolio initially and then adding the iTero product portfolio a year later in 2016. In October 2018, we announced that Mr. Pascaud was transitioning his marketing responsibilities, but would continue as our lead business development and strategy executive. Prior to Align, Mr. Pascaud spent 14 years in various management positions within Johnson & Johnson, including Vice President Orthopedics of EMEA and Vice President Marketing of International.

Raj Pudipeddi joined Align in February 2019 as our Senior Vice President and Chief Marketing Officer. Prior to joining us, Mr. Pudipeddi was the Director, Consumer Business and Chief Marketing Officer at Bharti Airtel, an Indian telecom leader from February 2017 to May 2018. Prior to Bharti Airtel, Mr. Pudipeddi spent 14 years at Procter & Gamble serving in a number of leadership roles across businesses in North America, Asia and Latin America, most recently as Vice President, North America, Oral Care.

Zelko Relic joined Align in 2013 as Vice President, Research & Development. In December 2017, he became Chief Technology Officer, Vice President, Research & Development, which title was changed to Chief Technology Officer, Senior Vice President, Global Research & Development in February 2018. Prior to joining us, Mr. Relic was Vice President, Engineering for Datalogic Automation, a global leader in automatic data capture and industrial automation markets from 2012. Mr. Relic was previously Vice President, Engineering at Danaher Corporation, Accu-Sort Systems business from 2010 to 2012 before it was acquired by Datalogic Automation. From 2005 to 2010, he was at Siemens Medical Solutions USA, most recently as Vice President, and from 2002 to 2004, he held senior management positions in engineering at Kulicke & Soffa Industries, designers and manufactures of semiconductor products. He

also held management positions at KLA-Tencor from 1994 to 2000.

Yuval Shaked joined Align in June 2017 as our Vice President, iTero Scanner and Services Business. In August 2018, Mr. Shaked was promoted to Senior Vice President, iTero Scanner and Services with global responsibility for Align's market development and operational execution of the iTero Scanner and Services business. Prior to joining Align, Mr. Shaked spent more than 15 years at GE Healthcare in the U.S. and Israel in a variety of roles at multiple business units. Most recently, he served as General Manager, Diagnostic Cardiology, leading on- and off-shore R&D and marketing teams in the U.S., Germany, India and China. Prior to that, he was General Manager for GE's VersaMed business unit, with responsibility for R&D, innovation, manufacturing, quality and commercial activity. Mr. Shaked was the former CEO of SHL Telemedicine Ltd., an Israel-based advanced personal telemedicine company.

Julie Tay was appointed Vice President and Managing Director, Asia Pacific in March 2013 and became Senior Vice President and Managing Director, Asia Pacific in February 2018. Prior to joining us, Ms. Tay was regional head of Bayer Healthcare (Diabetes

Care) overseeing operations across Asia from 2010 to 2013. From 2006 to 2010, Ms. Tay served as director of marketing and corporate accounts at Sealed Air Corporation (formerly Johnson Diversey), a global provider of food safety and security, facility hygiene and product protection. Prior to that, Ms. Tay spent 15 years with Johnson & Johnson Medical.

Emory M. Wright has served as our Vice President, Operations since December 2007 and became Senior Vice President, Global Operations in February 2018. 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 served as Manager of Manufacturing and Process Development for Metra Biosystems Inc.

ITEM 1A.RISK FACTORS

We depend on the sale of the Invisalign System for the vast majority of our net revenues, and any decline in sales of Invisalign treatment for any reason, or a decline in average selling prices would adversely affect net revenues, gross margin and net income.

We expect that net revenues from the sale of the Invisalign System, primarily our comprehensive products, will continue to account for the vast majority of our total net revenues for the foreseeable future. Continued and widespread market acceptance of Invisalign by orthodontists, GPs and consumers is critical to our future success. If orthodontists and GPs experience a reduction in consumer demand for orthodontic services, if consumers prove unwilling to adopt Invisalign as rapidly as we anticipate or in the volume that we anticipate, if orthodontists or GPs choose to use a competitive product rather than Invisalign or if the average selling price of our product declines for any reason, including as a result of a shift in product mix towards lower priced products, our operating results would be harmed.

Competition in the markets for our products is increasing and we expect aggressive competition from existing competitors and other companies that may introduce new technologies in the future.

Currently, our products compete directly against products manufactured and distributed by various companies, both within and outside the U.S. Although the number of competitors varies by segment, geography and customer, we encounter a wide variety of competitors, including 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 key patents owned by us beginning in 2017, we are facing increased competition in the clear aligner market as a result of the entry of new, large companies into certain markets who have the ability to leverage their existing channels in the dental market to compete directly with us. In addition, corresponding foreign patents started to expire in 2018 and will likely result in increased competition in some of the markets outside the U.S. Large consumer product companies may also enter the orthodontic supply market. Furthermore, we also face competition from companies that now offer clear aligners directly to the consumer and do not require the consumer to see a doctor before or during orthodontic treatment. Unlike these direct to consumer competitors, we are committed to a doctor in the core of everything we do, and Invisalign Treatment requires a doctor's prescription and an in person physical examination of the patients dentition before treatment can begin. In addition, we may also face competition in the future from new companies that may introduce new technologies. We may be unable to compete with these competitors and one or more of these competitors may render our technology obsolete or economically unattractive. If we are unable to compete effectively with existing products or respond effectively to any products developed by new or existing competitors, our business could be harmed. Increased competition has resulted in the past and may in the future result in volume discounting and price reductions, reduced

gross margins, reduced profitability and loss of market share, and reduce dental professionals' efforts and commitment to expand their use of our products, any of which could have a material adverse effect on our net revenues, volume growth, net income and stock price. 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.

We are dependent on our international operations, which exposes us to foreign operational, political and other risks that may harm our business.

Our key production steps are performed in operations located outside of the U.S. Technicians use a sophisticated, internally developed computer-modeling program to prepare digital treatment plans, which are then transmitted electronically to our aligner fabrication facilities. These digital files form the basis of the ClinCheck treatment plan and are used to manufacture aligner molds and aligners. Our digital treatment planning and aligner fabrication are performed in multiple international locations. We will continue to establish treatment planning and aligner fabrication facilities closer to our international customers in order to improve our operational efficiency. In addition to the research and development efforts conducted in our North America facilities, we also carry out research and development in Moscow, Russia. We also have operations in Israel where we design and assemble wands,

and our intraoral scanner is manufactured. Our reliance on international operations exposes us to risks and uncertainties that may affect our business or results of operation, including:

- difficulties in hiring and retaining employees generally, as well as difficulties in hiring and retaining employees with the necessary skills to perform the more technical aspects of our operations;
- difficulties in managing international operations, including any travel restrictions to or from our facilities;
- fluctuations in currency exchange rates;
- import and export controls, license requirements and restrictions;
- controlling production volume and quality of the manufacturing process;
- political, social and economic instability, including increased levels of violence in Juarez, Mexico or the Middle East. We cannot predict the effect on us of any future armed conflict, political instability or violence in these regions. In addition, some of our employees in Israel are obligated to perform annual reserve duty in the Israeli military and are subject to being called for additional active duty under emergency circumstances. We cannot predict the full impact of these conditions on us in the future, particularly if emergency circumstances or an escalation in the political situation occurs. If many of our employees are called for active duty, our operations in Israel and our business may not be able to function at full capacity;
- acts of terrorism and acts of war;
- general geopolitical instability and the responses to it, such as the possibility of additional sanctions against China and Russia which continue to bring uncertainty to these regions;
- interruptions and limitations in telecommunication services;
- product or material transportation delays or disruption, including as a result of customs clearance, increased levels of violence, acts of terrorism, acts of war or health epidemics restricting travel to and from our international locations or as a result of natural disasters, such as earthquakes or volcanic eruptions;
- burdens of complying with a wide variety of local country and regional laws, including the risks associated with the Foreign Corrupt Practices Act and local anti-bribery compliance;
- trade restrictions and changes in tariffs, including the recent tariffs imposed by the U.S. and China and the possibility of additional tariffs or other trade restrictions related to trade between the two countries; and
- potential adverse tax consequences.

If any of these risks materialize in the future, we could experience production delays and lost or delayed revenue.

We earn an increasingly larger portion of our total revenues from international sales and face risks attendant to those operations.

We earn an increasingly larger portion of our total revenues from international sales generated through our foreign direct and indirect operations. Since our growth strategy depends in part on our ability to further penetrate markets outside the U.S. and increase the localization of our products and services, we expect to continue to increase our sales and presence outside the U.S., particularly in the high-growth markets. Our international operations are subject to risks that are customarily encountered in non-U.S. operations, including:

- local political and economic instability;
- the engagement of activities by our employees, contractors, partners and agents, especially in countries with developing economies, that are prohibited by international and local trade and labor laws and other laws prohibiting corrupt payments to government officials, including the Foreign Corrupt Practices Act, the United Kingdom (“UK”) Bribery Act of 2010 and export control laws, in spite of our policies and procedures designed to ensure compliance with these laws;
- fluctuations in currency exchange rates; and
- increased expense of developing, testing and making localized versions of our products.

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

We face risks related to our international sales, including the need to obtain necessary foreign regulatory clearance or approvals.

We currently sell our products outside of North America. As a result, we are subject to foreign regulatory requirements that vary widely from country to country. The time required to obtain clearances or approvals required by other countries may be longer than that required for U.S. Food and Drug Administration ("FDA") clearance or approval, and requirements for such approvals may differ from FDA requirements. We may be unable to obtain regulatory approvals in one or more of the other countries in which we do business or in which we may do business in the future. We may also incur significant costs in attempting to obtain and maintain foreign regulatory approvals. If we experience delays in receipt of approvals to market our products outside of the U.S., or if we fail to receive these approvals, we may be unable to market our products or enhancements in international markets in a timely manner, if at all, which 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 due to a variety of factors including a weakness in general economic conditions.

Consumer spending habits are affected by, among other things, prevailing economic conditions, levels of employment, salaries and wage rates, gas prices, consumer confidence and consumer perception of economic conditions. A general slowdown in the U.S. economy and certain international economies or an uncertain economic outlook would adversely affect consumer spending habits which may, among other things, result in a decrease in the number of overall orthodontic case starts, reduced patient traffic in dentists’ offices, reduction in consumer spending on elective or higher value procedures or a reduction in the demand for dental services generally, each of which would have a material adverse effect on our sales and operating results. Weakness in the global economy results in a challenging environment for selling dental technologies and dentists may postpone investments in capital equipment, such as intraoral scanners. In addition, Invisalign treatment, which currently accounts for the vast majority of our net revenues, represents a significant change from traditional orthodontic treatment, and customers and consumers may be reluctant to accept it or may not find it preferable to traditional treatment. We have generally received positive feedback from orthodontists, GPs and consumers regarding Invisalign treatment as both an alternative to braces and as a clinical method for the treatment of malocclusion, but a number of dental professionals believe that the Invisalign treatment is appropriate for only a limited percentage of their patients. Increased market acceptance of all of our products will depend 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.

Our future success may depend on our ability to develop, successfully introduce and achieve market acceptance of new products or product offerings.

Our future success may depend on our ability to develop, manufacture, market and obtain regulatory approval or clearance of new products or product offerings. There can be no assurance that we will be able to successfully develop, sell and achieve market acceptance of these and other new products and applications and enhanced versions of our existing product or software. The extent of, and rate at which, market acceptance and penetration are achieved by new or future products or offerings is a function of many variables, which include, among other things, our ability to:

- correctly identify customer needs and preferences and predict future needs and preferences;
- include functionality and features that address customer requirements;
- ensure compatibility of our computer operating systems and hardware configurations with those of our customers;

- allocate our research and development funding to products with higher growth prospects;
- anticipate and respond to our competitors' development of new products. product offerings and technological innovations;
- differentiate our products and product offerings from our competitors;
- innovate and develop new technologies and applications;
- the availability of third-party reimbursement of procedures using our products;
- obtain adequate intellectual property rights; and
- encourage customers to adopt new technologies.

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 revenue. Even if we successfully innovate and develop new products and product enhancements, we may incur substantial costs in doing so and our profitability may suffer. In addition, even if our new products are successfully introduced, it is unlikely that they will rapidly gain market share and acceptance primarily due to the relatively long period of time it takes to successfully treat a patient with Invisalign. Since it typically takes approximately 12 to 24 months to treat a patient, our customers may be unwilling to rapidly adopt our new products until they successfully complete at least one case or until more historical clinical results are available.

Our ability to market and sell new products may also be subject to government regulation, including approval or clearance by the FDA and foreign government agencies. Any failure in our ability to successfully develop and introduce or achieve market acceptance of our new products or enhanced versions of existing products could have a material adverse effect on our operating results and could cause our net revenues to decline.

The frequency of use of the Invisalign System by orthodontists or GPs may not increase at the rate that we anticipate or at all.

One of our key objectives is to continue to increase utilization, or the adoption and frequency of use, of the Invisalign System by new and existing customers. If utilization of the Invisalign System by our existing and newly trained orthodontists or GPs does not occur or does not occur as quickly as we anticipate, our operating results could be harmed.

We may experience declines in average selling prices of our products which may decrease our net revenues.

We provide volume-based discount programs to our doctors. In addition, we sell a number of products at different list prices. If we change the volume-based discount programs affecting our average selling prices; if we introduce any price reductions or consumer rebate programs; if we expand our discount programs in the future or participation in these programs increases; or if our product mix shifts to lower priced products or to products that have a higher percentage of deferred revenue, our average selling prices would be adversely affected and our net revenues, gross profit, gross margin and net income may be reduced.

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

Although the U.S. dollar is our reporting currency, a 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 exchange rates effective during the respective period and are affected by changes in exchange rates. As a result, negative movements in currency exchange rates against the U.S. dollar will adversely affect our net revenues and net income in our consolidated financial statements. The exchange rate between the U.S. dollar and foreign currencies has fluctuated substantially in recent years and may continue to fluctuate substantially in the future. As a result, we enter into currency forward contract transactions in an effort to cover some of our exposure to foreign currency exchange fluctuations. These transactions may not operate to fully or effectively hedge our exposure to currency fluctuations, and, under certain circumstances, these transactions could have an adverse effect on our financial condition.

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

We are subject to growth related risks, including excess or constrained capacity and pressure on our internal systems and personnel. In order to manage current operations and future growth effectively, we will need to continue to implement and improve our operational, financial and management information systems and to hire, train, motivate, manage and retain employees. We may be unable to manage such growth effectively. Any such failure could have a material adverse impact on our business, operations and prospects. We are establishing additional order acquisition, treatment planning and manufacturing facilities closer to our international customers in order to improve our operational efficiency and provide doctors with a better experience to further improve their confidence in using Invisalign to treat more patients, more often. Our ability to plan, construct and equip additional order acquisition, treatment planning and manufacturing facilities is subject to significant risk and uncertainty, including risks inherent in the establishment of a facility, such as hiring and retaining employees and delays and cost overruns as a result of a number of factors, any of which may be out of our control and may negatively impact our gross margin. In addition, these new facilities are located in higher cost regions compared to Mexico and Costa Rica, which may negatively impact our gross margin. If the transition into these additional facilities is significantly delayed or demand for our product exceeds our current expectations, we may not be able to fulfill orders timely, which may negatively impact our financial results and overall business. In addition, because we cannot immediately adapt our production capacity and related cost structures to changing market conditions, our facility capacity may at times exceed or fall short of our production requirements. In addition, if product demand decreases or we fail to forecast demand

accurately, we could be required to write off inventory or record excess capacity charges, which would lower our gross margin. Production of our intraoral scanners may also be limited by capacity constraints due to a variety of factors, including our dependency on third party vendors for key components in addition to 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.

We are subject to risks associated with leasing retail space subject to long-term and non-cancelable leases. We may be unable to renew leases at the end of their terms. If we close a leased retail space, we remain obligated under the applicable lease.

We have recently increased the number of retail locations leased by us as we continue to expand our Invisalign Experience program. We do not own any of our retail locations. We currently lease the majority of our Invisalign locations under long-term, non-cancelable leases, which usually have initial terms ranging from three to ten years. We believe that the majority of the leases we enter into in the future will likely be long-term and non-cancelable. Generally, our leases are “net” leases, which require us to pay our proportionate share of the cost of insurance, taxes, maintenance and utilities. If we determine that it is no longer economical to operate a retail location subject to a lease and decide to, or are otherwise required to, close it for any reason, including as a result of an adverse ruling in the SDC dispute (see “Item 3 Legal Proceedings - SDC Dispute”), we may remain obligated under the applicable lease for, among other things, payment of the base rent for the balance of the lease term. In addition, as each of our leases expire, we may be unable to negotiate renewals, either on commercially acceptable terms or at all, which could cause us to close retail spaces in desirable locations. Our inability to secure desirable retail space or favorable lease terms could impact our ability to grow our Invisalign Experience program as desired. Likewise, our obligation to continue making lease payments in respect of leases for closed retail spaces could have a material adverse effect on our business, financial condition and results of operations.

If we fail to sustain or increase profitability or revenue growth in future periods, the market price for our common stock may decline.

If we are to sustain or increase profitability in future periods, we will need to continue to increase our net revenues, while controlling our expenses. Because our business is evolving, it is difficult to predict our future operating results or levels of growth, and we have not in the past and may not in the future be able to sustain our historical growth rates. If we do not increase profitability, Invisalign volume and revenue growth or otherwise meet the expectations of securities analysts or investors, the market price of our common stock will likely decline.

Our financial results have fluctuated in the past and may fluctuate in the future which may cause volatility in our stock price.

Our operating results have fluctuated in the past and we expect our future quarterly and annual operating results to fluctuate as we focus on increasing doctor and consumer demand for our products. These fluctuations could cause our stock price to decline or significantly fluctuate. Some of the factors that could cause our operating results to fluctuate include:

- limited visibility into and difficulty predicting from quarter to quarter, the level of activity in our customers’ practices including limited visibility into the number of aligners purchased by SmileDirectClub, LLC (“SDC”) under the supply agreement;
- weakness in consumer spending as a result of a slowdown in the global, U.S. or other economies;
- changes in product mix;
- higher manufacturing costs driven by an increase in the numbers of aligners per case;
- changes in relationships with our dental support organizations, including timing of orders;

- changes in the timing of receipt of Invisalign case product orders during a given quarter which, given our cycle time and the delay between case receipts and case shipments, could have an impact on which quarter revenues can be recognized;
- fluctuations in currency exchange rates against the U.S. dollar;
- our inability to scale production of our iTero Element scanner to meet customer demand;
- if participation in our customer rebate or discount programs increases, our average selling price will be adversely affected;
- seasonal fluctuations in the number of doctors in their offices and their availability to take appointments;
- success of or changes to our marketing programs from quarter to quarter;

- our reliance on our contract manufacturers for the production of sub-assemblies for our intraoral scanners;
- timing of industry tradeshows;
- changes in the timing of when revenues are recognized, including as a result of the introduction of new products, product offerings or promotions, modifications to our terms and conditions or as a result of changes to critical accounting estimates or new accounting pronouncements;
- changes to our effective tax rate;
- unanticipated delays in production caused by insufficient capacity or availability of raw materials;
- any disruptions in the manufacturing process, including unexpected turnover in the labor force or the introduction of new production processes, power outages or natural or other disasters beyond our control;
- underutilization of manufacturing and treat facilities;
- the development and marketing of directly competitive products by existing and new competitors;
- changes in relationships with our distributors;
- impairments in the value of our investments in SDC and other privately held companies could be material;
- major changes in available technology or the preferences of customers may cause our current product offerings to become less competitive or obsolete;
- aggressive price competition from competitors;
- costs and expenditures in connection with litigation;
- costs and expenditures in connection with establishment of treatment planning and Aligner fabrication in international locations;
- costs and expenditures in connection with hiring and deployment of direct sales force personnel;
- the timing of new product introductions by us and our competitors, as well as customer order deferrals in anticipation of enhancements or new products;
- unanticipated delays in our receipt of patient records made through an intraoral scanner for any reason;
- disruptions to our business due to political, economic or other social instability, including the impact of an epidemic any of which results in changes in consumer spending habits, consumers unable or unwilling to visit the orthodontist or general practitioners office, 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;

- disruptions to our business as a result of our agreement to manufacture clear aligners for SDC, including market acceptance of the SDC business model and product, possible adverse customer reaction and negative publicity about us and our products;

- changes in accounting standards, policies and estimates including changes made by our equity investee; and

- our ability to successfully hedge against a portion of our foreign currency-denominated assets and liabilities.

To respond to these and other factors, we may need to make business decisions that could adversely affect our operating results such as modifications to our pricing policy, business structure or operations. Most of our expenses, such as employee compensation and lease payment obligations, are relatively fixed in the short term. Moreover, our expense levels are based, in part, on our expectations regarding future revenue levels. As a result, if our net revenues for a particular period fall below our expectations, whether caused by changes in consumer spending, consumer preferences, weakness in the U.S. or global economies, changes in customer behavior related to advertising and prescribing our product or other factors, we may be unable to adjust spending quickly enough to offset any shortfall in net revenues. Due to these and other factors, we believe that quarter-to-quarter comparisons of our

operating results may not be meaningful. You should not rely on our results for any one quarter as an indication of our future performance.

A disruption in the operations of our primary freight carrier or higher shipping costs could 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 to our customers. If the operations of these carriers are disrupted for any reason, we may be unable to deliver our products to our customers on a timely basis. If we cannot deliver our products in an efficient and timely manner, our customers may reduce their orders from us and our net revenues and gross margin could materially decline. In a rising fuel cost environment, our freight costs will increase. 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 pass that increase along to our customers for any reason or otherwise offset such increases in our cost of net revenues, our gross margin and financial results could be adversely affected.

If we are unable to accurately predict our volume growth, and fail to hire a sufficient number of technicians in advance of such demand, the delivery time of our products could be delayed which could adversely affect our results of operations.

Treatment planning is a key step leading to our manufacturing process which relies on sophisticated computer technology requiring new technicians to undergo a relatively long training process. Training production technicians takes approximately 90 to 120 days. As a result, if we are unable to accurately predict our volume growth, we may not have a sufficient number of trained technicians to deliver our products within the time frame our customers expect. Such a delay could cause us to lose existing customers or fail to attract new customers. This could cause a decline in our net revenues and net income and could adversely affect our results of operations.

Our headquarters, digital dental modeling processes, and other manufacturing processes are principally located in regions that are subject to earthquakes and other natural disasters.

Our digital dental modeling is primarily processed in our facility located in San Jose, Costa Rica. The operations team in Costa Rica creates ClinCheck treatment plans using sophisticated computer software. In addition, our customer facing operations are located in Costa Rica. Our aligner molds and finished aligners are fabricated in Juarez, Mexico. Both locations in Costa Rica and Mexico are in earthquake zones and may be subject to other natural disasters. If there is a major earthquake or any other natural disaster in a region where one of these facilities is located, 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 a significant delay in receiving their completed aligners and a decrease in service levels for a period of time. In addition, our corporate headquarters in California is located in the San Francisco Bay Area. An earthquake or other natural disaster in this region could result in a disruption in our operations. Any such business interruption could materially and adversely affect our business, financial condition and results of operations.

Our information technology systems are critical to our business. System integration and implementation issues and system security risks could disrupt our operations, which could have a material adverse impact on our business and operating results.

We rely on the efficient and uninterrupted operation of complex information technology systems. All information technology systems are vulnerable to damage or interruption from a variety of sources. As our business has grown in size and complexity, the growth has placed, and will continue to place, significant demands on our information

technology systems. To effectively manage this growth, our information systems and applications require an ongoing commitment of significant resources to maintain, protect and enhance existing systems and develop new systems to keep pace with continuing changes in information processing technology, evolving industry and regulatory standards and changing customer preferences. We are continuing to transform certain business processes, extend established processes to new subsidiaries and/or implement additional functionality in our enterprise resource planning (“ERP”) software system which entails certain risks, including difficulties with changes in business processes that could disrupt our operations, such as our ability to track orders and timely ship products, manage our supply chain and aggregate financial and operational data.

System upgrades 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 our customer facing software applications, specifically the ClinCheck and MyAligntech software. Software applications frequently contain errors or defects, especially when they are first introduced or when new versions are released. The discovery of a defect or error or the incompatibility with the computer operating system and hardware configurations

of customers in a new upgraded version or the failure of our primary information systems may result in the following consequences, among others: loss of revenues or delay in market acceptance, damage to our reputation or increased service costs, any of which could have a material adverse effect on our business, financial condition or results of operations.

If the information we rely upon to run our businesses were to be found to be inaccurate or unreliable, if we fail to properly maintain our information systems and data integrity, or if we fail to develop new capabilities to meet our business needs in a timely manner, we could have operational disruptions, have customer disputes, lose our ability to produce timely and accurate reports, have regulatory or other legal problems, have increases in operating and administrative expenses, lose existing customers, have difficulty in attracting new customers or in implementing our growth strategies, or suffer other adverse consequences. In addition, experienced computer programmers and hackers may be able to penetrate our network security or our cloud-based software servers hosted by third party and misappropriate our confidential information or that of third parties, 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 which we depend upon may contain defects in design and manufacture, including “bugs” and other problems that can unexpectedly interfere with the operation of the system. The costs to eliminate or alleviate security problems, viruses and bugs could be significant, and the efforts to address these problems could result in interruptions that may have a material adverse impact on our operations, net revenues and operating results.

Furthermore, our business requires the secure transmission of confidential information over public networks. Because of the confidential health information we store and transmit, security breaches could expose us to a risk of regulatory action, litigation, possible liability and loss. We have experienced breaches in the past and our security measures may be inadequate to prevent security breaches, and our business operations and profitability would be adversely affected by, among other things, loss of customers and potential criminal and civil sanctions if they are not prevented.

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

If the security of our customer and patient information is compromised, patient care could suffer, and we could be liable for related damages, and our reputation could be impaired.

We retain confidential customer and patient information in our processing centers. Therefore, it is critical that our facilities and infrastructure remain secure and are also perceived by the marketplace and our customers to be secure. Despite the implementation of security measures, we have experienced breaches in the past and our infrastructure may be vulnerable to physical break-ins, computer viruses, programming errors or other technical malfunctions, hacking or phishing attacks by third parties, employee error or malfeasance or similar disruptive problems. If we fail to meet our customer and patient’s expectations regarding the security of healthcare information, we could be liable for damages and our reputation and competitive position could be impaired. Affected parties could initiate legal or regulatory action against us, which could cause us to incur significant expense and liability or result in orders forcing us to modify our business practices. Concerns over our privacy practices could adversely affect others’ perception of us and deter customers, advertisers and partners from using our products. In addition, patient care could suffer, and we could be liable if our systems fail to deliver correct information in a timely manner. We have cybersecurity insurance 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 fines and penalties, potential payment card industry fines and penalties and costs related to cyber extortion;

however, damage and claims arising from such incidents may not be covered or may exceed the amount of any insurance available.

We are also subject to several federal, state and foreign laws and regulations, including ones relating to privacy, data protection, content regulation, and consumer protection. 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 protection requirements that span from individual state and national laws in the U.S. to multinational requirements in the EU. In the EU, Align must comply with the General Data Protection Regulation ("GDPR"), which became effective on May 25, 2018 and serves as a harmonization of European data-privacy laws. We believe we have designed our product and service offerings to be compliant with the requirements of applicable data protection laws and regulations. Maintaining systems that are compliant 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 in managing data protection requirements.

Our success depends in part on our proprietary technology, and if we are unable to successfully enforce our intellectual property 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 will depend in part on our ability to maintain existing intellectual property and to obtain and maintain further intellectual property protection for our products, both in the U.S. and in other countries. Our inability to do so could harm our competitive position. As of December 31, 2018, we had 449 active U.S. patents, 423 active foreign patents, and 486 pending global patent applications.

We intend to rely on our portfolio of issued and pending patent applications in the U.S. and in other countries to protect a large part of our intellectual property and our competitive position; however, our currently pending or future patent filings may not result in the issuance of patents. Additionally, any patents issued to us 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. In addition, any protection afforded by foreign patents may be more limited than that provided under U.S. patents and intellectual property laws. Certain of our key patents began to expire in 2017, which may result in increased competition or less expensive alternatives to our products. We also rely on protection of our copyrights, trade secrets, know-how and proprietary information. We generally enter into confidentiality agreements with our employees, consultants and our 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 if unauthorized use or disclosure were to 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 proprietary rights might allow competitors to copy our technology, which could adversely affect our pricing and market share. In addition, in an effort to protect our intellectual property we have in the past been and may in the future be involved in litigation. The potential effects on our business operations resulting from litigation that we may participate in the future, whether or not ultimately determined in our favor or settled by us, are costly and divert the efforts and attention of our management and technical personnel from normal business operations.

Litigation, interferences, oppositions, re-exams, inter partes reviews, post grant reviews or other proceedings are, have been and may in the future be necessary in some instances to determine the validity and scope of certain of our proprietary rights, and in other instances to determine the validity, scope or non-infringement of certain patent rights claimed by third parties to be pertinent to the manufacture, use or sale of our products. Litigation, interference, oppositions, re-exams, inter partes reviews, post grant reviews, administrative challenges or other similar types of proceedings are unpredictable and may be protracted, expensive and distracting to management. The outcome of such proceedings could adversely affect the validity and scope of our patent or other proprietary rights, hinder our ability to manufacture and market our products, require us to seek a license for the infringed product or technology or result in the assessment of significant monetary damages. An unfavorable ruling could include monetary damages or, in cases where injunctive relief is sought, an injunction prohibiting us from selling our products. Any of these results from our litigation could adversely affect our results of operations and stock price.

While we believe we currently have adequate internal control over financial reporting, we are required to assess our internal control over financial reporting on an annual basis and any future adverse results from such assessment could result in a loss of investor confidence in our financial reports and have an adverse effect on our stock price.

Pursuant to the Sarbanes-Oxley Act of 2002 and the rules and regulations promulgated by the SEC, 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. The report 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 or not our internal control over

financial reporting is effective. This assessment must include disclosure of any material weaknesses in our internal control over financial reporting identified by management. While we believe our internal control over financial reporting is currently effective, the effectiveness of our internal controls in future periods is subject to the risk that our controls may become inadequate because of changes in conditions including our transition of further business operations into our ERP software system, 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 would increase 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), we could lose investor confidence in the accuracy and completeness of our financial reports, which could have an adverse effect on our stock price.

If we lose our key personnel or are unable to attract and retain key personnel, we may be unable to pursue business opportunities or develop our products.

We are highly dependent on the key employees in our clinical engineering, technology development, sales, training and marketing personnel and management teams. The loss of the services provided by those individuals may significantly delay or prevent the achievement of our product development and other business objectives and could harm our business. Our future success will also depend on our ability to identify, recruit, train and retain additional qualified personnel, including orthodontists and production technicians in our treat facilities. Few orthodontists are accustomed to working in a manufacturing environment since they are generally trained to work in private practices, universities and other research institutions. Thus, we may be unable to attract and retain personnel with the advanced qualifications necessary for the further development of our business. Furthermore, we may not be successful in retaining our key personnel or their services. If we are unable to attract and retain key personnel, our business could be materially harmed.

If we infringe the patents or proprietary 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 intellectual property rights is common in the medical device industry. We have been sued for infringement of third party's patents in the past and we may be the subject of patent or other litigation in the future. From time to time, we have received and may in the future receive letters from third parties drawing our attention to their patent rights. While we do not believe that 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 intellectual property suits, 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 of any litigation or interference proceeding to which we may become a party could subject us to significant liabilities. An adverse determination of this nature could also put our patents at risk of being invalidated or interpreted narrowly or 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.

We maintain single supply relationships for certain of our key machines and materials technologies, 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 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 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 scanners are provided by single suppliers. We are also committed to purchasing the vast majority of our resin and polymer, the primary raw materials used in our manufacturing process for clear aligners, from a single source. If these or other suppliers encounter financial, operating or other difficulties or if our relationship with them changes, we might not be able to quickly establish or qualify replacement sources of supply and could face production interruptions, delays and inefficiencies. In addition, 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. Our growth may exceed the capacity of one or more of these manufacturers to produce the needed equipment and materials in sufficient quantities to support our growth. Conversely, 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. In the event of technology changes, delivery delays, or shortages of or increases in price for these items, our business and growth prospects may be harmed.

We depend on a single contract manufacturer and supplier of parts used in our iTero scanner and any disruption in this relationship may cause us to fail to meet the demands of our customers and damage our customer relationships.

We rely on a third party manufacturer to supply key sub-assemblies for our iTero Element scanner. As a result, if this third party manufacturer fails to deliver its components, if we lose its services or if we fail to negotiate acceptable terms, we may be unable to deliver our products in a timely manner and our business may be harmed. Any difficulties encountered by the third party manufacturer with respect to hiring personnel and maintaining acceptable manufacturing standards, controls, procedures and policies could disrupt our ability to deliver our products in a timely manner. Finding a substitute manufacturer may be expensive, time-consuming or impossible and could result in a significant interruption in the supply of our intraoral scanning products. Any failure by our contract manufacturer that results in delays in our fulfillment of customer orders may cause us to lose revenues and suffer damage to our customer relationships.

We primarily rely on our direct sales force to sell our products, and any failure to maintain our direct sales force could harm our business.

Our ability to sell our products and generate revenues primarily depends upon our direct sales force within our Americas and International markets. We do not have any long-term employment contracts with the members of our direct sales force. The loss of the services provided by these key personnel may harm our business. We recently hired approximately 100 sales personnel in the Americas and plan on hiring 50 in the EMEA region in the first quarter of 2019. To adequately train and successfully deploy new representatives into these regions and to establish strong customer relationships takes approximately six to twelve months. As a result, if we are unable to retain our direct sales force personnel or replace them with individuals of equivalent technical expertise and qualifications, or if we are unable to successfully instill such technical expertise in recently hired sales representatives or if we fail to establish and maintain strong relationships with our customers within a relatively short period of time, our net revenues and our ability to maintain market share could be materially harmed. In addition, due to our large and fragmented customer base, we may not be able to provide all of our customers with product support immediately upon the launch of a new product. As a result, adoption of new products by our customers may be slower than anticipated and our ability to grow market share and increase our net revenues may be harmed.

Complying with regulations enforced by the FDA and other regulatory authorities is an expensive and time-consuming process, and any failure to comply could result in substantial penalties.

Our products are considered medical devices and are subject to extensive regulation in the U.S. and internationally. 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.

Our failure to comply with applicable regulatory requirements could result in enforcement action by the FDA or state agencies, which may include any 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 that have already been granted; and
- criminal prosecution.

If any of these events were to occur, they could harm our business. We must 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 take satisfactory corrective action in response to an adverse inspection or the failure to comply with applicable manufacturing regulations could result in enforcement action, and we may be required to find alternative manufacturers, which could be a long and costly process. Any FDA enforcement action could have a material adverse effect on us.

Before we can sell a new medical device in the U.S., or market a new use of or claim for an existing product, we must obtain FDA clearance or approval unless an exemption applies. Obtaining regulatory clearances or approvals can be a

lengthy and time-consuming process. Even though the devices we market have obtained the necessary clearances from the FDA, we may be unable

to maintain such clearances in the future. Furthermore, we may be unable to obtain the necessary clearances for new devices that we intend to market in the future. Our inability to maintain or obtain regulatory clearances or approvals could materially harm our business.

In addition, as part of the Dodd-Frank Wall Street Reform and Consumer Protection Act, the SEC adopted disclosure requirements regarding the use of certain minerals, known as conflict minerals, which are mined from the Democratic Republic of Congo and adjoining countries, as well as procedures regarding a manufacturer's efforts to identify and discourage the sourcing of such minerals and metals produced from those minerals. Additional reporting obligations are being proposed by the European Union. The U.S. requirements and any additional requirements in Europe could affect the sourcing and availability of metals used in the manufacture of a limited number of parts (if any) contained in our products. For example, these disclosure requirements may decrease the number of suppliers capable of supplying our needs for certain metals, thereby negatively affecting our ability to obtain products in sufficient quantities or at competitive prices. Our material sourcing is broad based and multi-tiered, and we may be unable to conclusively verify the origins for all metals used in our products. We may suffer financial and reputational harm if customers require, and we are unable to deliver, certification that our products are conflict free. Regardless, we will incur additional costs associated with compliance with these disclosure requirements, including time-consuming and costly efforts to determine the source of any conflict minerals used in our products.

If compliance with healthcare regulations becomes costly and difficult for our customers or for us, we may not be able to grow our business.

Participants in the healthcare industry are subject to extensive and frequently changing regulations under numerous laws administered by governmental entities at the federal, state and local levels, some of which are, and others of which may be, applicable to our business.

Furthermore, our healthcare provider customers are also subject to a wide variety of laws and regulations that could affect the nature and scope of their relationships with us. The healthcare market itself is highly regulated and subject to changing political, economic and regulatory influences. Regulations implemented pursuant to the Health Insurance Portability and Accountability Act ("HIPAA"), including regulations affecting the security and privacy of patient healthcare information held by healthcare providers and their business associates 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. The effect of HIPAA and newly enforced regulations on our business is difficult to predict, and there can be no assurance that we will adequately address the business risks created by HIPAA and its implementation or that we will be able to take advantage of any resulting business opportunities.

Extensive and changing government regulation of the healthcare industry may be expensive to comply with and exposes us to the risk of substantial government penalties.

In addition to medical device laws and regulations, numerous state and federal healthcare-related laws regulate our business, covering areas such as:

- 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.

Complying with these laws and regulations could be expensive and time-consuming, and could increase our operating costs or reduce or eliminate certain of our sales and marketing activities or our revenues.

Our business exposes us to potential product liability claims, and we may incur substantial expenses if we are subject to product liability claims or litigation.

Medical devices involve an inherent risk of product liability claims and associated adverse publicity. We may be held liable if any product we develop or any product that uses or incorporates any of our technologies causes injury or is otherwise found unsuitable. Although we intend to continue to maintain product liability insurance, adequate insurance may not be available on acceptable terms, if at all, and may not provide adequate coverage against potential liabilities. A product liability claim, regardless of its merit or eventual outcome, could result in significant legal defense costs. These costs would have the effect of increasing our expenses and diverting management's attention away from the operation of our business, and could harm our business.

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

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

- quarterly variations in our results of operations and liquidity;
- changes in recommendations by the investment community or in their estimates of our net revenues or operating results;
- speculation in the press or investment community concerning our business and results of operations;
- strategic actions by our competitors, such as product announcements or acquisitions;
- announcements of technological innovations or new products or product offerings by us, our customers or competitors;
- key decisions in pending litigation; 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 have often been unrelated to or disproportionate to the operating performance of those companies. These broad market and industry factors may seriously harm the market price of our common stock, regardless of our operating performance. Historically, class action litigation is often brought against an issuing company following periods of volatility in the market price of a company's securities.

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 our existing stockholders may adversely affect the market price of our common stock. Such sales could create public perception of difficulties or problems with our business and may depress our stock price.

We are subject to risks associated with our strategic investments. Impairments in the value of our investments and receivables could negatively impact our financial results.

We have invested in SDC and other privately held companies for strategic reasons and to support key business initiatives, and we may not realize a return on our strategic investments. Many of such companies generate net losses and the market for their products, services or technologies may be slow to develop. Further, valuations of privately held companies are inherently complex due to the lack of readily available market data. If we determine that our investments and receivables in SDC or investments in other privately held companies have experienced a decline in value, we may be required to record impairments which could be material and could have an adverse impact on our financial results. In addition, SDC is seeking through the arbitration described below under "Item 3 Legal Proceedings - SDC Dispute," the right to repurchase all of the Company's SDC membership interests for a purchase price equal to the current capital account balance as defined by the Internal Revenue Service which likely is significantly below the current fair market value of such investment.

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

We prepare our consolidated financial statements in conformity with Generally Accepted Accounting Principles in the 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 can have a significant effect on our reported results and may even retroactively affect previously reported transactions. Our accounting policies that recently have been, or may be affected by changes in the accounting rules relate to revenue recognition and leases.

If we fail to manage our exposure to global financial and securities market risk 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 our investments exceeds the fair value, and the decline in fair value is deemed to be other-than-temporary, we will be required to write down the value of our investments, 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 environment, we might incur significant realized, unrealized or impairment losses associated with these investments.

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. 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 asset group are 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 tax laws such as the TCJA enacted into law on December 22, 2017, regulations and/or rates, new or changes to accounting pronouncements, non-deductible goodwill impairments, 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, the future levels of tax benefits of stock-based compensation, settlement of income tax audits, and changes in overall levels of pretax earnings. As a result of the adoption of Accounting Standards Update ("ASU") 2016-09 in 2017, we anticipate our effective tax rate to vary significantly in our first quarter due to the timing of when the majority of our equity compensation vests each year. Other quarters can also be impacted depending on the timing of equity vests.

Changes in tax laws or tax rulings could negatively impact our income tax provision and net income.

As a U.S. multinational corporation, we are subject to changing tax laws both within and outside of the U.S. Changes in tax laws or tax rulings, or changes in interpretations of existing tax laws, could affect our income tax provision and net income or require us to change the manner in which we operate our business. In addition, governmental tax authorities are increasingly scrutinizing the tax positions of companies. Many countries in Europe, as well as a number of other countries and organizations, have recently proposed or recommended changes to existing tax laws or have enacted new laws. For example, the Organization for Economic Cooperation and Development ("OECD") has been working on a "Base Erosion and Profit Shifting Project," which is focused on a number of issues, including the shifting of profits between affiliated entities in different tax jurisdictions. In 2015, the OECD issued and is expected to continue to issue, guidelines and proposals that may change various aspects of the existing framework under which our tax obligations are determined in many of the countries in which we do business.

ITEM 1B.UNRESOLVED STAFF COMMENTS
None.

ITEM 2.PROPERTIES
We occupy several leased and owned facilities. At December 31, 2018, the significant facilities occupied were as follows:

Location	Lease/Own	Primary Use	Expiration of Lease
San Jose, California	Own	Office for corporate headquarters, research & development and administrative personnel	N/A

Juarez, Mexico	Own	Manufacturing and office for administrative personnel	N/A
San Jose, Costa Rica	Own	Office for administrative personnel, treatment personnel, and customer care	N/A
Or Yehuda, Israel	Lease	Manufacturing and office for research & development and administrative personnel	February 2022
Amsterdam, The Netherlands	Lease	Office for European headquarters, sales and marketing and administrative personnel	March 2020
Moscow, Russia	Lease	Office for research & development	March 2024
Raleigh, North Carolina	Lease	Office for research & development and administrative personnel	March 2026
Ziyang, China	Lease	Manufacturing and office for administrative personnel	May 2021

ITEM 3.LEGAL PROCEEDINGS

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 between July 25, 2018 and October 24, 2018. The complaint generally alleges claims under the federal securities laws and seeks 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 between April 25, 2018 and October 24, 2018 (together with the first lawsuit, the "Securities Actions"). Motions for appointment as lead plaintiff were filed on January 4, 2019. 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 nor estimate a range of possible loss.

Shareholder Derivative Lawsuit

In January 2019, three derivative lawsuits were also 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 complaints are similar to those presented in the Securities Action, but the complaints assert various state law causes of action, including for breaches of fiduciary duty, insider trading, and unjust enrichment, among others. 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. 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.

Patent Infringement and Related Lawsuits

On November 14, 2017, Align filed six patent infringement lawsuits asserting 26 patents against 3Shape, a Danish corporation, and a related U.S. corporate entity, asserting that 3Shape's Trios intraoral scanning system and Dental System software infringe Align patents. Align filed two Section 337 complaints with the U.S. International Trade Commission ("ITC") alleging that 3Shape violates U.S. trade laws by selling for importation and importing its infringing Trios intraoral scanning system and Dental System software. Align's ITC complaints seek cease and desist orders and exclusion orders prohibiting the importation of 3Shape's Trios scanning system and Dental System software products into the U.S. Align also filed four separate complaints in the U.S. District Court for the District of Delaware alleging patent infringement by 3Shape's Trios intraoral scanning system and Dental System software.

On May 9, 2018, 3Shape filed a complaint in the U.S. District Court for the District of Delaware alleging patent infringement by Align's iTero Element scanner of a single 3Shape patent. On June 14, 2018, 3Shape filed another complaint in the U.S. District Court for the District of Delaware alleging patent infringement by Align's iTero Element scanner of a single 3Shape patent.

On August 28, 2018, 3Shape filed a complaint against Align in the U.S. District Court for the District of Delaware alleging antitrust violations and seeking monetary damages and injunctive relief relating to Align's market activities, including Align's assertion of its patent portfolio, in the clear aligner and intraoral scanning markets.

On December 10, 2018, Align filed three additional patent infringement lawsuits asserting 10 additional patents against 3Shape. Align filed one Section 337 complaint with the ITC alleging that 3Shape violates U.S. trade laws through unfair competition by selling for importation and importing the infringing TRIOS intraoral scanning system, Trios Lab Scanners and TRIOS software, TRIOS Module software, Dental System software, and Ortho System

Software. On December 11, 2018, Align filed two separate complaints in the U.S. District Court for the District of Delaware alleging patent infringement by 3Shape's Trios intraoral scanning system, Lab Scanners and Dental and Ortho System Software.

Except for 3Shape’s antitrust complaint, each of the District Court complaints seek monetary damages and injunctive relief against further infringement. We are currently unable to predict the outcome of this dispute and therefore cannot determine the likelihood of loss, if any, nor estimate a range of possible loss.

SDC Dispute
In February 2018, we received a communication on behalf of SDC Financial LLC, SmileDirectClub LLC, and the Members of SDC Financial LLC other than the Company (collectively, the SDC Entities) alleging that the launch and operation of the

Invisalign locations pilot program constitutes a breach of non-compete provisions applicable to the members of SDC Financial LLC, including Align. As a result of this alleged breach, SDC Financial LLC notified us that its members (other than Align) seek to exercise a right to repurchase all of Align's SDC Financial LLC membership interests for a purchase price equal to the current capital account balance. The SDC Entities' communication also alleged that we breached confidentiality provisions applicable to the SDC Financial LLC members and demanded that we cease all activities related to the Invisalign pilot project, close existing Invisalign locations and cease using SDC's confidential information. In April 2018, the SDC Entities served a Demand for Arbitration alleging that we breached the non-compete clause and confidentiality clause, misused the SDC Entities' alleged trade secrets, and violated fiduciary duties to SDC Financial LLC. The SDC Entities seek through the arbitration the rights to repurchase all of Align's SDC Financial LLC membership interests for a purchase price equal to the current capital account balance as defined by the Internal Revenue Service which likely is significantly below the current fair market value of such investment, an injunction requiring us to close our Invisalign locations and to cease using the SDC Entities' confidential information, and financial damages in an unspecified amount. We filed a response in which we denied the SDC Entities' allegations and denied that the SDC Entities are entitled to any relief. In April 2018 the SDC Entities also filed a motion for preliminary injunction in the Tennessee Court of Chancery seeking to enjoin Align from opening additional Invisalign locations until the arbitration is completed. In June 2018, the Tennessee court denied the SDC Entities' motion for a preliminary injunction. In December 2018, the parties participated in binding arbitration proceedings and presented closing arguments on January 23, 2019. The arbitrator's decision is due on or before March 4, 2019. This dispute does not impact Align's existing supply agreement with SDC which remains in place through 2019. We do not intend to renew this agreement. We are currently unable to predict the outcome of this dispute and therefore cannot determine the likelihood of loss, if any, nor estimate a range of possible loss.

In addition, in the 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 (Refer to Note 8 "Legal Proceedings" of the Notes to the Consolidated Financial Statements for details on legal proceedings).

ITEM 4.MINE SAFETY DISCLOSURES

Not applicable.

PART II

ITEM 5.MARKET FOR REGISTRANT’S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

Our common stock trades on the NASDAQ Global Market under the symbol "ALGN". As of February 22, 2019, there were approximately 73 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 shareholder return on common stock with the cumulative total returns of the NASDAQ Composite index, the S&P 500 and the S&P 1500 Composite Health Care Equipment & Supplies index. The graph tracks the performance of a $100 investment in our common stock, in the peer group, and the index (with the reinvestment of all dividends) from December 31, 2013 to December 31, 2018.

UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

Following is a summary of stock repurchases for the three months ended December 31, 2018:

Period	Total Number of Shares Repurchased	Average Price Paid per Share	Total Number of Shares Repurchased as Part of Publicly Announced Program	Approximate Dollar Value of Shares that May Yet Be Repurchased Under the Program [1]
October 1, 2018 through October 31, 2018	—	$—	—	$550,000,000
November 1, 2018 through November 30, 2018	142,677	$245.31	142,677	$500,000,000
December 1, 2018 through December 31, 2018	91,865	$163.28	91,865	$500,000,000

[1] Stock Repurchase Program
May 2018 Repurchase Program. In May 2018, we announced that our Board of Directors had authorized a plan to repurchase up to $600.0 million of our common stock. In August 2018, we repurchased $50.0 million of our common stock on the open market. In November 2018, we entered into an accelerated share repurchase ("2018 ASR") to repurchase $50.0 million of our common stock which was completed in December 2018. As of December 31, 2018, we have $500.0 million remaining under the May 2018 Repurchase Program (Refer to Note 11 "Common Stock Repurchase Programs" of the Notes to Consolidated Financial Statements for details on common stock repurchase programs).

ITEM 6.SELECTED CONSOLIDATED FINANCIAL DATA

The following tables set forth the selected consolidated financial data for each of the years in the five-year period ended December 31, 2018. The selected consolidated financial data should be read in conjunction with the consolidated financial statements and accompanying notes and Management's Discussion and Analysis of Financial Condition and Results of Operations.

SELECTED CONSOLIDATED FINANCIAL DATA
(in thousands, except per share data)

	Year Ended December 31,				
	2018	2017	2016	2015	2014
Consolidated Statements of Operations Data:					
Net revenues	$1,966,492	$1,473,413	$1,079,874	$845,486	$761,653
Gross profit	$1,447,867	$1,116,947	$815,294	$640,110	$578,443
Income from operations	466,564	353,611	248,921	188,634	193,576
Interest income	8,576	6,948	4,213	2,938	1,818
Other income (expense), net	(8,489)	4,240	(10,568)	(5,471)	(5,025)
Net income before provision for income taxes and equity in losses of investee	466,651	364,799	242,566	186,101	190,369
Provision for income taxes	57,723	130,162	51,200	42,081	44,537
Equity in losses of investee, net of tax	8,693	3,219	1,684	—	—
Net income	$400,235	$231,418	$189,682	$144,020	$145,832
Net income per share:					
Basic	$5.00	$2.89	$2.38	$1.80	$1.81
Diluted	$4.92	$2.83	$2.33	$1.77	$1.77
Shares used in computing net income per share:					
Basic	80,064	80,085	79,856	79,998	80,754
Diluted	81,357	81,832	81,484	81,521	82,283

	December 31,				
	2018	2017 [2]	2016 [2]	2015	2014
Consolidated Balance Sheet Data:					
Working capital [1]	$610,406	$658,316	$597,772	$460,338	$455,349
Total assets	2,052,458	1,784,009	1,402,305	1,158,633	987,997
Total long-term liabilities	107,494	129,670	46,427	39,035	33,415
Stockholders' equity	$1,252,891	$1,154,288	$999,307	$847,926	$752,771

[1] Working capital is calculated as the difference between total current assets and total current liabilities.

[2] Balances have been recast to reflect the adoption of new revenue accounting standard (Refer to Note 1 "Summary of Significant Accounting Policies" of the Notes to Consolidated Financial Statements for details).

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 "Selected Consolidated Financial Data" and our consolidated financial statements and related notes included elsewhere in this Annual Report on Form 10-K.

Overview

Our goal is to establish Invisalign clear aligners as the standard method for treating malocclusion and to establish the iTero intraoral scanner as the preferred scanning device for 3D digital scans, ultimately driving increased product adoption by dental professionals. We intend to achieve this by continued focus and execution of our strategic growth drivers set forth in the Business Strategy section in this Annual Report on Form 10-K.

The successful execution of our business strategy in 2019 and beyond may be affected by a number of other factors including:

- New Invisalign Product Portfolio and Pricing. In July 2018, we launched a new expanded Invisalign product portfolio which includes new options and greater flexibility to treat a broader range of patients. The new Invisalign product portfolio offers doctors more choices by extending desirable features across the entire portfolio and creating new Invisalign treatment packages, as well as new options to treat young patients with early mixed dentition (with a mixture of primary/baby and permanent teeth). The new end-to-end Invisalign product portfolio includes clear aligner product offerings for almost every patient age group and case complexity to make it easier for our doctors to tailor treatment planning to the needs of each patient. Pricing and availability for the new Invisalign product offerings and the associated terms and conditions vary by region.

- New Invisalign Products and Feature Enhancements. Product innovation drives greater treatment predictability, clinical applicability and ease of use for our customers which supports adoption of Invisalign treatment in their practices. Our focus is to develop solutions and features to treat a wide range of cases from simple to complex.

In March 2017, we announced Invisalign treatment with Mandibular Advancement, the first clear aligner solution for Class II correction in growing tween and teen patients. This offering combines the benefits of our clear aligner system with features for moving the lower jaw forward while simultaneously aligning the teeth. Invisalign treatment with Mandibular Advancement is available in Canada, select Europe, Middle East and Africa ("EMEA"), Asia Pacific ("APAC") and Latin America ("LATAM") countries and, in the U.S. starting November 2018 as we received 510(k) clearance from the United States ("U.S.") Food and Drug Administration in October 2018.

Beginning July 2018, Invisalign First clear aligners, a treatment option designed with features specifically for younger patients with early mixed dentition, are available to Invisalign-trained doctors in the U.S., Canada, Australia, New Zealand, Japan, and the EMEA region. Invisalign First clear aligners are designed specifically to address a broad range of younger patients' malocclusions, including shorter clinical crowns, management of erupting dentition and predictable dental arch expansion. Phase 1 treatment is an early interceptive orthodontic treatment for young patients, traditionally done through arch expanders, or partial metal braces, before all permanent teeth have erupted, typically at ages seven through ten years.

In April 2018, we announced a new Invisalign Go product with more user-friendly iTero digital chairside experience and greater flexibility to treat a wider range of mild to moderate cases, such as crowded or gap teeth that require teeth straightening prior to restorative treatments. Invisalign Go is available to Invisalign-trained doctors in the U.S., the majority of European countries as well as in select APAC markets. Invisalign Go also incorporates new data-driven clinical protocols for predictable tooth movement and automated case assessments that leverages our Invisalign

patients treated to date. These improvements make it easier for general practitioner dentists to tailor their treatment plans to the individual needs of each patient.

- New iTero Products and Technology Innovation. The iTero scanner is an important component to our customer experience and is central to a digital approach as well as overall customer utilization of Invisalign.

In April 2018, we expanded the iTero Element portfolio with the launch of the iTero Element 2 and the iTero Element Flex scanners, building on the existing high precision, full-color imaging and fast scan times of the

iTero Element portfolio while streamlining orthodontic and restorative workflows. The next-generation iTero Element 2 is designed for greater performance with 2X faster start-up and 25% faster scan processing time compared to the iTero Element. The new iTero Element Flex wand-only configuration is a portable scanner for easy transport from office to office. iTero Element 2 and iTero Element Flex scanners are available in the U.S., Canada, the majority of European countries as well as in select APAC markets. The existing iTero Element scanner continues to be available in all markets.

In April 2018, we announced that we received market approval for the iTero Element intra-oral scanner from the China Food and Drug Administration, and we began offering this scanner in China. The iTero Element scanner launch in China not only supports growth of our base Invisalign clear aligner business but also represents a major milestone for digital dentistry in China. As we continue to expand into markets where we sell our intra-oral scanners, we expect continued growth for the foreseeable future due to the size of the market opportunities and our relatively low market penetration in these regions.

We believe that over the long-term, clinical solutions and treatment tools will increase adoption of Invisalign and increase sales of our intraoral scanners; however, it is difficult to predict the rate of adoption which may vary by region and channel.

The use of iTero and other digital scanners for Invisalign case submission in place of PVS impressions continues to grow and remains a positive catalyst for Invisalign utilization. For the fourth quarter of 2018, total Invisalign cases submitted with a digital scanner in the Americas increased to 72.6%, up from 71.0% in the third quarter of 2018. International scans increased to 57.5%, up from 53.9% in the third quarter of 2018. In China, Invisalign cases submitted using a digital scanner increased to 45.9% from close to 0% in only one year. We believe that over the long-term, technology innovation and added features and functionality of our iTero scanners will increase adoption of Invisalign and increase sales of our intraoral scanners; however, it is difficult to predict the rate of adoption which may vary by region and channel.

- Invisalign Adoption. Our goal is to establish Invisalign as the treatment of choice for treating malocclusion ultimately driving increased product adoption and frequency of use by dental professionals, also known as "utilization rates." Our annual utilization rates for the last three fiscal years are as follows:

* Invisalign utilization rates = # of cases shipped divided by # of doctors cases were shipped to. Beginning in the first quarter of 2018, we report International region to include EMEA and APAC. LATAM is excluded from above chart as it is not material. Our historical utilization numbers have been recast to reflect this new classification.

Total utilization in 2018 increased to 15.7 cases per doctor compared to 14.5 cases in 2017.
North America: Utilization among our North American orthodontist customers increased in 2018 to 56.7 cases per doctor compared to 46.6 cases per doctor in 2017. The increase in North American

orthodontist utilization in 2018 reflects improvements in product and technology which continues to strengthen our doctors' clinical confidence such that they now utilize Invisalign more often and on more complex cases, including their teenage patients.

International: International doctor utilization was 13.9 cases per doctor in 2018 compared to 13.2 cases in 2017. The increase in International utilization reflects increased utilization and continued expansion of our customer base in both EMEA and APAC regions due to increasing adoption of the product due in part to its ability to treat more complex cases.

We expect that over the long-term, our utilization rates will gradually improve as a result of advancements in product and technology, which continue to strengthen our doctors' clinical confidence in the use of Invisalign. In addition, since the teenage and younger market makes up 75% of the approximately 12 million total orthodontic case starts each year, and as we continue to drive adoption of teenage and younger patients through sales and marketing programs, we expect our utilization rate to improve. Our utilization rates, however, may fluctuate from period to period due to a variety of factors, including seasonal trends in our business along with adoption rates of new products and features.

- Number of New Invisalign Doctors Trained. We continue to expand our Invisalign customer base through the training of new doctors. In 2018, we trained approximately 19,655 new Invisalign doctors of which 7,885 were trained in the Americas region and 11,770 in the International region.

International Invisalign Growth. We continue to focus our efforts towards increasing Invisalign clear aligner adoption by dental professionals in the EMEA and APAC markets. On a year-over-year basis, our international Invisalign volume increased 45.3% driven primarily by increased adoption as well as expansion of our customer base in both the EMEA and APAC regions. We continue to see growth from our international orthodontists and general practitioner ("GP") customers and are seeing more positive traction in the GP channel from segmenting our sales and marketing resources and programs specifically around each customer channel. In addition, we believe that continuous product introductions and feature improvements, such as Invisalign treatment with mandibular advancement, provide our customers with continued confidence in treating complex cases as well as teen-aged patients with Invisalign clear aligners. In 2019, we are continuing to expand in our existing markets through targeted investments in sales coverage and professional marketing and education programs, along with consumer marketing in select country markets. We expect International revenues to continue to grow at a faster rate than the Americas for the foreseeable future due to our continued investment in international market expansion, the size of the market opportunities, and our relatively low market penetration of these regions. Our future growth is dependent upon the continued growth of Invisalign adoption and international market penetration (Refer to Item 1A Risk Factors - "We are exposed to fluctuations in currency exchange rates, which could negatively affect our financial condition and results of operations." for information on related risk factors).

- Establish Regional Order Acquisition, Treatment Planning and Manufacturing Operations. We will continue to establish and expand additional order acquisition, treatment planning and manufacturing operations closer to our international customers in order to improve our operational efficiency and to provide doctors confidence in using Invisalign clear aligners to treat more patients and more often. In the fourth quarter of 2018, we began fabricating our aligners in our new manufacturing facility in Ziyang, China, our first aligner fabrication facility outside of Juarez, Mexico. We expect that it will take several quarters to ramp this facility up to full capacity and as a result manufacturing labor and overhead in this facility will be underutilized during this transition period. (Refer to Item 1A Risk Factors - "As we continue to grow, we are subject to growth related risks, including risks related to excess or constrained capacity at our existing facilities." for information on related risk factors).
- Invisalign Experience Program. In 2018, we expanded the interactive brand experience that was piloted in 2017 and finished the year with a total of twelve Invisalign locations in major U.S. cities. The program expansion is designed to address the rapidly-evolving consumer market for clear aligners and connects consumers interested in Invisalign treatment with Invisalign doctors in their communities (Refer to Item 3 "Legal Proceedings" for details on SDC dispute which may impact the Invisalign locations).
- Increased Sales Force. In order to provide more comprehensive sales and service coverage, in the fourth quarter of 2018, we increased our sales force in the Americas by adding approximately 100 sales team members. In the first

quarter of 2019, we plan to add 50 new sales representatives in EMEA to cover GP dentist channel. (Refer to Item 1A Risk Factors - “We primarily rely on our direct sales force to sell our products, and any failure to maintain our direct sales force could harm our business" for information on related risk factors).

Explanation of Responses: 66

- Expenses. We expect expenses to increase in 2019 due in part to:

Investments in manufacturing capacity and facilities to enhance our regional capabilities;
Investments in international expansion in new country markets;
Investments in expansion of number of direct sales force personnel;
Increases in sales, marketing and customer support resources;
Product and technology innovation to enhance product efficiency and operational productivity;
Increases in legal expenses, primarily related to the continued protection of our intellectual property rights including our patents along with the additional costs related to the planned corporate structure reorganization.

We believe that these investments will position us to increase our revenues and continue to grow our market share, but will negatively impact results of operations, particularly in the near term.

- Stock Repurchases:

April 2016 Repurchase Program. In 2018, we repurchased approximately $200.0 million of our common stock on the open market, completing the April 2016 Repurchase Program.

May 2018 Repurchase Program. In May 2018, we announced that our Board of Directors had authorized a plan to repurchase up to $600.0 million of our common stock. In August 2018, we repurchased $50.0 million of our common stock on the open market. In November 2018, we entered into an accelerated share repurchase ("2018 ASR") to repurchase $50.0 million of our common stock which was completed in December 2018. As of December 31, 2018, we have $500.0 million remaining under the May 2018 Repurchase Program. In February 2019, we repurchased $50.0 million of our common stock on the open market (Refer to Note 11 "Common Stock Repurchase Programs" of the Notes to Consolidated Financial Statements for details on common stock repurchase programs).

SmileDirectClub. In February 2018, we received a communication on behalf of SDC Financial LLC, SmileDirectClub LLC, and the Members of SDC Financial LLC other than the Company (collectively, the SDC Entities) alleging that the launch and operation of the Invisalign locations pilot program constitutes a breach of non-compete provisions applicable to the members of SDC Financial LLC, including Align. As a result of this alleged breach, SDC Financial LLC notified us that its members (other than Align) seek to exercise a right to repurchase all of Align's SDC Financial LLC membership interests for a purchase price equal to the current capital account balance. The SDC Entities' communication also alleged that we breached confidentiality provisions applicable to the SDC Financial LLC members and demanded that we cease all activities related to the Invisalign pilot project, close existing Invisalign locations and cease using SDC's confidential information. In April 2018, the SDC Entities served a Demand for Arbitration alleging that we breached the non-compete clause and confidentiality clause, misused the SDC Entities' alleged trade secrets, and violated fiduciary duties to SDC Financial LLC. The SDC Entities seek through the arbitration the rights to repurchase all of Align's SDC Financial LLC membership interests for a purchase price equal to the current capital account balance as defined by the Internal Revenue Service which likely is significantly below the current fair market value of such investment, an injunction requiring us to close our Invisalign locations and to cease using the SDC Entities' confidential information, and financial damages in an unspecified amount. We filed a response in which we denied the SDC Entities' allegations and denied that the SDC Entities are entitled to any relief. In April 2018 the SDC Entities also filed a motion for preliminary injunction in the Tennessee Court of Chancery seeking to enjoin Align from opening additional Invisalign locations until the arbitration is completed. In June 2018, the Tennessee court denied the SDC Entities' motion for a preliminary injunction. In December 2018, the parties participated in binding arbitration proceedings and presented closing arguments on January 23, 2019. The arbitrator's decision is due on or before March 4, 2019. This dispute does not impact Align's existing supply agreement with SDC which remains in place through 2019. We do not intend to renew this agreement. We are currently unable to predict the outcome of this dispute and therefore cannot determine the likelihood of loss, if any, nor estimate a range of possible loss. (Refer to Note 8 "Legal Proceedings" of the Notes to Consolidated Financial Statements for details on SDC dispute).

Results of Operations

We group our operations into two reportable segments: Clear Aligner segment and Scanner segment

- Our Clear Aligner segment consists of Comprehensive Products, Non-Comprehensive Products and Non-Case revenues as defined below:
  - Comprehensive Products include, but not limited to, Invisalign Comprehensive (formerly known as Invisalign Full and Invisalign Teen), Invisalign Assist and Invisalign First.
  - Non-Comprehensive Products include, but not limited to, Invisalign Express 10, Invisalign Express 5, Express Package, Lite Package and Invisalign Go in addition to revenues from the sale of aligners to SmileDirectClub (“SDC”) under our supply agreement.
  - Non-Case includes, but not limited to, Vivera retainers along with our training and ancillary products for treating malocclusion.
- Our Scanner segment consists of intraoral scanning systems, additional services and ancillary products available with the intraoral scanners that provide digital alternatives to the traditional cast models. This segment includes our iTero scanner and OrthoCAD services.

Effective in the first quarter of 2018, Americas region includes North America and LATAM. International region includes EMEA and APAC. Historical data has been recasted to reflect the change.

Net Revenues for Reportable Segments by Region

Net revenues for our Clear Aligner and Scanner segments by region for the year ended December 31, 2018, 2017 and 2016 are as follows (in millions):

Net Revenues	Year Ended December 31, 2018	December 31, 2017	Change		Year Ended December 31, 2017	December 31, 2016	Change	
Clear Aligner revenues:								
Americas	$903.3	$ 754.1	$149.2	19.8%	$754.1	$ 571.6	$182.5	31.9%
International	684.2	473.5	210.7	44.5%	473.5	323.7	149.8	46.3%
Non-Case	104.0	81.7	22.3	27.3%	81.7	63.0	18.7	29.7%
Total Clear Aligner net revenues	$1,691.5	$ 1,309.3	$382.2	29.2%	$1,309.3	$ 958.3	$351.0	36.6%
Scanner net revenues	275.0	164.1	110.9	67.6%	164.1	121.5	42.6	35.1%
Total net revenues	$1,966.5	$ 1,473.4	$493.1	33.5%	$1,473.4	$ 1,079.8	$393.6	36.5%

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

Clear Aligner Case Volume by Region

Case volume data which represents Clear Aligner case shipments by region, for the year ended December 31, 2018, 2017 and 2016 is as follows (in thousands):

Region	Year Ended December 31, 2018	December 31, 2017	Change		Year Ended December 31, 2017	December 31, 2016	Change	
Americas	780.7	631.6	149.1	23.6%	631.6	469.4	162.2	34.6%
International	499.9	344.8	155.1	45.0%	344.8	239.8	105.0	43.8%
Total case volume	1,280.6	976.4	304.2	31.2%	976.4	709.2	267.2	37.7%

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

Explanation of Responses:

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Explanation of Responses: 70

Fiscal Year 2018 compared to Fiscal Year 2017

Total net revenues increased by $493.1 million in 2018 as compared to 2017 primarily as a result of Clear Aligner case and scanner volume growth across all regions.

Clear Aligner - Americas

Americas net revenues increased by $149.2 million in 2018 as compared to 2017, primarily due to case volume growth across all channels and products which increased net revenues by $177.9 million. This increase was offset in part by lower average selling prices ("ASP"), which was mainly the result of higher promotional discounts, which reduced net revenues by $44.7 million, and increased net revenue deferrals by $3.0 million. This decline was partially offset by higher prices from the new products introduced in July 2018, which increased net revenues by $19.2 million.

Clear Aligner - International

International net revenues increased by $210.7 million in 2018 as compared to 2017, primarily driven by case volume growth across all channels and products which increased net revenues by $213.0 million. This increase was slightly offset by lower ASP which reduced net revenues by $2.3 million. The ASP decline was mainly the result of increased net revenue deferrals mostly for additional aligners, which reduced net revenues by $20.1 million, and higher promotions discounts, which reduced net revenues by $17.4 million. These were partially offset by the favorable foreign exchange rates of $20.8 million and the higher prices of $18.3 million related to our new products effective July 2018.

Clear Aligner - Non-Case

Non-case net revenues, consisting of Vivera Retainers, training fees and other product revenues, increased by $22.3 million in 2018 compared to 2017. This was primarily due to increased Vivera volume across all regions, which increased revenue by $14.4 million, and training revenues across all regions, which increased revenue by $6.5 million.

Scanner

Scanner and services net revenues increased by $110.9 million in 2018 as compared to 2017. This increase is primarily due to an increase in the number of scanners recognized, which increased revenues $87.8 million. Additionally, a larger scanner install base resulted in higher computer-aided design/computer-aided manufacturing ("CAD/CAM") services which increased net revenues by $21.3 million and higher disposable sleeve volume which increased net revenue by $6.9 million. These factors were offset in part by a decrease in scanner ASP mostly due to increased promotional discounts, which reduced net revenues by $5.5 million.

Fiscal Year 2017 compared to Fiscal Year 2016

Total net revenues increased by $393.6 million in 2017 as compared to 2016 primarily as a result of Clear Aligner case volume growth across all regions and products as well as increased non-case revenue.

Clear Aligner - Americas

Americas net revenues increased by $182.5 million in 2017 compared to 2016 primarily due to case volume growth across all channels and most products which increased net revenues by $195.5 million. This increase was offset in part by lower ASP which decreased net revenues by $13.1 million. The ASP decline was a result of a shift in product mix towards Non-Comprehensive Products, primarily driven by increased SDC revenues which carry a lower ASP and higher Invisalign promotional discounts, which collectively reduced revenues by $58.4 million. These factors

contributing to the decline in ASP were partially offset in part by price increases on our Comprehensive Products effective on April 1, 2017 which contributed $28.4 million to net revenues as well as an increase in additional aligner revenue which contributed $10.8 million to net revenues, among other factors.

Clear Aligner - International

International net revenues increased by $149.8 million in 2017 compared to 2016 primarily driven by case volume growth across all channels and products which increased net revenues by $142.9 million and, to a lesser extent, higher ASP which contributed approximately $6.8 million to the increase in net revenues. The increase in ASP was primarily due to price increases in our Comprehensive Products effective on July 1, 2017, as well as the impact from acquiring certain distributors as we now recognize direct sales at full ASP rather than the discounted ASP, which collectively contributed $24.4 million to net revenues. The factors contributing to an increase in ASP were partially offset in part by higher promotional discounts which decreased net revenues by $13.7 million as well as an increase in net revenue deferrals of $3.0 million, among other factors.

Clear Aligner - Non-Case

Non-case net revenues, consisting of Vivera Retainers, training fees and ancillary product revenues, increased by $18.7 million in 2017 compared to 2016 primarily due to increased Vivera volume both in Americas and International.

Scanner

Scanner net revenues increased by $42.6 million in 2017 compared to 2016 primarily as a result of an increase in the number of scanners recognized which increased net revenues by $29.7 million as well as higher CAD/CAM services resulting from a larger installed base of scanners which contributed $16.2 million to net revenues. These increases were offset in part by a decrease in scanner ASP which reduced net revenues by $3.3 million.

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

	Year Ended December 31, 2018		Year Ended December 31, 2017		Change	Year Ended December 31, 2017		Year Ended December 31, 2016		Change
Clear Aligner										
Cost of net revenues	$411.0		$ 289.7		$121.3	$289.7		$ 210.8		$78.9
% of net segment revenues	24.3	%	22.1	%		22.1	%	22.0	%	
Gross profit	$1,280.5		$ 1,019.6		$260.9	$1,019.6		$ 747.5		$272.1
Gross margin %	75.7	%	77.9	%		77.9	%	78.0	%	
Scanner										
Cost of net revenues	$107.7		$ 66.8		$40.9	$66.8		$ 53.7		$13.1
% of net segment revenues	39.1	%	40.7	%		40.7	%	44.2	%	
Gross profit	$167.4		$ 97.4		$70.0	$97.4		$ 67.8		$29.6
Gross margin %	60.9	%	59.3	%		59.3	%	55.8	%	
Total cost of net revenues	$518.6		$ 356.5		$162.1	$356.5		$ 264.6		$91.9
% of net revenues	26.4	%	24.2	%		24.2	%	24.5	%	
Gross profit	$1,447.9		$ 1,116.9		$331.0	$1,116.9		$ 815.3		$301.6
Gross margin %	73.6	%	75.8	%		75.8	%	75.5	%	

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

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

Fiscal Year 2018 compared to Fiscal Year 2017

Clear Aligner

The gross margin percentage decreased in 2018 compared to 2017 primarily due to higher manufacturing spend driven by operational expansion activities and an increase in aligners per case driven by additional aligners.

Scanner

The gross margin percentage increased in 2018 compared to 2017 primarily driven by manufacturing efficiencies offset in part by a lower ASP.

Fiscal Year 2017 compared to Fiscal Year 2016

Clear Aligner

The gross margin percentage declined slightly in 2017 compared to 2016 primarily due to an increase in aligners per case driven by additional aligners which was partially offset by higher absorption as a result of increased production volumes.

Scanner

The gross margin percentage increased in 2017 compared to 2016 primarily due to a favorable product mix shift to our lower cost iTero Element scanner. This was partially offset by a lower ASP.

Selling, general and administrative (in millions):

	Year Ended December 31, 2018		Year Ended December 31, 2017	Change	Year Ended December 31, 2017		Year Ended December 31, 2016	Change
Selling, general and administrative	$852.4		$ 665.8	$186.6	$665.8		$ 490.7	$175.1
% of net revenues	43.3	%	45.2 %		45.2	%	45.4 %	

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

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

Fiscal Year 2018 compared to Fiscal Year 2017

Selling, general and administrative expense increased in 2018 compared to 2017 primarily due to higher compensation related costs of $110.9 million mainly from increased headcount resulting in higher salaries expense, incentive bonuses and fringe benefits as a result of investments in sales coverage and international expansion. We also incurred higher expenses from equipment, software and maintenance costs of $27.0 million from investments in facilities to enhance our regional capabilities, advertising and marketing of $24.3 million and $22.3 million of legal and outside services costs.

Fiscal Year 2017 compared to Fiscal Year 2016

Selling, general and administrative expense increased in 2017 compared to 2016 primarily due to higher compensation related costs of $85.6 million mainly from increased headcount resulting in higher salaries expense, incentive bonuses and fringe benefits. We also incurred higher expenses from advertising and marketing of $34.2 million, equipment and maintenance costs of $21.9 million and outside services costs of $20.3 million.

Research and development (in millions):

	Year Ended December 31, 2018		Year Ended December 31, 2017	Change	Year Ended December 31, 2017		Year Ended December 31, 2016	Change
Research and development	$ 128.9		$ 97.6	$ 31.3	$ 97.6		$ 75.7	$ 21.9
% of net revenues	6.6	%	6.6 %		6.6	%	7.0 %	

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

Research and development expense includes the personnel-related costs including payroll and stock-based compensation and outside consulting expenses associated with the research and development of new products and enhancements to existing products and allocations of corporate overhead expenses including facilities and IT.

Research and development expense increased for both periods primarily due to higher compensation costs mainly from increased headcount resulting in higher salaries expense, incentive bonuses and fringe benefits.

Income from operations (in millions):

	Year Ended December 31, 2018		Year Ended December 31, 2017		Change	Year Ended December 31, 2017		Year Ended December 31, 2016		Change
Clear Aligner										
Income from operations	$712.4		$ 564.6		$147.8	$564.6		$ 411.8		$152.8
Operating margin %	42.1	%	43.1	%		43.1	%	43.0	%	
Scanner										
Income from operations	$99.0		$ 49.6		$49.4	$49.6		$ 37.5		$12.1
Operating margin %	36.0	%	30.2	%		30.2	%	30.9	%	
Total income from operations [1]	$466.6		$ 353.6		$113.0	$353.6		$ 248.9		$104.7
Operating margin %	23.7	%	24.0	%		24.0	%	23.1	%	

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

[1] Refer to Note 16 "Segments and Geographical Information" of the Notes to Consolidated Financial Statements for details on unallocated corporate expenses and the reconciliation to Consolidated Income from Operations.

Fiscal Year 2018 compared to Fiscal Year 2017

Clear Aligner

Operating margin percentage decreased in 2018 compared to 2017 due to higher manufacturing spend driven by operational expansion activities and an increase in aligners per case driven by additional aligners partially offset by leveraged spend of operating expenses on higher Clear Aligner revenues.

Scanner

Operating margin percentage increased in 2018 compared to 2017 due to leveraged spend of operating expenses on higher Scanner revenues and manufacturing efficiencies partially offset by a lower ASP.

Fiscal Year 2017 compared to Fiscal Year 2016

Clear Aligner

Operating margin percentage increased slightly in 2017 compared to 2016 due to leveraged spend of operating expenses on higher Clear Aligner revenues.

Scanner

Operating margin percentage decreased in 2017 compared to 2016 due to higher operating expenses and, to a lesser extent, lower ASP. This was partially offset by a favorable product mix shift to our lower cost iTero Element scanner.

Interest income (in millions):

	Year Ended December 31, 2018	Year Ended December 31, 2017	Change	Year Ended December 31, 2017	Year Ended December 31, 2016	Change
Interest income	$ 8.6	$ 6.9	$ 1.7	$ 6.9	$ 4.2	$ 2.7

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

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

Fiscal Year 2018 compared to Fiscal Year 2017

Interest income increased in 2018 compared to 2017 mainly due to higher interest rates.

Fiscal Year 2017 compared to Fiscal Year 2016

Interest income increased in 2017 compared to 2016 mainly due to a larger investment portfolio.

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

	Year Ended December 31, 2018	Year Ended December 31, 2017	Change	Year Ended December 31, 2017	Year Ended December 31, 2016	Change
Other income (expense), net	$ (8.5)	$ 4.2	$ (12.7)	$ 4.2	$ (10.6)	$ 14.8

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

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

Fiscal Year 2018 compared to Fiscal Year 2017

Other income (expense), net, decreased in 2018 compared to 2017 mainly due to foreign exchange losses partially offset by gains on foreign currency forward contracts.

Fiscal Year 2017 compared to Fiscal Year 2016

Other income (expense), net, increased in 2017 compared to 2016 mainly due to higher foreign exchange gains as a result of the Euro strengthening to the U.S. dollar.

Equity in losses of investee, net of tax (in millions):

	Year Ended December 31, 2018	Year Ended December 31, 2017	Change	Year Ended December 31, 2017	Year Ended December 31, 2016	Change
Equity in losses of investee, net of tax	$ 8.7	$ 3.2	$ 5.5	$ 3.2	$ 1.7	$ 1.5

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

Fiscal Year 2018 compared to Fiscal Year 2017

Equity in losses of investee, net of tax increased in 2018 compared to 2017 due to higher losses attributable from our equity method investments including a higher proportional share of the losses due to our additional investment made in the third quarter of 2017.

Fiscal Year 2017 compared to Fiscal Year 2016

Equity in losses of investee, net of tax increased in 2017 compared in 2016 due to a full year of losses attributable to equity method investments as well as a higher share due to our additional investment made in the third quarter of 2017 (Refer to Note 4 "Equity Method Investments" of the Notes to Consolidated Financial Statements for details on equity method investments).

Provision for income taxes (in millions):

	Year Ended December 31, 2018	Year Ended December 31, 2017	Change	Year Ended December 31, 2017	Year Ended December 31, 2016	Change
Provision for income taxes	$57.7	$ 130.2	$(72.5)	$130.2	$ 51.2	$ 79.0
Effective tax rates	12.4 %	35.7 %		35.7 %	21.1 %	

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

Our provision for income taxes was $57.7 million, $130.2 million and $51.2 million for the year ended December 31, 2018, 2017 and 2016, respectively, representing effective tax rates of 12.4%, 35.7% and 21.1%, respectively.

The decrease in effective tax rate for the year ended December 31, 2018 compared to the same period in 2017 is mainly driven by the provisional amounts recorded in 2017 related to the TCJA that did not recur in 2018, the recognition of tax benefits related to a statute of limitations expiration and the increase in excess tax benefits related to stock-based compensation, offset in part by the unfavorable tax impact of the TCJA including non-deductible officers' compensation and reduced tax benefits from foreign earnings being taxed at a lower rate. For the year ended December 31, 2018, the excess tax benefits related to stock-based compensation we recognized in our provision for income taxes was $26.5 million.

In June 2017, the Costa Rica Ministry of Foreign Trade, an agency of the Government of Costa Rica, granted an extension of certain income tax incentives for an additional twelve year period. Under these incentives, all of the income in Costa Rica is subject to a reduced tax rate. In order to receive the benefit of these incentives, we must hire specified numbers of employees and maintain certain minimum levels of fixed asset investment in Costa Rica. If we do not fulfill these conditions for any reason, our incentive could lapse, and our income in Costa Rica would be subject to taxation at higher rates which could have a negative impact on our operating results. The Costa Rica corporate income tax rate that would apply, absent the incentives, is 30% for 2018, 2017 and 2016. As a result of these incentives, our income taxes were reduced by $2.4 million, $1.8 million and $19.1 million in the year ended December 31, 2018, 2017 and 2016, respectively, representing a benefit to diluted net income per share of $0.03, $0.02 and $0.23 in the year ended December 31, 2018, 2017 and 2016, respectively (Refer to Note 13 "Accounting for Income Taxes" of the Notes to Consolidated Financial Statements for details on income taxes).

Liquidity and Capital Resources

We fund our operations from product and services sales. As of December 31, 2018 and 2017, we had the following cash and cash equivalents, and short-term and long-term marketable securities (in thousands):

	Year Ended December 31, 2018	2017
Cash and cash equivalents	$636,899	$449,511
Marketable securities, short-term	98,460	272,031
Marketable securities, long-term	9,112	39,948
Total	$744,471	$761,490

As of December 31, 2018, we had $744.5 million in cash, cash equivalents, and short-term and long-term marketable securities. Cash equivalents and marketable securities are comprised of money market funds and highly liquid debt instruments which primarily include commercial paper, corporate bonds, U.S. government agency bonds, U.S. government treasury bonds and certificates of deposit.

As of December 31, 2018, approximately $312.0 million of cash, cash equivalents and short-term and long-term marketable securities was held by our foreign subsidiaries. We repatriated $360.0 million to the U.S. during the year

ended December 31, 2018 and we may further repatriate funds in the future to invest in market expansion opportunities, provide additional working capital, and have greater flexibility to fund our stock repurchase programs (Refer to Note 13 "Income Taxes" of the Notes to Consolidated Financial Statements for details).

Cash flows (in thousands):

	Year Ended December 31,		
	2018	2017	2016
Net cash provided by (used in):			
Operating activities	$554,681	$438,539	$247,654
Investing activities	6,927	(251,477)	73,028
Financing activities	(369,434)	(135,500)	(95,524)
Effects of foreign exchange rate changes on cash, cash equivalents, and restricted cash	(4,733)	5,544	(3,374)
Net increase in cash, cash equivalents, and restricted cash	$187,441	$57,106	$221,784

Operating Activities

For the year ended December 31, 2018, cash flows from operations of $554.7 million resulted primarily from our net income of approximately $400.2 million as well as the following:

Significant non-cash activities

- Stock-based compensation was $70.8 million related to equity incentive compensation granted to employees and directors;
- Depreciation and amortization of $54.7 million related to our investments in property, plant and equipment and intangible assets; and
- Net change in deferred tax assets of $15.7 million.

Significant changes in working capital

- Increase of $136.4 million in deferred revenues corresponding to the increase in case volume;
- Increase of $109.2 million in accounts receivable which is primarily a result of the increase in net revenues; and
- Decrease of $36.5 million in long-term income tax payable due to timing of payments made to IRS.

For the year ended December 31, 2017, cash flows from operations of $438.5 million resulted primarily from our net income of approximately $231.4 million as well as the following:

Significant non-cash activities

- Stock-based compensation was $58.9 million related to equity incentive compensation granted to employees and directors;
- Depreciation and amortization of $37.7 million related to our investments in property, plant and equipment and intangible assets; and
- Net change in deferred tax assets of $17.6 million.

Significant changes in working capital

- Increase of $91.0 million in accounts receivable which is a result of the increase in net revenues;
- Increase of $79.7 million in deferred revenues corresponding to the increases in case volume;
- Increase of $69.0 million in long-term income tax payable due to the new TCJA enacted on December 22, 2017; and
- Increase of $24.2 million in accrued and other long-term liabilities due to timing of payments and activities.

For the year ended December 31, 2016, cash flows from operations of $247.7 million resulted primarily from our net income of approximately $189.7 million as well as the following:

Significant non-cash activities

- Stock-based compensation was $54.1 million related to our equity incentive compensation granted to employees and directors;

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Explanation of Responses:

- Depreciation and amortization of $24.0 million related to our investments in property, plant and equipment and intangible assets;
- Excess tax benefits from our share-based compensation arrangements of $16.8 million;
- Net change in deferred tax assets of $16.4 million; and
- Net tax benefits from stock-based compensation of $15.9 million.

Significant changes in working capital

- Increase of $95.8 million in accounts receivable which is a result of the increase in net revenues;
- Increase of $60.7 million in deferred revenues corresponding to the increases in case volume and full year effect of our additional aligner product policy effective in July 2015; and
- Increase of $31.4 million in accrued and other long-term liabilities due to timing of payments and activities.

Investing Activities

Net cash provided by investing activities was $6.9 million for the year ended December 31, 2018, which primarily consisted of maturities and sales of our marketable securities of $384.7 million and loan repayment from equity investee of $30.0 million. These inflows were partially offset by purchases property, plant and equipment of $223.3 million, purchases of marketable securities of $180.2 million and purchases of investments in privately held companies of $5.0 million.

For 2019, we expect to invest $250.0 million to $260.0 million on capital expenditures primarily related to operational expansion and ongoing growth of the business.

Net cash used in investing activities was $251.5 million for the year ended December 31, 2017, which primarily consisted of purchases of marketable securities of $390.2 million, property, plant and equipment purchases of $195.7 million for additional manufacturing capacity and to purchase our new headquarters, $30.0 million of loan advances to equity investee, net of repayments and $12.8 million related to our equity interest investment in SDC. These outflows were partially offset by maturities and sales of marketable securities of $388.8 million.

Net cash provided by investing activities was $73.0 million for the year ended December 31, 2016, which primarily consisted of maturities and sales of our marketable securities of $604.0 million. These inflows were partially offset by purchases of marketable securities of $405.6 million, property, plant and equipment purchases of $70.6 million including the implementation of our new ERP system and $46.7 million related to our equity interest investment in SDC.

Financing Activities

Net cash used in financing activities was $369.4 million for the year ended December 31, 2018 primarily consisted of common stock repurchases of $300.0 million (Refer to Note 11 "Common Stock Repurchase Programs" of the Notes to Consolidated Financial Statements for details on stock repurchase programs) and payroll taxes of $86.1 million paid for vesting of restricted stock units ("RSUs") through share withholdings. These outflows were offset in part by $16.6 million from proceeds from the issuance of common stock.

Net cash used in financing activities was $135.5 million for the year ended December 31, 2017 primarily resulting from common stock repurchases of $103.8 million (Refer to Note 11 "Common Stock Repurchase Programs" of the Notes to Consolidated Financial Statements for details on stock repurchase programs) and payroll taxes of $46.2 million paid for vesting of RSUs through share withholdings. These outflows were offset in part by $14.5 million from proceeds from the issuance of common stock.

Net cash used in financing activities was $95.5 million for the year ended December 31, 2016 primarily resulting from common stock repurchases of $96.2 million (Refer to Note 11 "Common Stock Repurchase Programs" of the Notes to Consolidated Financial Statements for details on stock repurchase programs) and payroll taxes of $29.9 million paid for vesting of RSUs through share withholdings, partially offset by excess tax benefit from our share-based compensation arrangements of $16.8 million and proceeds from issuance of common stock of $13.8 million.

Common Stock Repurchases

Refer to Note 11 "Common Stock Repurchase Programs" of the Notes to Consolidated Financial Statements for details on stock repurchase programs.

April 2016 Repurchase Program. In 2018, we repurchased approximately $200.0 million of our common stock on the open market, completing the April 2016 Repurchase Program.

May 2018 Repurchase Program. In May 2018, we announced that our Board of Directors had authorized a plan to repurchase up to $600.0 million of our common stock. In August 2018, we repurchased $50.0 million of our common stock on the open market. In November 2018, we entered into an accelerated share repurchase ("2018 ASR") to repurchase $50.0 million of our common stock which was completed in December 2018. As of December 31, 2018, we have $500.0 million remaining under the May 2018 Repurchase Program

We believe that our current cash, cash equivalents and short-term marketable securities combined with our existing borrowing capacity will be sufficient to fund our operations for at least the next 12 months. If we are unable to generate adequate operating cash flows and need more funds beyond our available liquid investments and those available under our credit facility, we may need to suspend our stock repurchase programs or seek additional sources of capital through equity or debt financing, collaborative or other arrangements with other companies, bank financing and other sources in order to realize our objectives and to continue our operations. There can be no assurance that we will be able to obtain additional debt or equity financing on terms acceptable to us, or at all. If adequate funds are not available, we may need to make business decisions that could adversely affect our operating results such as modifications to our pricing policy, business structure or operations. Accordingly, the failure to obtain sufficient funds on acceptable terms when needed could have a material adverse effect on our business, results of operations and financial condition.

Credit Facility

On February 27, 2018, we entered into a new credit facility for a $200.0 million revolving line of credit, with a $50.0 million letter of credit sublimit, and a maturity date of February 27, 2021, replacing the existing credit facility which provided for a $50.0 million revolving line of credit with a $10.0 million letter of credit. As of December 31, 2018, we had no outstanding borrowings under this credit facility (Refer to Note 7 "Credit Facility" of the Notes to Consolidated Financial Statements for details of the credit facility).

Contractual Obligations/Off Balance Sheet Arrangements

The impact that our contractual obligations as of December 31, 2018 are expected to have on our liquidity and cash flows in future periods is as follows (in thousands):

		Payments Due by Period			
	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
Operating lease obligations [1]	$106,676	$21,429	$39,380	$27,496	$ 18,371
Unconditional purchase obligations	476,904	166,701	189,523	120,680	—
Total contractual cash obligations	$583,580	$188,130	$228,903	$148,176	$ 18,371

[1] Sublease income is not material and excluded from the table above.

Our contractual obligations table above excludes approximately $28.2 million of non-current uncertain tax benefits which are included in other long-term obligations and deferred tax assets on our balance sheet as of December 31, 2018. We have not included this amount because we cannot make a reasonably reliable estimate regarding the timing

of settlements with taxing authorities, if any.

We had no material off-balance sheet arrangements as defined in Regulation S-K Item 303(a) (4) as of December 31, 2018 other than certain items disclosed in Note 9 "Commitments and Contingencies" of the Notes to Consolidated Financial Statements.

Indemnification Provisions

In the normal course of business to facilitate transactions in our services and products, we indemnify 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 certain of our 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, 2018, we did not have any material indemnification claims that were probable or reasonably possible.

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, including those related to revenue recognition, stock-based compensation, goodwill and finite-lived assets and related impairment, and income taxes. We use authoritative pronouncements, historical experience and other assumptions as the basis for making 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 Scanner 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 true: 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”) and allocation of consideration from a 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 historical sales, usage rates (the number of times a customer is expected to order additional aligners), costs, and expected margin, which may vary over time depending upon the unique facts and circumstances related to each performance obligation in making these

estimates. Further, our process for estimating usage rates require significant judgment and evaluation of inputs, including historical data and forecasted usages. 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 Full, Invisalign Teen, Invisalign First, Invisalign Express 10, Invisalign Express 5, Express Package, Lite Package and Invisalign Assist products include optional additional aligners at no charge for a certain period of time ranging from one to five years after initial shipment, and Invisalign Go includes optional additional aligners at no charge for a period of up to two years after initial shipment.

We determined that our treatment plans comprise the following performance obligations that also represent distinct deliverables: initial aligners, additional aligners, case refinement, and replacement aligners. We elected to 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 and 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 considered whether a significant financing component exists; however, as the delivery of the performance obligations are at the customer's discretion, we concluded that no significant financing component exists.

Scanner

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 SSPs of the scanner and the subscription service. We estimate the SSP of each element, taking into consideration historical prices as well as our discounting strategies. Revenues are then recognized over time as the monthly services are rendered and upon shipment for the scanner, as that is when we deem the customer to have obtained control. Most consideration is collected upfront and in cases where there are payment plans, consideration is collected by the one year mark and, therefore, there are no significant financing components.

Warranties

For both Clear Aligner and Scanner segments, we offer an assurance warranty which provides the customer assurance that the product will function as the parties intended because it complies with agreed-upon specifications, and thus is not treated as a separate performance obligation and will continue to be accrued in accordance with the Financial Accounting Standards Board guidance on guarantees.

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 accrue for sales return reserve based on historical sales returns as a percentage of revenue.

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 revenue, we evaluate the individual components and capitalize the eligible components, recognizing the costs over the treatment period.

Unfulfilled Performance Obligations for Clear Aligners and Scanners

Our unfilled performance obligations as of December 31, 2018 and the estimated revenues expected to be recognized in the future related to these performance obligations are $431.8 million. This includes performance obligations from the Clear Aligner segment, primarily the shipment of additional aligners, which are fulfilled over one to five years, and performance obligations from the iTero scanner segment, primarily support, and contracted deliveries of additional scanners, which are fulfilled over one to five years. 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 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.
Goodwill and Finite-Lived Acquired Intangible Assets and Long-Lived Assets

Goodwill

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.

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, the first step of the two-step impairment test is performed by estimating the fair value of the reporting unit and comparing it with its carrying value, including goodwill. Refer to Note 6 "Goodwill and Intangible Assets" of Notes to Consolidated Financial Statements for details on goodwill.

Finite-Lived Intangible Assets and Long-Lived Assets

Our intangible assets primarily consist of intangible assets acquired as part of acquisitions and are amortized using the straight-line method over their estimated useful lives, reflecting the period in which the economic benefits of the assets are expected to be realized.

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 the asset or asset group is expected to generate. 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 factors. 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. 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 of the impairment analysis.

Accounting for 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 revenue and expense 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 Sheet.

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 realized.

The U.S. Tax Cuts and Jobs Act was enacted into law on December 22, 2017 which included provisions for certain foreign-sourced earnings referred to as Global Intangible Low-Taxed Income (“GILTI”). GILTI imposes a tax on foreign income in excess of a deemed return on tangible assets of foreign corporations. FASB guidance issued in January 2018 allows companies to make an accounting policy election to either (i) account for GILTI as a component of tax expense in the period in which the tax is incurred (the “period cost method”), or (ii) account for GILTI in the measurement of deferred taxes (the “deferred method”). We have made the election to record GILTI tax using the period cost method.

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.

Interest Rate Risk

Changes in interest rates could impact our anticipated interest income on our cash equivalents and investments in marketable securities. Our investments include 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,

2018, we had approximately $107.6 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. We do not have material interest bearing liabilities as of December 31, 2018, and, therefore, 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.

In March 2018, we started entering 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. The fair value of foreign exchange forward contracts outstanding as of December 31, 2018 was not material.

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.

ITEM 8.CONSOLIDATED FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Quarterly Results of Operations

	Three Months Ended							
	2018				2017			
	December 31, 2018	September 30, 2018	June 30, 2018	March 31, 2018	December 31, 2017	September 30, 2017	June 30, 2017	March 31, 2017
	(in thousands, except per share data) (unaudited)							
Net revenues	$534,020	$505,289	$490,259	$436,924	$421,323	$385,267	$356,482	$310,341
Gross profit	383,096	371,781	365,582	327,408	317,917	292,488	270,917	235,625
Income from operations	120,473	125,208	122,691	98,192	109,606	98,763	83,569	61,673
Net income	97,392	100,872	106,105	95,866	10,264	82,555	69,179	69,420
Net income per share:								
Basic	$1.22	$1.26	$1.32	$1.20	$0.13	$1.03	$0.86	$0.87
Diluted	$1.20	$1.24	$1.30	$1.17	$0.13	$1.01	$0.85	$0.85
Shares used in computing net income per share:								
Basic	79,891	80,111	80,216	80,036	80,080	80,163	80,188	79,904
Diluted	80,943	81,359	81,471	81,628	81,863	81,789	81,631	81,534

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF MANAGEMENT ON INTERNAL CONTROL OVER FINANCIAL REPORTING

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

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

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

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

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

Management assessed the effectiveness of our internal control over financial reporting as of December 31, 2018. 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, 2018, 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, 2018 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report which is included herein.

/S/ JOSEPH M. HOGAN
Joseph M. Hogan
President and Chief Executive Officer
February 28, 2019

/S/ JOHN F. MORICI
John F. Morici
Chief Financial Officer and Senior Vice President, Global Finance
February 28, 2019

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Explanation of Responses: 100

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, 2018 and 2017, 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, 2018, 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, 2018, 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, 2018 and 2017, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2018 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, 2018, based on criteria established in Internal Control - Integrated Framework (2013) issued by the COSO.

Change in Accounting Principle

As discussed in Note 1 to the consolidated financial statements, the Company changed the manner in which it accounts for certain elements of its employee share-based payments in 2017.

Basis for Opinions

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

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

Our audits of the consolidated financial statements included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. Our audit of internal control over financial reporting included obtaining an understanding of

internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

Definition and Limitations of Internal Control over Financial Reporting

A company’s internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company’s internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the

company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company’s assets that could have a material effect on the financial statements.

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

/s/ PricewaterhouseCoopers LLP
San Jose, California
February 28, 2019

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,		
	2018	2017	2016
Net revenues	$1,966,492	$1,473,413	$1,079,874
Cost of net revenues	518,625	356,466	264,580
Gross profit	1,447,867	1,116,947	815,294
Operating expenses:			
Selling, general and administrative	852,404	665,777	490,653
Research and development	128,899	97,559	75,720
Total operating expenses	981,303	763,336	566,373
Income from operations	466,564	353,611	248,921
Interest income	8,576	6,948	4,213
Other income (expense), net	(8,489)	4,240	(10,568)
Net income before provision for income taxes and equity in losses of investee	466,651	364,799	242,566
Provision for income taxes	57,723	130,162	51,200
Equity in losses of investee, net of tax	8,693	3,219	1,684
Net income	$400,235	$231,418	$189,682
Net income per share:			
Basic	$5.00	$2.89	$2.38
Diluted	$4.92	$2.83	$2.33
Shares used in computing net income per share:			
Basic	80,064	80,085	79,856
Diluted	81,357	81,832	81,484

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,		
	2018	2017	2016
Net income	$400,235	$231,418	$189,682
Net change in foreign currency translation adjustment	(3,631)	1,741	(670)
Change in unrealized gains (losses) on investments, net of tax	286	(232)	712
Other comprehensive income (loss)	(3,345)	1,509	42
Comprehensive income	$396,890	$232,927	$189,724

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

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

	December 31,	
	2018	2017
ASSETS		
Current assets:		
Cash and cash equivalents	$636,899	$449,511
Marketable securities, short-term	98,460	272,031
Accounts receivable, net of allowance for doubtful accounts of $2,378 and $5,814, respectively	439,009	324,189
Inventories	55,641	31,688
Prepaid expenses and other current assets	72,470	80,948
Total current assets	1,302,479	1,158,367
Marketable securities, long-term	9,112	39,948
Property, plant and equipment, net	521,329	348,793
Equity method investments	45,913	54,606
Goodwill and intangible assets, net	81,949	89,068
Deferred tax assets	64,689	49,334
Other assets	26,987	43,893
Total assets	$2,052,458	$1,784,009
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$64,256	$36,776
Accrued liabilities	234,679	195,562
Deferred revenues	393,138	267,713
Total current liabilities	692,073	500,051
Income tax payable	78,008	114,091
Other long-term liabilities	29,486	15,579
Total liabilities	799,567	629,721
Commitments and contingencies (Notes 8 and 9)		
Stockholders' equity:		
Preferred stock, $0.0001 par value (5,000 shares authorized; none issued)	—	—
Common stock, $0.0001 par value (200,000 shares authorized; 79,778 and 80,040 issued and outstanding, respectively)	8	8
Additional paid-in capital	877,514	886,435
Accumulated other comprehensive income (loss), net	(2,774)	571
Retained earnings	378,143	267,274
Total stockholders' equity	1,252,891	1,154,288
Total liabilities and stockholders' equity	$2,052,458	$1,784,009

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

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

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss), Net	Retained Earnings	Total
	Shares	Amount				
Balances at December 31, 2015	79,500	$ 8	$821,507	$ (980)	$27,391	$847,926
Cumulative effect adjustment from adoption of ASU 2014-09	—	—	—	—	3,918	3,918
Net income	—	—	—	—	189,682	189,682
Net change in unrealized gains (losses) from investments	—	—	—	712	—	712
Net change in foreign currency translation adjustment	—	—	—	(670)	—	(670)
Issuance of common stock relating to employee equity compensation plans	1,163	—	13,778	—	—	13,778
Tax withholdings related to net share settlements of restricted stock units	—	—	(29,857)	—	—	(29,857)
Common stock repurchased and retired	(1,110)	—	(10,593)	—	(85,625)	(96,218)
Net tax benefits from stock-based awards	—	—	15,888	—	—	15,888
Stock-based compensation	—	—	54,148	—	—	54,148
Balances at December 31, 2016	79,553	8	864,871	(938)	135,366	999,307
Cumulative effect adjustment from adoption of ASU 2016-16	—	—	—	—	(1,300)	(1,300)
Net income	—	—	—	—	231,418	231,418
Net change in unrealized gains (losses) from investments	—	—	—	(232)	—	(232)
Net change in foreign currency translation adjustment	—	—	—	1,741	—	1,741
Issuance of common stock relating to employee equity compensation plans	1,073	—	14,461	—	—	14,461
Tax withholdings related to net share settlements of restricted stock units	—	—	(46,168)	—	—	(46,168)
Common stock repurchased and retired	(586)	—	(5,583)	—	(98,210)	(103,793)
Stock-based compensation	—	—	58,854	—	—	58,854
Balances at December 31, 2017	80,040	8	886,435	571	267,274	1,154,288
Net income	—	—	—	—	400,235	400,235
Net change in unrealized gains (losses) from investments	—	—	—	286	—	286
Net change in foreign currency translation adjustment	—	—	—	(3,631)	—	(3,631)
Issuance of common stock relating to employee equity compensation plans	795	—	16,635	—	—	16,635
	—	—	(86,067)	—	—	(86,067)

Tax withholdings related to net share settlements of restricted stock units						
Common stock repurchased and retired	(1,057)	—	(10,252)	—	(289,750)	(300,002)
Stock-based compensation	—	—	70,763	—	—	70,763
Other	—	—	—	—	384	384
Balances at December 31, 2018	79,778	$ 8	$877,514	$ (2,774)	$378,143	$1,252,891

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,		
	2018	2017	2016
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net income	$400,235	$231,418	$189,682
Adjustments to reconcile net income to net cash provided by operating activities:			
Deferred taxes	(15,680)	17,572	(16,401)
Depreciation and amortization	54,727	37,739	24,002
Stock-based compensation	70,763	58,854	54,148
Net tax benefits from stock-based awards	—	—	15,888
Excess tax benefit from share-based payment arrangements	—	—	(16,773)
Equity in losses of investee	8,693	3,219	1,684
Other non-cash operating activities	17,252	13,847	12,031
Changes in assets and liabilities, net of effects of acquisitions:			
Accounts receivable	(109,224)	(90,990)	(95,808)
Inventories	(24,109)	(5,481)	(7,663)
Prepaid expenses and other assets	(9,122)	(8,669)	(9,390)
Accounts payable	25,045	8,175	(3,395)
Accrued and other long-term liabilities	36,250	24,235	31,371
Long-term income tax payable	(36,548)	68,958	7,622
Deferred revenues	136,399	79,662	60,656
Net cash provided by operating activities	554,681	438,539	247,654
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchase of property, plant and equipment	(223,312)	(195,695)	(70,576)
Purchase of marketable securities	(180,191)	(390,244)	(405,612)
Proceeds from maturities of marketable securities	375,105	349,240	387,873
Proceeds from sales of marketable securities	9,560	39,536	216,119
Purchases of investments in privately held companies	(5,000)	(12,764)	(46,745)
Loan advances to equity investee	—	(36,000)	—
Loan repayment from equity investee	30,000	6,000	—
Acquisition, net of cash acquired	—	(8,953)	—
Other investing activities	765	(2,597)	(8,031)
Net cash provided by (used in) investing activities	6,927	(251,477)	73,028
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from issuance of common stock	16,635	14,461	13,778
Common stock repurchases	(300,002)	(103,793)	(96,218)
Excess tax benefit from share-based payment arrangements	—	—	16,773
Employees' taxes paid upon the vesting of restricted stock units	(86,067)	(46,168)	(29,857)
Net cash used in financing activities	(369,434)	(135,500)	(95,524)
Effect of foreign exchange rate changes on cash, cash equivalents, and restricted cash	(4,733)	5,544	(3,374)
Net increase in cash, cash equivalents, and restricted cash	187,441	57,106	221,784
Cash, cash equivalents, and restricted cash at beginning of year	450,125	393,019	171,235
Cash, cash equivalents, and restricted cash at end of year	$637,566	$450,125	$393,019

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

Explanation of Responses:

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Explanation of Responses: 110

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 engaged in the design, manufacture and marketing of Invisalign® clear aligners and iTero® intraoral scanners and services for orthodontics and restorative and aesthetic dentistry. Align’s products are intended primarily for the treatment of malocclusion or the misalignment of teeth and are designed to help dental professionals achieve the clinical outcomes that they expect. We are headquartered in San Jose, California with offices worldwide. Our Americas regional headquarters is located in Raleigh, North Carolina; our European regional headquarters is located in Amsterdam, the Netherlands; and our Asia Pacific regional headquarters is located in Singapore. We have two operating segments: (1) Clear Aligner, known as the Invisalign System, and (2) Scanners and Services ("Scanner"), known as the iTero intraoral scanner and OrthoCAD 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.

During fiscal year 2018, we adopted Accounting Standards Codification (“ASC”) 606, “Revenues from Contracts with Customers,” using the full retrospective method and Accounting Standards Update (“ASU”) 2016-18, “Statement of Cash Flows - Restricted Cash,” on a retrospective basis. The Consolidated Balance Sheet as of December 31, 2017, Consolidated Statements of Cash Flow for the year ended December 31, 2017 and 2016, and Consolidated Statements of Stockholders' Equity for the year ended December 31, 2017 and 2016 have been recast to comply with the adoption of these standards.

Use of Estimates

The preparation of financial statements in conformity with generally accepted accounting principles ("GAAP") in the 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 the fair values of financial instruments, valuation of investments in privately held companies, useful lives of intangible assets and property and equipment, revenue recognition, stock-based compensation, long-lived assets and goodwill, income taxes and contingent liabilities, 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

We measure the fair value of financial assets as the price 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. Fair value is estimated by applying the following hierarchy, which prioritizes the inputs used to measure fair value into three levels and bases the categorization within the hierarchy upon the lowest level of input that is available and significant to the fair value measurement:
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.

Level 3 – Inputs that are generally unobservable and typically reflect management’s estimate of assumptions that market participants would use in pricing the asset or liability.

Cash and Cash Equivalents

We consider currency on hand, demand deposits, time deposits, and all highly liquid investments with an original or remaining 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 included in other current assets and other assets within our Consolidated Balance Sheet.

Marketable Securities

Marketable securities are classified as available-for-sale and are carried at fair value. Marketable securities classified as current assets have maturities of less than one year. Unrealized gains or losses on such securities are included in accumulated other comprehensive income (loss), net in stockholders' equity. Realized gains and losses from maturities of all such securities are reported in earnings and computed using the specific identification cost method. Realized gains or losses and charges for other-than-temporary declines in value, if any, on available-for-sale securities are reported in other income (expense), net, as incurred. We periodically evaluate these investments for other-than-temporary impairment.

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 ASC 323, "Investments -Equity Method and Joint Ventures." Equity securities qualified as equity method investments are reported on our Consolidated Balance Sheet as a single amount, and 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 ASC 321, "Investments -Equity Securities." The equity securities without readily determinable fair values are recorded at cost and adjusted for impairments and observable price changes with a same or similar security from the same issuer ("Measurement Alternative"). Equity securities under ASC 321 are reported on our Consolidated Balance Sheet as other assets, and we record a change in carrying value of our equity securities, if any, in other income (expense), net in our Consolidated Statement of Operations.

Equity securities are evaluated for impairment as events or circumstances indicate that there is an other-than-temporary loss in value. The decrease in value is recognized in the period the impairment occurs and

recorded in other income (expense), net in the 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 an 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, 2018, 2017 and 2016, we had foreign currency net gains (losses) of $(5.6) million, $9.0 million and $(8.0) 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.

Our cash and investments are held primarily by three 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, corporate bonds, U.S. government agency bonds, U.S. government treasury bonds and certificates of deposits. If the carrying value of our investments exceeds the fair value, and the decline in fair value is deemed to be other-than-temporary, we will be required to write down the value of our investments, which could adversely affect 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. economy.

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 reserves for potential credit losses and such losses have been within management's expectations. No individual customer accounted for 10% or more of our accounts receivable at December 31, 2018 or 2017, or net revenues for the year ended December 31, 2018, 2017 or 2016.

In the U.S., the Food and Drug Administration ("FDA") regulates 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.

We have manufacturing facilities located outside the U.S. In Juarez, Mexico and Ziyang, China, we manufacture our clear aligners, distribute and repair our scanners and perform our computer-aided design/computer-aided manufacturing ("CAD/CAM") services. In Or Yehuda, Israel, we produce our handheld intraoral scanner wand and perform the final assembly of our iTero scanner. 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.

Inventories

Inventories are valued at the lower of cost or net realizable value, with cost computed using either standard cost, which approximates actual cost, or average 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

Property, plant and equipment 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 ("CIP") 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.

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 units 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, the first step of the two-step impairment test is performed by estimating the fair value of the reporting unit and comparing it with its carrying value, including goodwill.

Step one of the goodwill impairment test consists of a comparison of the fair value of a reporting unit against its carrying amount, including the goodwill allocated to each reporting unit. We determine the fair value of our reporting units based on the present value of estimated future cash flows under the income approach of the reporting units as well as various price or market multiples applied to the reporting unit's operating results along with the appropriate control premium under the marketing approach, both of which are classified as level 3 within the fair value hierarchy as described in Note 2 "Marketable Securities and Fair Value

Measurements" of the Notes of Consolidated Financial Statements. If the carrying amount of the reporting unit is in excess of its fair value, step two requires the comparison of the implied fair value of the reporting unit’s goodwill against the carrying amount of the reporting unit’s goodwill. Any excess of the carrying value of the reporting unit’s goodwill over the implied fair value of the reporting unit’s goodwill is recorded as an impairment loss in the Consolidated Statements of Operations.

Finite-Lived Intangible Assets and 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 the Notes of 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. During the year ended December 31, 2018, we capitalized approximately $2.7 million of internally developed software costs. Internally developed software costs capitalized during the year ended December 31, 2017 was not material.

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

Clear Aligner
We warrant our Invisalign products against material defects until the treatment plan is complete. We warrant clear aligners manufactured for SmileDirectClub, LLC (“SDC”) against material defects for one year. We accrue for warranty costs in cost of net revenues upon shipment of products. The estimated warranty costs liability is primarily based on historical experience as to product failures as well as current information on replacement costs. Actual warranty costs could differ materially from the estimated amounts. We regularly review our warranty liability and update these balances based on historical warranty cost trends.
Scanners and Services
We warrant our intraoral scanners for a period of one year, which include materials and labor. We accrue for these warranty costs based on average historical repair costs. An extended warranty may be purchased for additional fees.

Allowance for Doubtful Accounts

We maintain an allowance for doubtful accounts for customers that are not able to make payments. We periodically review these balances, including an analysis of the customers' payment history and information regarding the customers' creditworthiness. Actual write-offs have not materially differed from the estimated allowances.

Revenue Recognition

Our revenues are derived primarily from the sale of aligners, scanners, and services from our Clear Aligner and Scanner 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 true: 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”) and allocation of consideration from a 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 historical sales, usage rates (the number of times a customer is expected to order additional aligners), costs, and expected margin, which may vary over time depending upon the unique facts and circumstances related to each performance obligation in making these estimates. Further, our process for estimating usages rates require significant judgment and evaluation of inputs, including historical data and forecasted usages. 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 Full, Invisalign Teen, Invisalign First, Invisalign Express 10, Invisalign Express 5, Express Package, Lite Package and Invisalign Assist products include optional additional aligners at no charge for a certain period of time ranging from one to five years after initial shipment, and Invisalign Go includes optional additional aligners at no charge for a period of up to two years after initial shipment.

We determined that our treatment plans comprise the following performance obligations that also represent distinct deliverables: initial aligners, additional aligners, case refinement, and replacement aligners. We elected to 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 and 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 considered whether a significant financing component exists; however, as the delivery of the performance obligations are at the customer’s discretion, we concluded that no significant financing component exists.

Scanner

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 SSPs of the scanner and the subscription service. We estimate the SSP of each element, taking into consideration historical prices as well as our discounting strategies. Revenues are then recognized over time as the monthly services are rendered and upon shipment for the scanner, as that is when we deem the customer to have obtained control. Most consideration is collected upfront and in cases where there are payment plans, consideration is collected by the one year mark and, therefore, there are no significant financing components.

Warranties

For both Clear Aligner and Scanner segments, we offer an assurance warranty which provides the customer assurance that the product will function as the parties intended because it complies with agreed-upon specifications, and thus is not treated as a separate performance obligation and will continue to be accrued in accordance with the Financial Accounting Standards Board ("FASB") guidance on guarantees.

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 accrue for sales return reserve based on historical sales returns as a percentage of revenue.

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 revenue, we evaluate the individual components and capitalize the eligible components, recognizing the costs over the treatment period.

Unfulfilled Performance Obligations for Clear Aligners and Scanners

Our unfilled performance obligations as of December 31, 2018 and the estimated revenues expected to be recognized in the future related to these performance obligations are $431.8 million. This includes performance obligations from the Clear Aligner segment, primarily the shipment of additional aligners, which are fulfilled over one to five years, and performance obligations from the iTero scanner segment, primarily support, and contracted deliveries of additional scanners, which are fulfilled over one to five years. 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 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 expense is 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, outside consulting expenses 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, 2018, 2017 and 2016, we incurred advertising costs of $88.4 million, $70.1 million and $36.0 million, respectively.

Common Stock Repurchase

We repurchase our own common stock from time to time in the open market when our Board of Directors approve a stock repurchase program. 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.

Operating Leases

We lease office spaces, vehicles and equipment under operating leases with original lease periods of up to 10 years. Certain of these leases have free or escalating rent payment provisions and lease incentives provided by the landlord. We recognize rent expense under such leases on a straight-line basis over the term of the lease.

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 revenue and expense 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 Sheet.

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. The available positive evidence at December 31, 2018 included historical operating profits and a projection of future income sufficient to realize most of our remaining deferred tax assets. As of December 31, 2018,

it was considered more likely than not that our deferred tax assets would be realized with the exception of certain foreign loss carryovers as we are unable to forecast sufficient future profits to realize the deferred tax assets.

The U.S. Tax Cuts and Jobs Act was enacted into law on December 22, 2017 which included provisions for certain foreign-sourced earnings referred to as Global Intangible Low-Taxed Income (“GILTI”). GILTI imposes a tax on foreign income in excess of a deemed return on tangible assets of foreign corporations. FASB guidance issued in January 2018 allows companies to make an accounting policy election to either (i) account for GILTI as a component of tax expense in the period in which the tax is incurred (the “period cost method”), or (ii) account for GILTI in the measurement of deferred taxes (the “deferred method”). We have made the election to record GILTI tax using the period cost method.

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 estimate the fair value of market-performance based restricted stock units using a Monte Carlo simulation model 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.

Comprehensive Income

Comprehensive income includes all changes in equity during a period from non-owner sources including unrealized gains and losses on investments and foreign currency translation adjustments, net of their related tax effect.

Recent Accounting Pronouncements

(i) New Accounting Updates Recently Adopted

In March 2016, the FASB issued Accounting Standards Update ("ASU") 2016-09, "Improvements to Employee Share-Based Payment Accounting" (Topic 718). We adopted the standard in the first quarter of fiscal year 2017. With this adoption, excess tax benefits related to stock-based compensation expense are reflected in our consolidated statement of operations as a component of the provision for income taxes instead of additional paid-in capital in our consolidated balance sheet. In addition, we elected to continue to estimate expected forfeitures rather than as they occur to determine the amount of compensation cost to be recognized in each period. During the fiscal year ended December 31, 2017, we recognized excess tax benefits of $30.0 million in our provision for income taxes. Excess tax benefits from share-based payment arrangements are classified as an operating activity in our consolidated statement of cash flows.

In May 2014, FASB released ASU 2014-09, “Revenue from Contracts with Customers,” (Topic 606) to supersede nearly all existing revenue recognition guidance under GAAP. The core principle of the standard is to recognize revenues when promised goods or services are transferred to customers in an amount that reflects the consideration that is expected to be received for the goods or services. We adopted the guidance in the first quarter of fiscal year 2018 by applying the full retrospective method. The impact of adoption was primarily related to the Clear Aligner

segment. Our disaggregation of revenues can be found in Note 16 “Segments and Geographical Information.” We elected to take the practical expedient to exclude from the transaction price all taxes assessed by a governmental authority. Prior periods have been retrospectively adjusted, and we recognized a $3.9 million cumulative effect of adopting the guidance as an adjustment to our opening balance of retained earnings as of January 1, 2016 in our Consolidated Statements of Stockholders’ Equity.

The adoption of ASU 2014-09 did not have a material impact on our Consolidated Statement of Operations, Consolidated Statements of Comprehensive Income or Consolidated Statements of Cash Flows. Consolidated Balance Sheet line items, which reflect the adoption of the ASU 2014-09 are as follows (in thousands):

	December 31, 2017		
	As Previously Reported	Adjustment	As Adjusted
Asset Accounts:			
Accounts receivable, net	$322,825	$ 1,364	$324,189
Deferred tax assets	50,059	(725)	49,334
Other assets	38,379	5,514	43,893
Liability and Stockholders' Equity Accounts:			
Accrued liabilities	$194,198	$ 1,364	$195,562
Deferred revenues	266,842	871	267,713
Retained earnings	263,356	3,918	267,274

In August 2016, the FASB issued ASU 2016-15, "Classification of Certain Cash Receipts and Cash Payments," which clarifies the presentation and classification of certain cash receipts and cash payments in the statements of cash flows. The amendments are effective for fiscal years and interim periods within those years beginning after December 15, 2017. We adopted the standard in the first quarter of fiscal year 2018 on a retrospective basis, and it did not have an impact on our Consolidated Statements of Cash Flows.

In November 2016, the FASB issued ASU 2016-18, "Statement of Cash Flows—Restricted Cash," which provides guidance to address the classification and presentation of changes in restricted cash in the statements of cash flows. The amendments are effective for fiscal years and interim periods within those years beginning after December 15, 2017 on a retrospective basis. We adopted the guidance in the first quarter of fiscal year 2018 on a retrospective basis and presented the changes in the total of cash, cash equivalents, and restricted cash in the Consolidated Statements of Cash Flows. Consolidated Statement of Cash Flows line items, which reflect the adoption of the ASU 2016-18, are as follows (in thousands):

	December 31, 2017		
	As Previously Reported	Adjustment	As Adjusted
Cash Flows from Investing Activities			
Other investing activities	$567	$ (3,164)	$(2,597)
Net cash used in investing activities	(248,313)	(3,164)	(251,477)
Effect of foreign exchange rate changes on cash, cash equivalents, and restricted cash	5,510	34	5,544
Net increase in cash, cash equivalents, and restricted cash	60,236	(3,130)	57,106
Cash, cash equivalents, and restricted cash at beginning of the period	389,275	3,744	393,019
Cash, cash equivalents, and restricted cash at end of the period	$449,511	$ 614	$450,125

	December 31, 2016		
	As Previously Reported	Adjustment	As Adjusted
Cash Flows from Investing Activities			
Other investing activities	$(8,211)	$ 180	$(8,031)
Net cash provided by investing activities	72,848	180	73,028
Effect of foreign exchange rate changes on cash, cash equivalents, and restricted cash	(3,417)	43	(3,374)
Net increase in cash, cash equivalents, and restricted cash	221,561	223	221,784
Cash, cash equivalents, and restricted cash at beginning of the period	167,714	3,521	171,235
Cash, cash equivalents, and restricted cash at end of the period	$389,275	$ 3,744	$393,019

In May 2017, the FASB issued ASU 2017-09, “Compensation—Stock Compensation (Topic 718): Scope of Modification Accounting,” to clarify when to account for a change to the terms or conditions of a share-based payment award as a modification. The amendments are effective for fiscal years and interim periods within those years beginning after December 15, 2017 on a prospective basis. We adopted the standard in the first quarter of fiscal year 2018 on a prospective basis which did not have an impact on our consolidated financial statements and related disclosures.

(ii) Recent Accounting Updates Not Yet Effective

In February 2016, the FASB issued ASU 2016-02, “Leases” (Topic 842) to increase transparency and comparability among organizations by recognizing lease assets and lease liabilities on the balance sheet and disclosing key information about leasing arrangements. The updated guidance is effective for annual periods beginning after December 15, 2018, including interim periods within those fiscal years. In July 2018, the FASB issued ASU 2018-11, “Leases- Targeted Improvements,” which provides an additional transition method by allowing entities to initially apply the new leases standard at the adoption date and recognize a cumulative-effect adjustment to the opening balance of retained earnings. We will adopt this standard in the first quarter of fiscal year 2019 by electing the transition method issued in ASU 2018-11 and the package of practical expedients available in the standard. We are finalizing our implementation efforts related to policies, processes and internal controls to comply with the guidance. Upon adoption, based on our lease portfolio as of December 31, 2018, we anticipate recognizing right-of-use assets in the range of $67 million to $74 million and related lease liabilities in the range of $77 million to $86 million on our Consolidated Balance Sheet, with no material impact to our Consolidated Statement of Operations.

In June 2016, the FASB issued ASU 2016-13, “Financial Instruments - Credit Losses” (Topic 326). The FASB issued this update to provide financial statement users with more decision-useful information about the expected credit losses on financial instruments and other commitments to extend credit held by a reporting entity at each reporting date. The amendments in this update replace the existing guidance of incurred loss impairment methodology with an approach that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information to inform credit loss estimates. In November 2018, the FASB issued ASU 2018-19, “Codification Improvements to Topic 326, Financial Instruments - Credit Losses” which clarifies the scope of guidance in the ASU 2016-13. The updated guidance is effective for annual periods beginning after December 15, 2019, including interim periods within those fiscal years. Early adoption of the update is permitted in fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. We are currently evaluating the impact of this guidance on our consolidated financial statements and related disclosures.

In January 2017, the FASB issued ASU 2017-04, “Intangibles—Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment,” to simplify the subsequent measurement of goodwill by eliminating step two from the goodwill impairment test. Under the amendments, an entity will recognize an impairment charge for the amount by

which the carrying value exceeds the fair value. The amendments are effective for fiscal years and interim periods within those years beginning after December 15, 2019 on a prospective basis and early adoption is permitted. We are currently evaluating the impact of this guidance on our consolidated financial statements and related disclosures.

In February 2018, the FASB issued ASU 2018-02, “Income Statement - Reporting Comprehensive Income (Topic 220): Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income,” which gives entities the option to reclassify to retained earnings the tax effects resulting from the U.S. Tax Cuts and Jobs Act (the “TCJA”) related to items in

accumulated other comprehensive income. The amendments are effective for fiscal years and interim periods within those years beginning after December 15, 2018 on a retrospective basis and early adoption is permitted. We do not expect that the guidance will have a material impact on our consolidated financial statements and related disclosures.

In August 2018, the FASB issued ASU 2018-13, “Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement,” to modify the disclosure requirements on fair value measurements in Topic 820, Fair Value Measurement. The amendments are effective for fiscal years and interim periods within those years beginning after December 15, 2019 on a prospective basis and early adoption is permitted. We are currently evaluating the impact of this guidance on our related disclosures.

In August 2018, the FASB issued ASU 2018-15, “Intangibles—Goodwill and Other—Internal-Use Software (Subtopic 350-40) Customer’s Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract,” to clarify the guidance on the costs of implementing a cloud computing hosting arrangement that is a service contract. Under the amendments, the entity is required to follow the guidance in Subtopic 350-40, Internal-Use Software, to determine which implementation costs under the service contract to be capitalized as an asset and which costs to expense. The amendments are effective for fiscal years and interim periods within those years beginning after December 15, 2019 either on a retrospective or prospectively basis and early adoption is permitted. We are currently evaluating the impact of this guidance on our consolidated financial statements and related disclosures.

Note 2. Investments and Fair Value Measurements

As of December 31, 2018 and 2017, the estimated fair value of our short-term and long-term marketable securities, classified as available for sale, are as follows (in thousands):

Short-term

December 31, 2018	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Commercial paper	$ 17,793	$ —	$ —	$17,793
Corporate bonds	45,100	—	(48)	45,052
U.S. government agency bonds	19,981	—	(77)	19,904
U.S. government treasury bonds	15,292	—	(1)	15,291
Certificates of deposit	420	1	(1)	420
Total marketable securities, short-term	$ 98,586	$ 1	$ (127)	$98,460

Long-term

December 31, 2018	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Corporate bonds	$ 4,957	$ 5	$ (2)	$4,960
U.S. government agency bonds	1,399	8	—	1,407
U.S. government treasury bonds	2,235	9	—	2,244
Certificates of deposit	500	1	—	501
Total marketable securities, long-term	$ 9,091	$ 23	$ (2)	$9,112

Short-term

December 31, 2017	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Commercial paper	$58,503	$ —	$ (1)	$58,502
Corporate bonds	145,728	3	(174)	145,557
U.S. government agency bonds	3,013	—	(7)	3,006
U.S. government treasury bonds	60,650	—	(70)	60,580
Certificates of deposit	4,386	—	—	4,386
Total marketable securities, short-term	$272,280	$ 3	$ (252)	$272,031

Long-term

December 31, 2017	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. government agency bonds	$ 15,023	$ —	$ (68)	$ 14,955
Corporate bonds	25,067	2	(76)	24,993
Total marketable securities, long-term	$ 40,090	$ 2	$ (144)	$ 39,948

Cash equivalents are not included in the tables above as the gross unrealized gains and losses are not material. We have no short-term or long-term investments that have been in a continuous material unrealized loss position for greater than twelve months as of December 31, 2018 and 2017. Amounts reclassified to earnings from accumulated other comprehensive income (loss), net related to unrealized gains or losses were not material in 2018 and 2017. For the year ended December 31, 2018, 2017 and 2016, realized gains or losses were not material.

Our fixed-income securities investment portfolio consists of investments that have a maximum effective maturity of 40 months on any individual security. 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. The unrealized losses are due primarily to changes in credit spreads and interest rates. We expect to realize the full value of all these investments upon maturity or sale. The weighted average remaining duration of these securities was approximately four months and six months as of December 31, 2018 and 2017, respectively.

As the carrying value approximates the fair value for our short-term and long-term marketable securities shown in the tables above, the following table summarizes the fair value of our short-term and long-term marketable securities classified by contractual maturity as of December 31, 2018 and 2017 (in thousands):

	December 31,	
	2018	2017
One year or less	$98,460	$272,031
Due in greater than one year	9,112	39,948
Total marketable securities	$107,572	$311,979

Investments in Privately Held Companies

Our investments in privately held companies as of December 31, 2018 and December 31, 2017 are as follows (in thousands):

	December 31,	
	2018	2017
Equity securities under the equity method investment [1]	$45,913	$54,606
Equity securities without readily determinable fair values [2]	$9,862	$—

[1] Refer to Note 4 “Equity Method Investments” of the Notes to Consolidated Financial Statements for more information

[2] In April 2018, $4.9 million of convertible short term notes receivable (recurring Level 3 investment) was converted into equity securities as a result of qualified financing secured by the private company in accordance with ASC 321, “Investments—Equity Securities.” The equity securities issued upon conversion are reported as a nonrecurring investment within other assets in our Consolidated Balance Sheet. During the year ended December 31, 2018, there were no fair value adjustments to equity securities without readily determinable fair values.

Fair Value Measurements

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

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

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

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

The following tables summarize our financial assets measured at fair value on a recurring basis as of December 31, 2018 and 2017 (in thousands):

Description	Balance as of December 31, 2018	Level 1	Level 2
Cash equivalents:			
Money market funds	$ 431,081	$431,081	$—
Commercial paper	4,681	—	4,681
U.S. government treasury bonds	2,195	2,195	—
Corporate bonds	3,880	—	3,880
Short-term investments:			
Commercial paper	17,793	—	17,793
Corporate bonds	45,052	—	45,052
U.S. government agency bonds	19,904	—	19,904
U.S. government treasury bonds	15,291	15,291	—
Certificates of deposit	420	—	420
Long-term investments:			
U.S. government agency bonds	1,407	—	1,407
Corporate bonds	4,960	—	4,960
U.S. government treasury bonds	2,244	2,244	—
Certificate of deposit	501	—	501
Prepaid expenses and other current assets:			
Israeli funds	3,047	—	3,047
	$ 552,456	$450,811	$101,645

Description	Balance as of December 31, 2017	Level 1	Level 2	Level 3
Cash equivalents:				
Money market funds	$ 253,155	$253,155	$—	$—
Commercial paper	7,246	—	7,246	—
Corporate bonds	2,016	—	2,016	—
Short-term investments:				
Commercial paper	58,502	—	58,502	—
Corporate bonds	145,557	—	145,557	—
U.S. government agency bonds	3,006	—	3,006	—
U.S. government treasury bonds	60,580	60,580	—	—
Certificates of deposit	4,386	—	4,386	—
Long-term investments:				
U.S. government agency bonds	14,955	—	14,955	—
Corporate bonds	24,993	—	24,993	—
Prepaid expenses and other current assets:				
Israeli funds	3,075	—	3,075	—
Short-term notes receivable	4,476	—	—	4,476
	$ 581,947	$313,735	$263,736	$4,476

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Explanation of Responses: 136

Derivative Financial Instruments

In March 2018, we began entering 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. The gain from the settlement of foreign currency forward contracts during 2018 was $9.9 million. As of December 31, 2018, the fair value of foreign exchange forward contracts outstanding was not material.

The following table presents the gross notional value of all our foreign exchange forward contracts outstanding as of December 31, 2018 (in thousands):

	December 31, 2018	
	Local Currency Amount	Notional Contract Amount (USD)
Euro	€62,000	$71,095
Chinese Yuan	¥375,000	54,515
Brazilian Real	R$81,000	20,858
Canadian Dollar	C$27,000	19,808
British Pound	£13,000	16,635
Japanese Yen	¥1,700,000	15,357
Australian Dollar	A$3,000	2,114
		$200,382

Note 3. Balance Sheet Components

Inventories

Inventories consist of the following (in thousands):

	December 31,	
	2018	2017
Raw materials	$26,119	$12,721
Work in process	13,784	12,157
Finished goods	15,738	6,810
Total inventories	$55,641	$31,688

Other Assets

Other assets consist of the following (in thousands):

	December 31,	
	2018	2017
Capitalized commissions [1]	$9,185	$5,514
Equity securities	9,862	—
Security deposits	5,162	3,557
Loan receivable from equity investee	—	30,000
Other long-term assets	2,778	4,822
Total other assets	$26,987	$43,893

(1) December 31, 2017 balance has been recasted to reflect the adoption of ASU 2014-09 (Refer to Note 1“Summary of Significant Accounting Policies” of the Notes to Consolidated Financial Statements for more information).

Explanation of Responses:

Property, Plant and Equipment, Net

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

	Generally Used Estimated Useful Life	December 31, 2018	2017
Clinical and manufacturing equipment	Up to 10 years	$236,179	$183,392
Computer hardware	3 years	34,297	24,933
Computer software	3 years	59,617	54,756
Furniture and fixtures	5 years	33,436	16,271
Leasehold improvements	Lease term (1)	77,168	37,756
Building	20 years	139,315	63,887
Land	—	17,630	17,630
CIP	—	95,414	85,976
Total		693,056	484,601
Less: Accumulated depreciation and amortization and impairment charges		(171,727)	(135,808)
Total property, plant and equipment, net		$521,329	$348,793

(1) Shorter of remaining lease term or estimated useful lives of asset

Depreciation and amortization was $54.7 million, $37.7 million and $24.0 million for the year ended December 31, 2018, 2017 and 2016, respectively.

Accrued Liabilities

Accrued liabilities consist of the following (in thousands):

	December 31,	
	2018	2017
Accrued payroll and benefits	$127,109	$103,004
Accrued expenses	39,323	27,318
Accrued customer credits and deposits	12,439	5,373
Accrued warranty	8,551	5,929
Accrued property, plant and equipment	8,193	11,362
Accrued professional fees	6,752	6,316
Accrued sales return reserve [1]	6,534	1,364
Accrued sales tax and value added tax	6,276	5,503
Accrued income taxes	5,752	12,405
Accrued sales rebate	5,668	11,209
Other accrued liabilities	8,082	5,779
Total accrued liabilities	$234,679	$195,562

(1) December 31, 2017 balance has been reclassified from accounts receivable, net to reflect the adoption of ASU 2014-09 (Refer to Note 1 “Summary of Significant Accounting Policies” of the Notes to Consolidated Financial Statements for more information).

Warranty

We regularly review the balance for accrued warranty and update based on historical warranty trends. Actual warranty costs incurred have not materially differed from those accrued; however, future actual warranty costs could differ from the estimated amounts.

Warranty as of December 31, 2018 and 2017 consists of the following activity (in thousands):

Accrued warranty as of December 31, 2016	$3,841
Charged to cost of net revenues	7,195
Actual warranty expenditures	(5,107)
Accrued warranty as of December 31, 2017	5,929
Charged to cost of net revenues	15,059
Actual warranty expenditures	(12,437)
Accrued warranty as of December 31, 2018	$8,551

Deferred Revenues

Deferred revenues consist of the following (in thousands):

	December 31,	
	2018	2017
Deferred revenues - current	$393,138	$267,713
Deferred revenues - long-term [1]	17,051	4,588

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

During the year ended December 31, 2018 and 2017, we recognized $2.0 billion and $1.5 billion of revenue, respectively, of which $180.6 million and $119.0 million was included in the deferred revenues balance at December 31, 2017 and December 31, 2016, respectively.

Note 4. Equity Method Investments

On July 25, 2016, we acquired a 17% equity interest[1], on a fully diluted basis, in SDC for $46.7 million. The investment is accounted for under an equity method investment, and the investee, SDC, is considered a related party. The investment is reported in our Consolidated Balance Sheet under equity method investments, and we record our proportional share of SDC's losses within equity in losses of investee, net of tax, in our Consolidated Statement of Operations. On July 24, 2017, we purchased an additional 2% equity interest in SDC for $12.8 million. As of December 31, 2018 and 2017, the balance of our equity method investments was $45.9 million and $54.6 million, respectively.

Concurrently with the investment on July 25, 2016, we also entered into a supply agreement with SDC to manufacture clear aligners for SDC's doctor-led, at-home program for simple teeth straightening. The term of the supply agreement expires on December 31, 2019. We commenced supplying aligners to SDC in October 2016. The sale of aligners to SDC and the income from the supply agreement are reported in our Clear Aligner business segment. We eliminate unrealized profit on outstanding intercompany transactions. As of December 31, 2018 and 2017, the balance of accounts receivable due from SDC was $16.3 million and $14.3 million, respectively. For the year ended December 31, 2018 and 2017, net revenues recognized from SDC were $27.9 million and $24.1 million, respectively.

On July 25, 2016, we entered into a Loan and Security Agreement (the "Loan Agreement") with SDC and amended on July 24, 2017 where we agreed to provide SDC a loan of up to $30.0 million in one or more advances. On February 7, 2018, $30.0 million of outstanding advances and related accrued interest were repaid in full, and the Loan Agreement was terminated (Refer to Note 9 "Commitments and Contingencies" of the Notes to Consolidated Financial Statements for information on the Loan and Security Agreement with SDC).

[1] Our ownership percentage may change depending on SDC's equity share activities

Note 5. Business Combinations

During the first quarter of 2017, we completed the acquisitions of certain of our distributors for the total estimated cash consideration of approximately $9.5 million including cash acquired. We recorded $1.9 million of net tangible liabilities, $8.2 million of identifiable intangible assets and $3.2 million of goodwill. The goodwill is primarily related to the benefit we expect

to obtain from direct sales as we believe that the transition from our distributor arrangements to a direct sales model will increase our net revenues in the region as we will experience higher average sales prices ("ASP") compared to our discounted ASP under the distribution agreements. The goodwill is not deductible for tax purposes.

Pro forma results of operations for these acquisitions have not been presented as they were not material to our results of operations, either individually or in aggregate, for the year ended December 31, 2017.

Note 6. Goodwill and Intangible Assets

Goodwill

The change in the carrying value of goodwill for the year ended December 31, 2018, all attributable to our Clear Aligner reporting unit, is as follows (in thousands):

	Total
Balance as of December 31, 2016	$61,044
Goodwill from distributor acquisitions	3,247
Adjustments [1]	323
Balance as of December 31, 2017	64,614
Adjustments [1]	(585)
Balance as of December 31, 2018	$64,029

[1] The adjustments to goodwill during the period were related to foreign currency translation and/or purchase accounting adjustments within the measurement period.

Based on the qualitative assessments performed, there were no impairments to goodwill in 2018 and 2017.

Intangible Long-Lived Assets

We amortize our intangible assets over their estimated useful lives. We evaluate long-lived assets, which includes property, plant and equipment and intangible assets, for impairment whenever events or changes in circumstances indicate the carrying value of an asset may not be recoverable. The carrying value is not recoverable if it exceeds the undiscounted cash flows resulting from the use of the asset and its eventual disposition. 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 factors. 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 of our intraoral scanning business.

There were no triggering events in 2018 and 2017 that would cause impairments of our long-lived assets.

Acquired intangible long-lived assets are being amortized as follows (in thousands):

	Weighted Average Amortization Period (in years)	Gross Carrying Amount as of December 31, 2018	Accumulated Amortization	Accumulated Impairment Loss	Net Carrying Value as of December 31, 2018
Trademarks	15	$7,100	$ (1,907)	$ (4,179)	$ 1,014
Existing technology	13	12,600	(5,268)	(4,328)	3,004
	11	33,500	(16,542)	(10,751)	6,207

Customer relationships					
Reacquired rights	3	7,500	(4,341)	—	3,159
Patents	8	6,796	(2,334)	—	4,462
Other	2	618	(544)	—	74
Total intangible assets		$ 68,114	$ (30,936)	$ (19,258)	$ 17,920

	Weighted Average Amortization Period (in years)	Gross Carrying Amount as of December 31, 2017	Accumulated Amortization	Accumulated Impairment Loss	Net Carrying Value as of December 31, 2017
Trademarks	15	$ 7,100	$ (1,769)	$ (4,179)	$ 1,152
Existing technology	13	12,600	(4,704)	(4,328)	3,568
Customer relationships	11	33,500	(14,681)	(10,751)	8,068
Reacquired rights	3	7,500	(1,356)	—	6,144
Patents	8	6,798	(1,504)	—	5,294
Other	2	618	(390)	—	228
Total intangible assets		$ 68,116	$ (24,404)	$ (19,258)	$ 24,454

The total estimated annual future amortization expense for these acquired intangible assets as of December 31, 2018 is as follows (in thousands):

Fiscal Year	Amortization
2019	$ 6,134
2020	3,847
2021	3,389
2022	2,116
2023	1,495
Thereafter	939
Total	$ 17,920

Amortization expense was $6.0 million, $6.2 million and $3.2 million for the year ended December 31, 2018, 2017 and 2016, respectively.

Note 7. Credit Facility

On February 27, 2018, we enter into a credit facility that provides for a $200.0 million revolving line of credit, with a $50.0 million letter of credit sublimit, and a maturity date of February 27, 2021, replacing the previous credit facility which provided for a $50.0 million revolving line of credit with a $10.0 million letter of credit. The credit facility requires us to comply with specific financial conditions and performance requirements. The loans 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 1.25% to 1.75% for LIBOR loans and 0.25% to 0.75% for base rate loans. 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. Principal, together with accrued and unpaid interest, is due on the maturity date. As of December 31, 2018, we had no outstanding borrowings under this credit facility and were in compliance with the conditions and performance requirements.

Note 8. Legal Proceedings

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 between July 25, 2018 and October 24, 2018. The complaint generally alleges claims under the federal securities laws

and seeks 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 between April 25, 2018 and October 24, 2018 (together with the first lawsuit, the “Securities Actions”). Motions for appointment as lead plaintiff were filed on January 4, 2019. 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 nor estimate a range of possible loss.

Shareholder Derivative Lawsuit

In January 2019, three derivative lawsuits were also 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 complaints are similar to those presented in the Securities Action, but the complaints assert various state law causes of action, including for breaches of fiduciary duty, insider trading, and unjust enrichment, among others. 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. 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.

Patent Infringement and Related Lawsuits

On November 14, 2017, Align filed six patent infringement lawsuits asserting 26 patents against 3Shape, a Danish corporation, and a related U.S. corporate entity, asserting that 3Shape's Trios intraoral scanning system and Dental System software infringe Align patents. Align filed two Section 337 complaints with the U.S. International Trade Commission ("ITC") alleging that 3Shape violates U.S. trade laws by selling for importation and importing its infringing Trios intraoral scanning system and Dental System software. Align's ITC complaints seek cease and desist orders and exclusion orders prohibiting the importation of 3Shape's Trios scanning system and Dental System software products into the U.S. Align also filed four separate complaints in the U.S. District Court for the District of Delaware alleging patent infringement by 3Shape's Trios intraoral scanning system and Dental System software.

On May 9, 2018, 3Shape filed a complaint in the U.S. District Court for the District of Delaware alleging patent infringement by Align's iTero Element scanner of a single 3Shape patent. On June 14, 2018, 3Shape filed another complaint in the U.S. District Court for the District of Delaware alleging patent infringement by Align's iTero Element scanner of a single 3Shape patent.

On August 28, 2018, 3Shape filed a complaint against Align in the U.S. District Court for the District of Delaware alleging antitrust violations and seeking monetary damages and injunctive relief relating to Align's market activities, including Align's assertion of its patent portfolio, in the clear aligner and intraoral scanning markets.

On December 10, 2018, Align filed three additional patent infringement lawsuits asserting 10 additional patents against 3Shape. Align filed one Section 337 complaint with the ITC alleging that 3Shape violates U.S. trade laws through unfair competition by selling for importation and importing the infringing TRIOS intraoral scanning system, Trios Lab Scanners and TRIOS software, TRIOS Module software, Dental System software, and Ortho System Software. On December 11, 2018, Align filed two separate complaints in the U.S. District Court for the District of Delaware alleging patent infringement by 3Shape's Trios intraoral scanning system, Lab Scanners and Dental and Ortho System Software.

Except for 3Shape's antitrust complaint, each of the District Court complaints seek monetary damages and injunctive relief against further infringement. We are currently unable to predict the outcome of this dispute and therefore cannot determine the likelihood of loss, if any, nor estimate a range of possible loss.

SDC Dispute

In February 2018, we received a communication on behalf of SDC Financial LLC, SmileDirectClub LLC, and the Members of SDC Financial LLC other than the Company (collectively, the SDC Entities) alleging that the launch and operation of the Invisalign locations pilot program constitutes a breach of non-compete provisions applicable to the members of SDC Financial LLC, including Align. As a result of this alleged breach, SDC Financial LLC notified us

that its members (other than Align) seek to exercise a right to repurchase all of Align's SDC Financial LLC membership interests for a purchase price equal to the current capital account balance. The SDC Entities' communication also alleged that we breached confidentiality provisions applicable to the SDC Financial LLC members and demanded that we cease all activities related to the Invisalign locations pilot project, close existing Invisalign locations and cease using SDC's confidential information. In April 2018, the SDC Entities served a Demand for Arbitration alleging that we breached the non-compete clause and confidentiality clause, misused the SDC Entities' alleged trade secrets, and violated fiduciary duties to SDC Financial LLC. The SDC Entities seek through the arbitration the rights to repurchase all of Align's SDC Financial LLC membership interests for a purchase price equal to the current capital account balance as defined by the Internal Revenue Service which likely is significantly below the current fair market value of such investment, an injunction requiring us to close our Invisalign locations and to cease using the SDC Entities' confidential information, and

financial damages in an unspecified amount. We filed a response in which we denied the SDC Entities' allegations and denied that the SDC Entities are entitled to any relief. In April 2018 the SDC Entities also filed a motion for preliminary injunction in the Tennessee Court of Chancery seeking to enjoin Align from opening additional Invisalign locations until the arbitration is completed. In June 2018, the Tennessee court denied the SDC Entities' motion for a preliminary injunction. In December 2018, the parties participated in binding arbitration proceedings and presented closing arguments on January 23, 2019. The arbitrator's decision is due on or before March 4, 2019. This dispute does not impact Align's existing supply agreement with SDC which remains in place through 2019. We do not intend to renew this agreement. We are currently unable to predict the outcome of this dispute and therefore cannot determine the likelihood of loss, if any, nor estimate a range of possible loss.

In addition, in the 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 9. Commitments and Contingencies

Operating Leases

We lease our facilities and certain equipment and automobiles under non-cancelable operating lease arrangements that expire at various dates through 2029 and provide for pre-negotiated fixed rental rates during the terms of the lease. The terms of some of our leases provide for rental payments on a graduated scale. We recognize rent expense on a straight-line basis over the lease period. Total rent expense was $16.5 million, $13.8 million and $9.9 million for the year ended December 31, 2018, 2017 and 2016, respectively. Sublease income is not material and excluded from the table below.

Minimum future lease payments for non-cancelable leases as of December 31, 2018, are as follows (in thousands):

Fiscal Year	Operating Leases
2019	$ 21,429
2020	20,483
2021	18,897
2022	15,096
2023	12,400
Thereafter	18,371
Total minimum lease payments	$ 106,676

Other Commitments

On July 25, 2016, we entered into a Loan and Security Agreement (the "Loan Agreement") with SDC and subsequently amended on July 24, 2017 to provide a loan of up to $30.0 million in one or more advances to SDC (the "Loan Facility"). On February 7, 2018, $30.0 million of outstanding advances and related accrued interest were repaid in full, and the Loan Agreement was terminated (Refer to Note 4 "Equity Method Investments" of the Notes to Consolidated Financial Statements for more information on our investments in SDC).

On November 9, 2017, we entered into an Investment Agreement with the People's Republic of China ("China Government") where we have committed to invest a minimum of $46.0 million in Ziyang, China over five years to establish manufacturing operations.

On November 27, 2017, we entered into a Purchase Agreement with one of our existing single source suppliers. Under the terms of the original agreement, we are required to purchase a minimum of approximately $305.2 million of aligner materials over the next four years. On May 29, 2018, we entered into an amendment to the Purchase Agreement with the existing single source

supplier to increase the original term of the agreement to five years and total minimum purchase amount to approximately of $425.9 million.

On January 15, 2019, we entered into a Purchase Agreement to purchase five floors of a building under construction in Petach Tivka, Israel (the "Property") for a purchase price of approximately $27.0 million with an option to purchase additional three floors. The purchase price will be paid in six installments according to construction milestones and the delivery of the Property throughout 2019 and 2020.

On January 29, 2019, we entered into a Purchase and Sale Agreement to purchase our currently leased building located in Morrisville, North Carolina for a purchase price of $58.1 million. On January 30, 2019, we paid a $2.0 million deposit related to the Purchase and Sale Agreement and an additional $56.1 million will be paid on or before the closing date which is expected to occur on April 8, 2019.

Off-Balance Sheet Arrangements

As of December 31, 2018, 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 Other Commitments 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, 2018, we did not have any material indemnification claims that were probable or reasonably possible.

Note 10. Stockholders’ Equity

Common Stock

The holders of common stock are entitled to receive dividends whenever funds are legally available and when and if declared by the 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, market stock units, 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 stock units, performance share or performance unit ("full value awards") are counted against the authorized share reserve as one and nine-tenths (1 9/10) shares for every one (1) share subject to the award, and any shares canceled that were counted as one and nine-tenths against the plan reserve will be returned at the same ratio.

As of December 31, 2018, the 2005 Incentive Plan (as amended) has a total reserve of 27,783,379 shares for issuance of which 6,060,265 shares are available for issuance. We issue new shares from our pool of authorized but unissued shares to satisfy the exercise and vesting obligations of our stock-based compensation plans.

Stock-Based Compensation

Stock-based compensation is based on the estimated fair value of awards, net of estimated forfeitures, and recognized over the requisite service period. Estimated forfeitures are based on historical experience at the time of grant and may be revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. The stock-based compensation related to all of our stock-based awards and employee stock purchases for the year ended December 31, 2018, 2017 and 2016 is as follows (in thousands):

	For the Year Ended December 31,		
	2018	2017	2016
Cost of net revenues	$ 3,695	$ 3,330	$ 3,966
Selling, general and administrative	56,422	46,550	42,612
Research and development	10,646	8,974	7,570
Total stock-based compensation	$ 70,763	$ 58,854	$ 54,148

Stock Options

We have not granted options since 2011 and all outstanding options were fully vested and associated stock-based compensation expense was recognized as of December 31, 2015. Activity for the year ended December 31, 2018, under the stock option plans is set forth below:

	Number of Shares Underlying Stock Options (in thousands)	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding as of December 31, 2017	75	$ 11.36		
Exercised	(67)	11.76		
Cancelled or expired	—	—		
Outstanding as of December 31, 2018	8	$ 8.07	0.16	$ 1,649
Vested at December 31, 2018	8	$ 8.07	0.16	$ 1,649
Exercisable at December 31, 2018	8	$ 8.07	0.16	$ 1,649

The aggregate intrinsic value in the table above represents the total pre-tax intrinsic value (the difference between our closing stock price on the last trading day in 2018 and the exercise price, multiplied by the number of in-the-money options) that would have been received by the option holders had all option holders exercised their options on the last trading day of 2018. This amount will fluctuate based on the fair market value of our stock. The total intrinsic value of stock options exercised for the year ended December 31, 2018, 2017 and 2016 was $17.6 million, $18.1 million and $18.2 million, respectively.

Restricted Stock Units ("RSUs")

The fair value of RSUs is based on our closing stock price on the date of grant. A summary for the year ended December 31, 2018, 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)
Nonvested as of December 31, 2017	1,341	$ 82.30		

Granted	235	262.58		
Vested and released	(562)	75.22		
Forfeited	(83)	112.33		
Nonvested as of December 31, 2018	931	$ 129.42	1.04	$ 194,950

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 2018 by the number of nonvested RSUs) that would have been received by the unit holders had all RSUs been vested and released as of the last trading day of 2018. This amount will fluctuate based on the fair

market value of our stock. During 2018, of the 561,692 shares vested and released, 178,324 shares vested were withheld for employee statutory tax obligations, resulting in a net issuance of 383,368 shares.

The total intrinsic value of RSUs vested and released during 2018, 2017 and 2016 was $146.7 million, $99.5 million and $59.8 million, respectively. The total fair value of RSUs vested during the year ended December 31, 2018, 2017 and 2016 was $42.2 million, $46.2 million and $39.1 million, respectively. The weighted average grant date fair value of RSUs granted during 2018, 2017 and 2016 was $262.58, $118.77 and $67.82, respectively. As of December 31, 2018, there was $80.7 million of total unamortized compensation costs, net of estimated forfeitures, related to RSUs and these costs are expected to be recognized over a weighted average period of 1.9 years.

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

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, and certain MSU grants are also based on Align's stock price at the end of the performance period. Generally, the vesting period of MSUs is three years. For MSUs granted during the year ended December 31, 2018, the maximum number of MSUs which will be eligible to vest are between 250% to 300% of the MSUs initially granted.

The following table summarizes the MSU performance for the year ended December 31, 2018:

	Number of Shares Underlying MSUs (in thousands)	Weighted Average Grant Date Fair Value	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Nonvested as of December 31, 2017	428	$ 78.53		
Granted	208	266.78		
Vested and released	(312)	62.41		
Forfeited	—	—		
Nonvested as of December 31, 2018	324	$ 215.07	1.16	$ 67,897

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 2018 by the number of nonvested MSUs) that would have been received by the unit holders had all MSUs been vested and released as of the last trading day of 2018. This amount will fluctuate based on the fair market value of our stock. During 2018, of the 312,300 shares vested and released, 130,697 shares were withheld for tax payments, resulting in a net issuance of 181,603 shares.

The total intrinsic value of MSUs vested and released during 2018, 2017 and 2016 was $92.7 million, $28.8 million and $17.4 million, respectively. The total fair value of MSUs vested during the year ended December 31, 2018, 2017 and 2016 was $19.5 million, $15.0 million and $9.9 million, respectively. As of December 31, 2018, we expect to recognize $39.6 million of total unamortized compensation cost, net of estimated forfeitures, related to MSUs over a weighted average period of 1.2 years.

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

	Year Ended December 31,		
	2018	2017	2016
Expected term (in years)	3.0	3.0	3.0
Expected volatility	31.9 %	28.9 %	34.0 %

Risk-free interest rate	2.5	%	1.5	%	0.9 %
Expected dividends	—		—		—
Weighted average fair value per share at grant date	$470.75		$120.39		$68.88

Total payments to tax authorities for payroll taxes related to RSUs, including MSUs, that vested during the period were $86.1 million, $46.2 million and $29.9 million during the year ended December 31, 2018, 2017 and 2016, respectively, and are reflected as a financing activity in the Consolidated Statement of Cash Flows.

Employee Stock Purchase Plan ("ESPP")

In May 2010, our shareholders approved the 2010 Employee Stock Purchase Plan (the “2010 Purchase Plan”), which consists of consecutive overlapping twenty-four month offering periods with four six-month purchase periods in each offering period. Employees purchase shares at 85% of the lower of the fair market value of the common stock at either the beginning of the offering period or the end of the purchase period. The 2010 Purchase Plan will continue until terminated by either the Board of Directors or its administrator. The maximum number of shares available for issuance under the 2010 Purchase Plan is 2,400,000 shares.

The following table summarizes the ESPP shares issued:

	Year Ended December 31,		
	2018	2017	2016
Number of shares issued (in thousands)	164	202	197
Weighted average price	$96.95	$59.93	$48.65

As of December 31, 2018, 571,778 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,		
	2018	2017	2016
Expected term (in years)	1.3	1.2	1.2
Expected volatility	35.2 %	26.8 %	30.5 %
Risk-free interest rate	2.2 %	1.0 %	0.7 %
Expected dividends	—	—	—
Weighted average fair value at grant date	$94.71	$31.36	$22.23

We recognized stock-based compensation expense related to our employee stock purchase plan of $5.6 million, $5.4 million and $2.7 million for the year ended December 31, 2018, 2017 and 2016, respectively. As of December 31, 2018, there was $2.1 million of total unamortized compensation costs related to future employee stock purchases which we expect to be recognized over a weighted average period of 0.4 years.

Note 11. Common Stock Repurchase Programs

April 2014 Repurchase Program

In April 2014, we announced that our Board of Directors had authorized a plan to repurchase up to $300.0 million of our common stock ("April 2014 Repurchase Program").

Prior to 2017, we entered into accelerated share purchase agreements to repurchase $190 million of our common stock and received a total of approximately 3.2 million shares. In addition, we repurchased on the open market approximately 1.6 million shares of our common stock for an aggregate purchase price of approximately $106.2 million.

In 2017, we repurchased on the open market approximately 0.04 million shares of our common stock at an average price of $96.37 per share, including commission for an aggregate purchase price of approximately $3.8 million, completing the April 2014 Repurchase Program.

April 2016 Repurchase Program

In April 2016, we announced that our Board of Directors had authorized a plan to repurchase up to $300.0 million of our common stock ("April 2016 Repurchase Program").

In 2017, we entered into an accelerated share repurchase agreement ("2017 ASR") to repurchase $50.0 million of our common stock. The 2017 ASR was completed in August 2017. We received a total of approximately 0.4 million shares for an average share price of $146.48. During 2017, we repurchased on the open market approximately 0.2 million shares of our common stock at an average price of $243.40 per share, including commissions, for an aggregate purchase price of approximately $50.0 million.

In 2018, we repurchased on the open market approximately 0.7 million shares of our common stock at an average price of $293.21 per share, including commission for an aggregate purchase price of approximately $200.0 million, completing the April 2016 Repurchase Program.

May 2018 Repurchase Program

In May 2018, we announced that our Board of Directors had authorized a plan to repurchase up to $600.0 million of our common stock ("May 2018 Repurchase Program").

In 2018, we repurchased on the open market approximately 0.1 million shares of our common stock at an average price of $356.54 per share, including commissions, for an aggregate purchase price of approximately $50.0 million. In November 2018, we entered into an accelerated stock repurchase agreement to repurchase $50.0 million of our common stock which was completed in December 2018. We received a total of approximately 0.2 million shares for an average share price of $213.18. As of December 31, 2018, we have $500.0 million remaining under the May 2018 Repurchase Program.

In February 2019, we purchased on the open market approximately 0.2 million shares of our common stock at an average price of $243.42 per share, including commission for an aggregate purchase price of approximately of $50.0 million.

Note 12. Employee Benefit Plans

401(k) Plan

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 a 6% of the employee’s eligible compensation effective 2010. We contributed approximately $5.2 million, $4.3 million and $3.4 million to the 401(k) plan during the year ended December 31, 2018, 2017 and 2016, respectively.

Israeli Funds

Under the Israeli severance fund law, we are required to make payments to dismissed employees and employees leaving employment in certain circumstances. The funding requirement is calculated based on the salary of the employee multiplied by the number of years of employment as of the applicable balance sheet date. Our Israeli employees are entitled to one month’s salary for each year of employment, or a pro-rata portion thereof. We fund the liability through monthly deposits into funds, and the values of these contributions are recorded in other current assets in the Consolidated Balance Sheet. As of December 31, 2018 and 2017, the balance of the fund liability was approximately $3.3 million and $3.2 million, respectively.

Note 13. Income Taxes

The TCJA was enacted into law on December 22, 2017 and impacted our effective tax rate for the year ended December 31, 2017 and 2018. The TCJA made significant changes to the Internal Revenue Code, including, but not limited to, a corporate tax rate decrease from 35% to 21% effective for tax years beginning after December 31, 2017, the transition of U.S. international taxation from a worldwide tax system to a territorial system, and a one-time transition tax on the mandatory deemed repatriation of cumulative foreign earnings as of December 31, 2017.

On December 22, 2017, Staff Accounting Bulletin No. 118 ("SAB 118") was issued to address the application of GAAP in situations when a registrant does not have the necessary information available, prepared, or analyzed (including computations) in reasonable detail to complete the accounting for certain income tax effects of the TCJA. As of December 31, 2017, we recorded a provisional tax charge for the estimated impact of the TCJA of $84.3 million, of which $73.9 million was related to a provisional transition tax liability on the mandatory deemed repatriation of foreign earnings and $10.4 million was related to the remeasurement of certain deferred tax assets and liabilities. As of December 31, 2018, we have finalized our assessment of the impact of the TCJA

on our 2017 financial statements and recorded additional charges of $3.0 million in 2018, all of which relate to the transition tax on the mandatory deemed repatriation of foreign earnings.

The TCJA also includes provisions for certain foreign-sourced earnings, referred to as Global Intangible Low-Taxed Income ("GILTI"), which impose a tax on foreign income in excess of a deemed return on tangible assets of foreign corporations. FASB guidance issued in January 2018 allows companies to make an accounting policy election to either (i) account for GILTI as a component of tax expense in the period in which the tax is incurred (the "period cost method"), or (ii) account for GILTI in the measurement of deferred taxes (the "deferred method"). We have made the election to record GILTI tax using the period cost method.

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

	Year ended December 31,		
	2018	2017	2016
Domestic	$171,658	$123,696	$118,871
Foreign	294,993	241,103	123,695
Net income before provision for income taxes and equity in losses of investee	$466,651	$364,799	$242,566

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

	Year Ended December 31,		
	2018	2017	2016
Federal			
Current	$35,788	$91,214	$40,235
Deferred	(5,989)	15,724	24,794
	29,799	106,938	65,029
State			
Current	9,568	2,580	2,603
Deferred	(3,274)	2,677	2,636
	6,294	5,257	5,239
Foreign			
Current	22,753	15,285	8,964
Deferred	(1,123)	2,682	(28,032)
	21,630	17,967	(19,068)
Provision for income taxes	$57,723	$130,162	$51,200

The differences between income taxes using the federal statutory income tax rate of 21% for 2018 and 35% for 2017 and 2016 and our effective tax rate are as follows:

	Year Ended December 31,		
	2018	2017	2016
U.S. federal statutory income tax rate	21.0 %	35.0 %	35.0 %
State income taxes, net of federal tax benefit	1.3	1.4	2.1
U.S. tax on foreign earnings	4.1	1.5	0.2
Impact of U.S. Tax Cuts and Jobs Act ("TCJA")	2.1	23.1	—
Impact of differences in foreign tax rates	(6.7)	(18.0)	(6.3)
Impact of expiration of statute of limitations	(6.2)	—	—
Stock-based compensation	(3.4)	(6.3)	1.2
Other items not individually material	0.2	(1.0)	1.8
Valuation allowance release for Israel	—	—	(12.9)
	12.4 %	35.7 %	21.1 %

As of December 31, 2018, undistributed earnings of the Company's foreign subsidiaries totaled $533.5 million. As a result of the TCJA, during the year ended December 31, 2017, we provided for U.S. income taxes on undistributed foreign earnings through December 31, 2017, and we have reassessed our capital needs and investment strategy with regard to the indefinite reinvestment, determining that certain of those are no longer indefinitely reinvested. Of the total undistributed foreign earnings as of December 31, 2018, the amount that is not indefinitely reinvested is $239.2 million. The remaining amount of undistributed foreign earnings of approximately $294.3 million continues to be indefinitely reinvested in our international operations. Since U.S. income taxes have already been provided under the GILTI provisions of the TCJA, the additional tax impact of the distribution of such foreign earnings to the U.S. parent company would be limited to withholding taxes and is not significant.

On July 1, 2016, we implemented a new international corporate structure. This changed the structure of our international procurement and sales operations, as well as realigned the ownership and use of intellectual property among our wholly-owned subsidiaries. We continue to anticipate that an increasing percentage of our consolidated pre-tax income will be derived from, and reinvested in our foreign operations. We believe that income taxed in certain foreign jurisdictions at a lower rate relative to the U.S. federal statutory rate will have a beneficial impact on our worldwide effective tax rate over time. Although the license of intellectual property rights between consolidated entities did not result in any gain in the consolidated financial statements, we generated taxable income in certain jurisdictions in 2016 resulting in a tax expense of $34.3 million. Additionally, as a result of the restructuring in 2016, we reassessed the need for a valuation allowance against our deferred tax assets considering all available evidence. Given the earnings in 2016 and anticipated future earnings of our subsidiary in Israel, we concluded that we had sufficient positive evidence to release the valuation allowance against our Israel operating loss carryforwards of $31.4 million, which resulted in an income tax benefit in 2016 of the same amount.

In June 2017, the Costa Rica Ministry of Foreign Trade, an agency of the Government of Costa Rica, granted an extension of certain income tax incentives for an additional twelve year period. Under these incentives, all of the income in Costa Rica is subject to a reduced tax rate. In order to receive the benefit of these incentives, we must hire a specified number of employees and maintain certain minimum levels of fixed asset investment in Costa Rica. If we do not fulfill these conditions for any reason, our incentive could lapse, and our income in Costa Rica would be subject to taxation at higher rates, which could have a negative impact on our operating results. The Costa Rica corporate income tax rate that would apply, absent the incentives, is 30% for 2018, 2017 and 2016. As a result of these incentives, our income taxes were reduced by $2.4 million, $1.8 million and $19.1 million in the year ended December 31, 2018, 2017 and 2016, respectively, representing a benefit to diluted net income per share of $0.03, $0.02 and $0.23 in the year ended December 31, 2018, 2017 and 2016, respectively.

As of December 31, 2018 and 2017, the significant components of our deferred tax assets and liabilities are (in thousands):

	Year Ended December 31,	
	2018	2017
Deferred tax assets:		
Net operating loss and capital loss carryforwards	$ 25,410	$ 24,971
Reserves and accruals	24,769	12,547
Stock-based compensation	8,571	10,074
Deferred revenue	14,285	10,811
Net translation losses	1,158	1,928
Credit carryforwards	115	792
	74,308	61,123
Deferred tax liabilities:		
Depreciation and amortization	8,320	7,522
Prepaid expenses	902	751

Unremitted foreign earnings	612	3,305
	9,834	11,578
Net deferred tax assets before valuation allowance	64,474	49,545
Valuation allowance	(251)	(278)
Net deferred tax assets	$ 64,223	$ 49,267

The total valuation allowance as of December 31, 2018 was not material. During the year ended December 31, 2018, the valuation allowance decreased by a nominal amount which was mainly related to foreign currency translation adjustments.

As of December 31, 2018, we have fully utilized California net operating loss carryforwards. As of December 31, 2018, we have California research credit carryforwards of approximately $1.9 million which can be carried forward indefinitely. In addition, we have foreign net operating loss carryforwards of approximately $105.7 million, the majority of which can be carried forward indefinitely, and a minor portion of which, if not utilized, will expire beginning after 2023.

In the event of a change in ownership, as defined under federal and state tax laws, our tax credit carryforwards may be subject to annual limitations. The annual limitations may result in the expiration of the tax credit carryforwards before utilization.

The changes in the balance of gross unrecognized tax benefits, which exclude interest and penalties, for the year ended December 31, 2018, 2017 and 2016, are as follows (in thousands):

Unrecognized tax benefit as of December 31, 2015	$39,413
Tax positions related to current year:	
Additions for uncertain tax positions	6,971
Unrecognized tax benefit as of December 31, 2016	46,384
Tax positions related to current year:	
Additions for uncertain tax positions	1,819
Tax positions related to prior year:	
Additions for uncertain tax positions	1,809
Decreases for uncertain tax positions	(826)
Settlements with tax authorities	(1,527)
Reductions due to lapse of applicable statute of limitations	(3)
Unrecognized tax benefit as of December 31, 2017	47,656
Tax positions related to current year:	
Additions for uncertain tax positions	14,519
Tax positions related to prior year:	
Additions for uncertain tax positions	80
Reductions due to lapse of applicable statute of limitations	(28,993)
Unrecognized tax benefit as of December 31, 2018	$33,262

As of December 31, 2018, $29.9 million of our unrecognized tax benefits 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 the Netherlands. For U.S. federal and state tax returns, we are no longer subject to tax examinations for years before 2015. We are currently under examination by the Internal Revenue Service for tax years 2015 and 2016. With few exceptions, we are no longer subject to examination by foreign tax authorities for years before 2010.

We have elected to recognize interest and penalties related to unrecognized tax benefits as a component of income taxes. For the year ended December 31, 2018 and 2017, interest and penalties included in tax expense was a benefit of $1.5 million and an expense of $0.8 million, respectively. Our total interest and penalties accrued as of December 31, 2018 and 2017 was $0.9 million and $2.9 million, respectively. The timing and resolution of income tax examinations

is uncertain, and the amounts ultimately paid, if any, upon resolution of issues raised by the taxing authorities may differ materially from the amounts accrued for each year. Although it is possible that our balance of gross unrecognized tax benefits could materially change in the next 12 months, given the uncertainty in the development of ongoing income tax examinations, we are unable to estimate the full range of possible adjustments to this balance.

Note 14. Net Income per Share

Basic net income per share is computed using the weighted average number of shares of common stock outstanding during the period. Diluted net income per share is computed using the weighted average number of shares of common stock, adjusted for any dilutive effect of potential common stock. Potential common stock, computed using the treasury stock method, includes RSUs, MSUs, stock options 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,		
	2018	2017	2016
Numerator:			
Net income	$400,235	$231,418	$189,682
Denominator:			
Weighted average common shares outstanding, basic	80,064	80,085	79,856
Dilutive effect of potential common stock	1,293	1,747	1,628
Total shares, diluted	81,357	81,832	81,484
Net income per share, basic	$5.00	$2.89	$2.38
Net income per share, diluted	$4.92	$2.83	$2.33

For the year ended December 31, 2018, 2017 and 2016, potentially anti-dilutive shares excluded from diluted net income per share related to RSUs, MSUs, stock options and ESPP were not material.

Note 15. Supplemental Cash Flow Information

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

	Year Ended December 31,		
	2018	2017	2016
Taxes paid	$114,601	$51,231	$47,289
Non-cash investing activities:			
Fixed assets acquired with accounts payable or accrued liabilities	$15,069	$15,105	$4,434
Conversion of convertible notes receivable into equity securities	$4,862	$—	$—
Fair value of option to purchase property	$—	$3,936	$—

Note 16. Segments and Geographical Information

Segment Information

Operating segments are defined as components of an enterprise for which separate financial information is available that is evaluated regularly by the Chief Operating Decision Maker (“CODM”), or decision-making group, in deciding how to allocate resources and in assessing performance. Our CODM is our Chief Executive Officer. We report segment information based on the management approach. The management approach designates the internal reporting used by CODM 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.

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Explanation of Responses: 168

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

- Our Clear Aligner segment consists of Comprehensive Products, Non-Comprehensive Products and Non-Case revenues as defined below:

- Comprehensive Products include, but not limited to, our Invisalign Comprehensive (formerly known as Invisalign Full and Invisalign Teen), Invisalign Assist and Invisalign First.

- Non-Comprehensive Products include, Invisalign Express 10, Invisalign Express 5, Express Package, Lite Package and Invisalign Go products in addition to revenues from the sale of aligners to SDC under our supply agreement.

- Non-Case includes, but not limited to, Vivera retainers along with our training and ancillary products for treating malocclusion.

- Our Scanner segment consists of intraoral scanning systems, additional services and ancillary products available with the intraoral scanners that provide digital alternatives to the traditional cast models. This segment includes our iTero scanner and OrthoCAD services.

These reportable operating segments are based on how our CODM views and evaluates our operations as well as allocation of resources. The following information relates to these segments (in thousands):

	For the Year Ended December 31,		
	2018	2017	2016
Net revenues			
Clear Aligner	$1,691,467	$1,309,262	$958,327
Scanner	275,025	164,151	121,547
Total net revenues	$1,966,492	$1,473,413	$1,079,874
Gross profit			
Clear Aligner	$1,280,495	$1,019,563	$747,494
Scanner	167,372	97,384	67,800
Total gross profit	$1,447,867	$1,116,947	$815,294
Income from operations			
Clear Aligner	$712,439	$564,648	$411,817
Scanner	98,998	49,613	37,498
Unallocated corporate expenses	(344,873)	(260,650)	(200,394)
Total income from operations	$466,564	$353,611	$248,921
Depreciation and amortization			
Clear Aligner	$29,001	$21,581	$13,742
Scanner	4,965	4,385	3,871
Unallocated corporate expenses	20,761	11,773	6,389
Total depreciation and amortization	$54,727	$37,739	$24,002

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

	For the Year Ended December 31,		
	2018	2017	2016
Total segment income from operations	$811,437	$614,261	$449,315
Unallocated corporate expenses	(344,873)	(260,650)	(200,394)
Total income from operations	466,564	353,611	248,921
Interest income	8,576	6,948	4,213
Other income (expense), net	(8,489)	4,240	(10,568)
Net income before provision for income taxes and equity in losses of investee	$466,651	$364,799	$242,566

Geographical Information

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

	For the Year Ended December 31,		
	2018	2017	2016
Net revenues [1]:			
United States [2]	$1,023,559	$836,200	$692,254
The Netherlands [2]	610,039	456,108	286,911
China	155,790	81,661	46,480
Other International	177,104	99,444	54,229
Total net revenues	$1,966,492	$1,473,413	$1,079,874

[1] Net revenues are attributed to countries based on location of where revenue is recognized.
[2] Effective July 2016, we implemented a new international corporate structure. This changed the structure of our international procurement and sales operations.

Tangible long-lived assets are presented below by geographic area (in thousands):

	As of December 31,	
	2018	2017
Long-lived assets [3]:		
The Netherlands	$206,679	$143,673
United States	139,239	128,171
Costa Rica	80,218	30,738
China	36,249	5,480
Mexico	33,240	25,090
Other International	25,704	15,641
Total long-lived assets	$521,329	$348,793

[3] Long-lived assets are attributed to countries based on entity that owns 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, 2018 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, 2018 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B.OTHER INFORMATION

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 2018 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 “Section 16(a) Beneficial Ownership Reporting Compliance” 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 that applies to all of our employees, including our principal executive officer, principal financial officer and principal accounting officer. This code of ethics is posted on our Internet website. The Internet address for our website is www.aligntech.com, and the code of ethics may be found on the “Corporate Governance” section of our “Investor Relations” webpage.

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 “Compensation Committee 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 “Security Ownership of Certain Beneficial Owners and Management.”

Equity Compensation Plan Information

The following table provides information as of December 31, 2018 about our common stock that may be issued upon the exercise of options and 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 10“Stockholders’ Equity” of the Notes to Consolidated Financial Statements for a description of our equity compensation plans).

Plan Category	Number of securities to be issued upon exercise of outstanding options and restricted stock units(a)		Weighted average exercise price of outstanding options(b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column(a))	
Equity compensation plans approved by security holders	1,263,246	[1]	$ 8.07	6,632,043	[2, 3]
Equity compensation plans not approved by security holders	—		—	—	
Total	1,263,246		$ 8.07	6,632,043	

[1] Includes 930,859 restricted stock units and 324,200 market-performance based restricted stock units at target, which have an exercise price of zero.

[2] Includes 571,778 shares available for issuance under our ESPP. We are unable to ascertain with specificity the number of securities to be issued upon exercise of outstanding rights or the weighted average exercise price of outstanding rights under the ESPP.

[3] Includes 648,185 of potentially issuable MSUs if performance targets are achieved at maximum payout.

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 ACCOUNTING FEES AND SERVICES

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

PART IV

ITEM 15.EXHIBITS, FINANCIAL STATEMENT SCHEDULES
(a)Financial Statements
1.Consolidated financial statements
The following documents are filed as part of this Annual Report on Form 10-K:

2.The following financial statement schedule is filed as part of this Annual Report on Form 10-K:
Schedule II—Valuation and Qualifying Accounts and Reserves For the Year Ended December 31, 2018, 2017 and 2016
All other schedules have been omitted as they are not required, not applicable, or the required information is otherwise included.
SCHEDULE II: VALUATION AND QUALIFYING ACCOUNTS AND RESERVES

	Balance at Beginning of Period	Additions (Reductions) to Costs and Expenses	Write Offs	Balance at End of Period
	(in thousands)			
Allowance for doubtful accounts[1]:				
Year Ended December 31, 2016	$1,108	$ 8,585	$(6,747)	$ 2,946
Year Ended December 31, 2017	$2,946	$ 9,948	$(7,080)	$ 5,814
Year Ended December 31, 2018	$5,814	$ 12,321	$(15,757)	$ 2,378
Valuation allowance for deferred tax assets:				
Year Ended December 31, 2016	$31,685	$ (31,429)	$—	$ 256
Year Ended December 31, 2017	$256	$ 22	$—	$ 278
Year Ended December 31, 2018	$278	$ (27)	$—	$ 251

(1) Balances have been recast to reflect the adoption of new revenue accounting standard (Refer to Note 1 "Summary of Significant Accounting Policies" of the Notes to Consolidated Financial Statements for details).

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

Exhibit Number	Description	Form	Date	Exhibit Number Incorporated by Reference herein	Filed herewith
3.1	Amended and Restated Certificate of Incorporation of registrant	Form S-1, as amended (File No. 333-49932)	12/28/2000	3.1	
3.2	Amended and Restated Bylaws of registrant	Form 8-K	2/29/2012	3.2	
4.1	Form of Specimen Common Stock Certificate	Form S-1, as amended (File No. 333-49932)	1/17/2001	4.1	
10.1†	Registrant's 2005 Incentive Plan (as amended May 2016)	Form 10-K	2/28/2017	10.1	
10.2†	Form of RSU agreement under Registrant's 2005 Incentive Plan (Officer Form for officers appointed after September 2016)	Form 10-K	2/28/2017	10.2	
10.2A†	Form of RSU agreement under Registrant's 2005 Incentive Plan (Officer Form for officers appointed prior to September 2016)	Form 10-K	2/28/2017	10.2A	
10.3	Align’s 2010 Employee Stock Purchase Plan	Form 8-K	5/25/2010	10.2	
10.4†	Form of Indemnification Agreement by and between registrant and its Board of Directors and its executive officers	Form S-1 as amended (File No. 333-49932)	1/17/2001	10.15	
10.5†	Form of restricted stock unit award agreement under registrant’s 2005 Incentive Plan (General Form; Director Form)	Form 10-Q	11/5/2007	10.1C	
10.6†	Form of option award agreement under registrant’s 2005 Incentive Plan	Form 10-Q	8/4/2005	10.4	
10.7†	Form of Employment Agreement entered into by and between registrant and each executive officer (other than CEO for executives appointed prior to September 2016)	Form 10-Q	5/8/2008	10.3	
10.8†	Form of Employment entered into by and between registrant and each executive officer (other than CEO for executives appointed after September 2016)	Form 10-K	2/28/2017	10.8	
10.10†	Summary of 2018 Incentive Awards and Base Salary for NEOs	Form 8-K	2/5/2019		
10.11†	Form of Market Stock Unit Agreement under Registrant's 2005 Incentive Plan (Officer hired after 9/16)			10.1	*
10.12†	Form of Market Stock Unit Agreement under Registrant's 2015 Incentive Plan (Officers hired pre-9/16)			10.2	*
10.12†	Form of Market Stock Unit Agreement for CEO (Focal grants)			10.3	*
10.12†		Form 8-K	6/25/2018	10.1	

	Form of Market Stock Unit Agreement for CEO Special MSU Award June 2018			
10.15†	Amended and Restated Chief Executive Officer Employment Agreement between Align Technology, Inc. and Joseph Hogan	Form 10-Q	5/1/2015	10.3
10.16†	Form of Restricted Stock Unit Agreement (CEO)	Form 10-Q	7/30/2015	10.31
10.18†	Employment Agreement between registrant and John F. Morici (Chief Financial Officer)	Form 10-Q	11/8/2016	10.2
10.19	Purchase and Sale Agreement between registrant and LBA RIV-Company XXX, LLC dated December 19, 2016	Form 8-K	12/23/2016	10.1
10.20	Class C Non-Incentive Unit Purchase Agreement dated July 25, 2016	Form 8-K	7/28/2016	10.1

Exhibit Number	Description	Form	Date	Exhibit Number Incorporated by Reference herein	Filed herewith
10.21	Purchase and Sale Agreement dated July 24, 2017 between Align Technology de Costa Rica, S.R.L. and Belan Business Center, S.A.	Form 8-K	7/27/2017	10.1	
10.22	Membership Interest Purchase Agreement dated July 24, 2017 between Align Technology, Inc. and SmileDirectClub, LLC.	Form 8-K	7/27/2017	10.2	
10.23	Purchase and Sale Agreement between Align Technology de Costa Rica, S.R.L. and Belen Business Center, S.A. dated November 15, 2017	Form 8-K	11/20/2017	10.1	
10.25	Credit Agreement between Align Technology, Inc. and Wells Fargo Bank, National Association dated February 27, 2018	Form 8-K	2/27/2018	10.1	
10.26	Purchase and Sale Agreement between Align Technology, Inc. and Slater Road I, LLC dated January 29, 2019			10.4	*
10.27	Fixed Dollar Accelerated Share Repurchase Transaction dated November 7, 2018			10.5	*
10.28	Align 2019 Global RSU Agreement			10.6	*
21.1	Subsidiaries of Align Technology, Inc.				*
23.1	Consent of PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firm				*
31.1	Certifications of Chief Executive Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2003				*
31.2	Certifications of Chief Financial Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2003				*
32	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2003				*
101.INS	XBRL Instance Document				*
101.SCH	XBRL Taxonomy Extension Schema Document				*
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document				*
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document				*
101.LAB	XBRL Taxonomy Extension Label Linkbase Document				*
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document				*

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† 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.

†† Portions of the exhibit have been omitted pursuant to a request for confidential treatment. The confidential portions have been filed with the SEC.

ITEM 16.FORM 10-K SUMMARY

Not applicable.

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Explanation of Responses:

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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, on February 28, 2019.

ALIGN TECHNOLOGY, INC.

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

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

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

Signature	Title	Date
/S/ JOSEPH M. HOGAN Joseph M. Hogan	President and Chief Executive Officer (Principal Executive Officer)	February 28, 2019
/S/ JOHN F. MORICI John F. Morici	Chief Financial Officer and Senior Vice President, Global Finance (Principal Financial Officer and Principal Accounting Officer)	February 28, 2019
/S/ JOSEPH LACOB Joseph Lacob	Director	February 28, 2019
/S/ C. RAYMOND LARKIN, JR. C. Raymond Larkin, Jr.	Director	February 28, 2019
/S/ GEORGE J. MORROW George J. Morrow	Director	February 28, 2019
/S/ ANDREA L. SAIA Andrea L. Saia	Director	February 28, 2019
	Director	

/S/ GREG J. SANTORA Greg J. Santora		February 28, 2019
/S/ THOMAS M. PRESCOTT Thomas M. Prescott	Director	February 28, 2019
/S/ WARREN S. THALER Warren S. Thaler	Director	February 28, 2019
/S/ SUSAN E. SIEGEL Susan E. Siegel	Director	February 28, 2019
/S/ KEVIN J. DALLAS Kevin J. Dallas	Director	February 28, 2019

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