ALIGN TECHNOLOGY INC
Form 10-K
February 25, 2016
UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2015

Or

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

For the transition period from to

Commission file number: 0-32259

ALIGN TECHNOLOGY, INC.
(Exact name of registrant as specified in its charter)

Delaware	94-3267295
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)
2560 Orchard Parkway San Jose, California 95131 (Address of principal executive offices)	
(408) 470-1000 (Registrant's telephone number, including area code)	

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

Title of each class	Name of each exchange on which registered
Common Stock, $0.0001 par value (Including associated Preferred Stock Purchase Rights)	The NASDAQ Stock Market LLC (NASDAQ Global Market)

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

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

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ý No ¨

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ý

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

Large accelerated filer x	Accelerated filer o
Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company o

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 $3,646,077,546 as of June 30, 2015 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 19, 2016, 79,625,640 shares of the registrant’s common stock were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant’s definitive Proxy Statement relating to its 2016 Annual Stockholders’ Meeting to be filed pursuant to Regulation 14A within 120 days after the registrant’s fiscal year end of December 31, 2015 are incorporated by reference into Part III of this Annual Report on Form 10-K.

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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 including Invisalign G5 and ClinCheck Pro 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 financial and strategic benefits of our iTero scanner, our expectations regarding the continued expansion of our international markets 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 results. These forward-looking statements are subject to certain risks and uncertainties that could cause actual results to differ materially from those reflected in the forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in 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”) designs, manufactures and markets a system of clear aligner therapy, intra-oral scanners and CAD/CAM (computer-aided design and computer-aided manufacturing) digital services used in dentistry, orthodontics, and dental records storage. Align Technology was founded in March 1997 and incorporated in Delaware in April 1997. Our headquarters are located at 2560 Orchard Parkway, San Jose, California 95131, and our telephone number is 408-470-1000. Our internet address is www.aligntech.com. Our international headquarters are located in Amsterdam, the Netherlands.

We have two operating segments: (1) Clear Aligner, known as the Invisalign System; and (2) Scanners and Services ("Scanner"), known as the iTero intra-oral scanner and OrthoCAD services and formerly referred to as our Scanners and CAD/CAM Services segment. For the year ended December 31, 2015, Clear Aligner revenues represent approximately 95 percent of worldwide revenue, while Scanner represent the remaining 5 percent of worldwide revenues. We distribute the vast majority of our products directly to our customers: orthodontists and general practitioner dentists ("GPs"), as well as to restorative dentists, including prosthodontists, periodontists, and oral surgeons.

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 primarily sold through a direct sales force in the United States ("U.S."), Canada, Europe, and certain Asia Pacific countries including Australia, New Zealand, China and Japan. We use a distributor model for the sale of our products in non-core country markets in the Asia Pacific, Europe, Middle East and Africa ("EMEA"), and Latin America regions.

We acquired the iTero digital intra-oral scanner and CAD/CAM services business, our Scanner segment, in April 2011. Our iTero scanner is used by dental professionals and/or labs and services for restorative and orthodontic digital procedures as well as Invisalign digital impression submission. We received 501(k) clearance from the FDA to market iTero software for expanded indications in 2013. Scanners and CAD/CAM Services are primarily sold through our

direct sales force in North America and in select international markets primarily through distribution partners.

Our Products and Services

Our net revenues are generated from the sale of the following product offerings:

	Fiscal Year		
Percentage of Net Revenues by Product	2015	2014	2013
Invisalign Full Products	78 %	77 %	75 %
Invisalign Express Products	11	11	11
Invisalign Non-case*	6	6	7
Scanners and Services	5	6	7
Total net revenues	100 %	100 %	100 %

* Non-case net revenues include retainers, training revenues, and ancillary offerings under our Clear Aligner product lines.

Clear Aligner Segment

Malocclusion and Traditional Orthodontic Treatment

Malocclusion, or the misalignment of teeth, is one of the most prevalent clinical dental conditions, affecting nearly a billion people, or approximately 50% to 75% of the population of major developed countries. Approximately 6.8 million people annually elect treatment by orthodontists worldwide, of which approximately 2.6 million have mild to moderate malocclusion and are applicable to Invisalign treatment - our served market.

In the U.S., orthodontists and GPs treat malocclusion primarily with metal arch wires and brackets, referred to as braces, and augment braces with elastics, metal bands, headgear and other ancillary devices as needed. Available options for improving treatment aesthetics include the use of ceramic, tooth-colored brackets or bonding brackets on the inside, or lingual surface, of the patient’s teeth. The average treatment takes approximately 12 to 24 months to complete and requires several hours of direct dental professional involvement, known in the industry as “chair time,” including the initial diagnosis, creation of an appropriate treatment plan and bonding of the brackets to the patient’s teeth, and attachment of arch wires to the brackets. Subsequent visits involve tightening or otherwise adjusting the braces approximately every six weeks until the final visit when the dental professional removes each bracket and residual bonding agent from the patient’s teeth. Upon completion of the treatment, the dental professional may, at his or her discretion, have the patient use a retainer.

The Invisalign System

The Invisalign System is a proprietary method for treating malocclusion based on a series of doctor-prescribed, custom manufactured, clear plastic removable orthodontic 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 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. The Invisalign-trained dental professional can also submit an intra-oral scan or “digital impression” instead of a physical PVS impression through either Align's iTero scanner, 3M's True Definition or Sirona's CEREC Omnicam scanner, currently the only other Invisalign qualified intra-oral scanners.

Preparation of 3D computer models of the patient's initial malocclusion. Upon receipt, we use the treatment data package to construct digital models of the patient's dentition. In cases where a PVS impression has been submitted, we use computed tomography, known as CT scanning to develop a digital, three-dimensional computer model of the patient's current dentition. In cases where the dental professional submits a digital impression, this step in the process is eliminated.

Preparation of computer-simulated treatment and viewing of treatment using ClinCheck software. We transform this initial digital model into a proposed custom, three-dimensional treatment plan, called a ClinCheck treatment plan. The ClinCheck plan simulates appropriate tooth movement broken down into a series of two-week increments, and details timing and placement of

any 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. 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 and amending the treatment simulation, the dental professional retains control over the treatment plan. ClinCheck Pro is the next generation Invisalign treatment software tool, designed to provide more precise control over final tooth position and to help Invisalign providers achieve their treatment goals. This latest software innovation features interactive 3D controls that, for the first time, allow Invisalign providers to make adjustments to the position of individual teeth directly on the 3D model and to visualize the effects on the whole dentition in real time.

Construction of molds corresponding to each step of treatment. Upon the dental professional’s approval of the ClinCheck treatment plan, we use the data underlying the simulation, in conjunction with stereolithography 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 two-week stage of the simulated course of treatment.

Manufacture of aligners and shipment to the dental professional. 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 two-week stage of the ClinCheck animation. Aligners are generally worn for consecutive two-week periods which correspond to the approved ClinCheck treatment plan. After two weeks of use, the patient replaces them with the next pair in the series, 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.

Retention. Upon completion of the treatment, the patient may be prescribed our single clear retainer product or our Vivera Retainer product.

Clear Aligner Products

Invisalign Full. Used for a wide range of malocclusion, the Invisalign Full treatment consists of the number of aligners necessary to achieve the doctor’s treatment goals. Invisalign Full treatment aligners are manufactured and then delivered to the dental professionals in a single shipment. Invisalign Full is sold in the U.S., Canada, and our international regions. The Invisalign Full product is included in "Invisalign Full Products."

Invisalign Teen. The Invisalign Teen treatment includes all the features of Invisalign Full treatment, plus additional features that address the orthodontic needs of teenage patients such as compliance indicators, compensation for tooth eruption and six free single arch replacement aligners. This product is predominantly marketed to orthodontists who treat the vast majority of malocclusion in teenage patients. Invisalign Teen treatment aligners (other than the replacement aligners) are manufactured and then delivered to the dental professionals in a single shipment. Invisalign Teen is sold in the U.S., Canada, and our international regions. The Invisalign Teen product is included in "Invisalign Full Products".

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. The Invisalign Assist product is included in

"Invisalign Full Products".

Invisalign Express (10 and 5) and Invisalign Lite/i7. Invisalign Express treatment, Invisalign Lite treatment and Invisalign i7 treatment are lower-cost solutions for less complex orthodontic cases, non-comprehensive treatment relapse cases, or straightening prior to restorative or cosmetic treatments such as veneers. Invisalign Express 10 and Invisalign Express 5, which are sold in the U.S. and Canada, uses up to 10 and 5 sets of aligners, respectively, and are also available as a single arch option. Invisalign Lite and Invisalign i7, sold in our international regions, uses up to 14 and 7 sets of aligners, respectively. For Invisalign Express/Lite/i7, aligners are manufactured and then delivered to the dental professionals in a single shipment. The Invisalign Express (10 and 5) products and Invisalign Lite /i7 products are included in "Invisalign Express Products".

Retention. We offer two products for post treatment retention. The first is a single set of custom clear aligner retainers. The second is offered as a set of four custom clear aligners called Vivera Retainers made with proprietary material strong enough to maintain tooth position and correct minor relapse if necessary. Each set of Vivera Retainers is intended to be used for three

consecutive months and deliver one year of retention. Doctors can prescribe Vivera Retainers for their Invisalign and their non-Invisalign patients.

Invisalign non-case revenues. Invisalign non-case revenues represent retainer products discussed above, Invisalign training fees and sales of ancillary products, such as cleaning material and adjusting tools used by dental professionals during the course of treatment.

Feature Enhancements. We have consistently introduced enhanced features across the Invisalign System over the past several years, such as Invisalign G3 (launched in October 2010), Invisalign G4 (launched in November 2011), and Invisalign G5 (launched in February 2014). In 2015, we did a phased launch of Invisalign G6 clinical innovations for first premolar extraction. These feature enhancements are a collection of clinical innovations designed to address some of the most significant treatment challenges doctors encounter.

Invisalign G5 is our first set of innovations designed specifically as an integrated solution to enhance treatment predictability for deep bite, a specific type of malocclusion. Invisalign G5 feature enhancements include:

- Precision Cuts, which are custom mesial and distal hooks used to provide anchorage for elastics and button cutouts to accommodate buttons bonded to the tooth aimed to help treat patients with Class II and Class III malocclusion.
- SmartForce features engineered to achieve more predictable tooth movements using custom optimized attachments and Power Ridges designed to provide additional force in cases where certain types of root movement are prescribed.
- Precision aligner bite ramps designed to disocclude the posterior teeth for improved efficiency in deep bite treatments.

Invisalign G6 is engineered to improve clinical outcomes for orthodontic treatment of severe crowding and bimaxillary protrusion. Invisalign G6 clinical innovations was launched in Asia Pacific, Europe, Middle East and Africa, and Latin America geographies throughout 2015 and will be launched in North America in early 2016. Invisalign G6 feature enhancements include:

- New SmartStage programmed tooth movements that optimize the progression of tooth movements and provide aligner activation, engineered to eliminate unwanted tipping and unwanted anterior extrusion during retraction.
- New SmartForce features that are designed to deliver the force systems necessary to achieve predictable tooth movements. These new features include Optimized Retraction Attachments, designed to work with SmartStage technology for effective bodily movement during canine retraction, with or without elastics, and new Optimized Anchorage Attachments, designed to work with SmartStage technology to maximize posterior anchorage.

SmartTrack™ Aligner Material. SmartTrack is a proprietary, 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 two weeks that a 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.

Scanner Segment

Intra-oral 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 using a handheld intra-oral scanner inside the mouth, intra-oral scanning is more efficient and precise and more comfortable for patients, compared to the mess, discomfort and subjective nature of taking physical impressions. The digital model created with an intra-oral scanner 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 3D 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; Invisalign digital impression submission; digital records storage; orthodontic diagnosis; and orthodontic retainers and appliances.

iTero Scanner. The iTero scanner is available as a single hardware platform with software options for restorative or orthodontic procedures. The iTero scanner includes our innovative powderless technology and features a modern design, scanning wand and easy-to-use keyboard design with full color model rendering, enabling clinicians to show patients a life-like final model of their scanned dentition. We market and sell the iTero in North America and in select international markets.

The iTero scanner is interoperable with our Invisalign treatment such that a full arch digital scan can be submitted for the Invisalign case submission process treatment. In January 2014, we announced that we qualified the 3M™ True Definition scanner for use with Invisalign case submissions. This qualification enables Invisalign providers with a True Definition scanner to submit a digital impression in place of a traditional PVS impression as part of the Invisalign case submission process. In March 2015, we announced that the Sirona CEREC Omnicam with the new CEREC Ortho software 1.1 was qualified for use with Invisalign case submissions. The new CEREC Omnicam scanner was available in select markets in the summer of 2015. The 3M True Definition scanner and Sirona CEREC Omnicam scanner are the only third-party scanners that have been qualified for use with Invisalign treatment. We support an open systems approach to digital impressions and continue to work with intraoral scanning companies interested in developing interoperability for use with Invisalign treatment.

In March 2015, we announced our next generation iTero Element Intraoral Scanner which features a more compact footprint, enhanced wand and multi-touch display and is engineered to enable faster scan speeds for more efficient, real-time clinical evaluation. We began shipping the iTero Element Intraoral Scanner in September 2015 and expect to ramp up our production over the next few quarters accordingly.

Restorative software for iTero. Software designed for GPs, prosthodontists, periodontists, and oral surgeons which includes features for restorative procedures commonly performed in their practices such as veneers, inlays, onlays, crowns, bridges and implants. The iTero restorative software provides the ability to scan quadrants and full arches, and allows simple powder-free capture of digital impressions for single-unit cases as well as more complex restorative and implant treatment plans. The iTero software also contains Invisalign interoperability to support clear aligner orthodontic treatment.

In the past year, we have expanded the digital workflow options to include several partnerships which provide our customers with a broader spectrum of CAD/CAM options. Connectivity partnership announcements include:

- IOS Technologies Inc., a wholly owned subsidiary of Glidewell Laboratories, provides the option to mill same-day restorations in the office.
- DENTSPLY Implants featuring connectivity with ATLANTIS™ custom abutments.
- Zimmer Dental, Inc. with connectivity with Zimmer Zfx custom abutments for implants.

Orthodontic software for iTero. Software designed for orthodontists for digital records storage, orthodontic diagnosis, Invisalign digital impression submission, and for the fabrication of printed models and retainers. The iTero orthodontic software digitally captures the contours of the dentition and the gingival structures, providing an accurate, powder-free digital orthodontic scan in just minutes. This digital impression procedure ensures a more comfortable patient experience and produces a precise scan that can be seamlessly integrated with Invisalign treatment, OrthoCAD iCast, and OrthoCAD iRecord which allows a doctor to utilize sophisticated measurement and treatment planning tools.

CAD/CAM Services

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 provides a digital alternative to traditional stone cast models which allows for simplified storage and digital record retrieval. This simplified model without an ABO base is an economical option for record retention. iRecord is available exclusively from an iTero scan.

Chair Side Applications

Invisalign Outcome Simulator. The Invisalign Outcome Simulator is an interactive application that provides GPs and orthodontists an enhanced platform for patient education and is designed to increase treatment acceptance by helping patients visualize the benefits possible with Invisalign treatment. As the only Invisalign chair-side intra-oral scanning application on the market, the Invisalign Outcome Simulator's unique dual view layout shows a prospective patient an image of his/her own current

dentition next to his/her simulated final position of how their teeth may look after Invisalign treatment. Using a full arch Invisalign scan, the Invisalign Outcome Simulator takes a few minutes to run and may be viewed chair-side, on the scanner, or from a computer using MyAlignTech.com. Intuitive tools allow doctors to make real-time adjustments to individual teeth during consultations that increase patient education and the likelihood of patient acceptance.

Our iTero scanner includes orthodontic software, restorative software, or both, and the Invisalign Outcome Simulator. The orthodontic or restorative software may also be purchased subsequently for an upgrade fee. The Invisalign Outcome Simulator is 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 enhanced feature solutions such as Invisalign G6 are included as part of the Invisalign System and are not sold separately nor do they contribute as individual items of revenue.

Business Strategy

Our goal is to establish Invisalign clear aligners as the standard method for treating malocclusion and to establish the iTero intra-oral scanner as the preferred scanning protocol 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: Market Expansion, Doctor Preference, and Brand Strength.

1. Market Expansion. We expect to continue to grow and expand our business by investing in resources, infrastructure, and initiatives that will drive growth from both a geographic and market segment standpoint. From a geographic standpoint, we focus our efforts on expanding our sales territory coverage in all of our direct sales geographies, with particular emphasis in our highest growth areas such as Europe and the Asia Pacific region. We strive to make sure that our new geographies and our expanded territories internationally have everything they need from the products, to the support, to the people, in order to successfully establish Invisalign as the treatment of choice for orthodontics in each geographic market. From a market segment standpoint, we are focused on two important markets: adults and teenagers. We believe expansion in these two markets can be achieved through product innovations that can expand the types of indications our Invisalign products can treat, as well as by expanding the overall market for orthodontics, primarily with adults who would not otherwise seek treatment with traditional wires and brackets. We believe continued market expansion can be achieved by having the right products, services, and communications worldwide to give our doctors the confidence they need to treat with Invisalign more often and attract potential patients to their practice so they ask for Invisalign by name.

In parallel with these investments, we also engage in professional marketing, clinical support and education initiatives that support doctor practice development and facilitate the continued growth of their practices.

In our iTero scanner business, we leverage our combined sales and marketing resources to facilitate the adoption and penetration of each product into our doctors' practices. Many of our customers recognize that having an iTero scanner at chair-side improves practice effectiveness for Invisalign as evidenced by higher Invisalign utilization rates among customers with an iTero scanner.

2. Doctor Preference. We want all of our doctors to have the confidence and motivation to lead with Invisalign for every patient that walks into their practice. We strive to achieve this by investing in two areas. First, continuing to improve product predictability and applicability for more complex cases thereby expanding the types of malocclusion that our Invisalign products can treat. As an example, we launched Invisalign G5 in February 2014, which represented our first set of features engineered specifically to treat deep bite malocclusion. We estimate that deep bite manifests itself in approximately 30% to 40% of the orthodontic cases treated worldwide depending on geography. In 2015, we did a phased launch of Invisalign G6 clinical innovations for first premolar extractions. The

nature of malocclusion that requires first premolar tooth extraction is an orthodontic problem that affects more than 50% of people in Asia, 20% in Europe and 12% in North America. Secondly, enhancing the customer's experience by making it easier to treat with and integrate Invisalign into their practices. As an example, we launched ClinCheck Pro in February 2014, the next generation Invisalign treatment software tool, designed to simplify the treatment process and help our doctors achieve their treatment goals.

3. Brand Strength. Our goal is to make Invisalign a highly recognized name brand worldwide by creating awareness for Invisalign treatment among consumers and motiving potential patients to seek treatment from an Invisalign provider. In support of this objective, we invest in initiatives designed to strengthen our global brand name recognition and drive

consumer purchase intent. We accomplish this objective through an integrated consumer marketing strategy that includes television, media, social networking and event marketing.

Manufacturing and Suppliers

Our manufacturing facilities are located in Juarez, Mexico, where we conduct our aligner fabrication, distribute and repair our scanners, perform our CAD/CAM services, and in Or Yehuda, Israel where we produce our handheld intra-oral scanner wand. The final assembly of our iTero scanner is performed by a third party manufacturer located in Israel. Our Invisalign digital treatment planning and interpretation for iTero restorative cases are conducted primarily at our facility located in San Jose, Costa Rica. 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 Costa Rica. 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 intra-oral 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 intra-oral 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 and certain Asia Pacific country markets, we have direct sales and support organizations, which includes quota carrying sales representatives, sales management, and sales administration.

Currently, we have several distribution partners that sell the Invisalign System in smaller non-core country markets in the EMEA, Asia Pacific and Latin America regions. We evaluate adding distribution partners in other non-core country markets on a case-by-case basis or assess modifying our current distribution agreements, as our international business grows. We continued to expand in our existing markets through targeted investments in sales coverage, professional marketing and education programs, along with consumer marketing in selected country markets.

For the iTero scanner, we have a small team of direct sales representatives in North America. Our intra-oral scanner sales team leverages 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 look to grow the scanner business over time.

We provide training, marketing and clinical support to orthodontists and GPs. In 2015, we had approximately 48,170 active Invisalign providers.

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 intra-oral scanning platform as the preferred scanning protocol for 3D digital scans. Our research and development expenses were $61.2 million, $52.8 million, and $44.1 million for the year ended December 31, 2015, 2014 and 2013, respectively.

Our research and development activities are directed toward developing the technology innovations that we believe will deliver our next generation of products and platforms. Our research and development 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, 2015, we had issued 384 U.S. patents, 276 foreign issued patents, and 236 pending global patent applications.

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 related to our two operating segments, customer channels and the geographic locations that we serve. For example, European sales of Invisalign treatment are often weaker in the summer months due to our customers and their patients being on holiday. 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

Due to the individualized nature of an Invisalign treatment which is prescribed by a doctor, no two cases are alike, thus we maintain relatively low levels of backlog. 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 sales. 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 intra-oral scanner backlog as orders where payment is reasonably assured and credit and financing is approved but the scanner has not yet shipped. Our intra-oral scanner backlog as of December 31, 2015 was not material.

Competition

We operate in a highly competitive market and we encounter a wide variety of competitors, including larger companies or divisions of larger companies with substantial sales, marketing, research and financial capabilities. We also face competition from early stage companies. Although the number of competitors varies by segment, currently our products compete directly

against products manufactured and distributed by various companies, both within and outside the U.S., including Danaher Corporation, 3M, Sirona Dental Systems, Inc., Dentsply International, Inc. and other private competitors. In addition, the expiration of certain key patents commencing in 2017 owned by us may result in additional competition. 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 United States. 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 the Company's products are classified as medical devices under the United States Food, Drug, and Cosmetic Act (the "FDCA"). The FDCA requires these products, when sold in the United States, to be safe and effective for their intended use and to comply with the regulations administered by the United States Food and Drug Administration ("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, our products are subject to the medical devices laws of the various member states, which are based on a Directive of the European Commission. 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 federally 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. For example, the U.S. Federal Physician Payment Sunshine Act went into effect in 2014 which requires public transparency of transfers of value to physicians.

In addition, we must comply with numerous data protection requirements that span from individual state and national laws in the US 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. The EU is currently considering a proposal to enact legislation governing data protection which would transform the current mix of European countries' laws to one overarching multinational law. Meanwhile, the Asia Pacific region has also seen rapid development of privacy laws, including in 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, 2015, we had approximately 4,375 employees, including 2,805 in manufacturing and operations, 950 in sales and marketing which includes customer care, 310 in research and development and 310 in general and administrative functions.

Available Information

Our website is located at www.aligntech.com, and our investor relations website is located at 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, a copy of this Annual Report on Form 10-K is located at the SEC's Public Reference Room at 100 F Street, NE, Washington, D.C. 20549. Information on the operation of the Public Reference Room can be obtained by calling the SEC at 1-800-SEC-0330. The SEC maintains an internet site that contains reports, proxy and information statements and other information regarding our filings at www.sec.gov.

Executive Officers of the Registrant
The following table sets forth certain information regarding our executive officers as of February 25, 2016:

Name	Age	Position
Joseph M. Hogan	58	President and Chief Executive Officer
David L. White	60	Chief Financial Officer
Simon Beard	49	Vice President and Managing Director, EMEA
Jennifer M. Erfurth	46	Vice President, Global Human Resources
Roger E. George	50	Vice President, Corporate and Legal Affairs and General Counsel
Timothy A. Mack	57	Vice President, Business Development
Raphael Pascaud	44	Chief Marketing Portfolio and Business Development Officer
Christopher C. Puco	55	Vice President, North America
Zelko Relic	51	Vice President, Research & Development
Julie Tay	49	Vice President and Managing Director, Asia Pacific
Emory M. Wright	46	Vice President, 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.

David L. White has served as our Chief Financial Officer ("CFO") since August 2013. Prior to joining us, Mr. White was CFO of Enecsys, Ltd., a privately-held supplier of solar micro inverters and monitoring systems from June 2012. Prior to Enecsys, he was Executive Vice President and CFO at NVIDIA Corporation, a fabless semiconductor company known for its development of advanced graphics and high performance computing processors from February 2009 to June 2011. Prior to NVIDIA, he was Executive Vice President of Finance and CFO at SANMINA-SCI Corporation, which provides contract design, supply chain, and manufacturing services from 2004 to 2009. He also served as CFO at Asyst Technologies Corporation, CEO at Candescent Technologies Corporation, and Senior Vice President of Finance at Connor Peripherals.

Simon Beard has served as our Vice President and Managing Director, EMEA since November 2014. Prior to joining us, from December 2012 to October 2014, Mr. Beard was Regional Director for the South East Asia business of Smith & Nephew, a multinational medical equipment manufacturing company. From October 2006 to November 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.

Jennifer M. Erfurth has served as our Vice President, Global Human Resources since October 2012. Prior to joining us, Ms. Erfurth was Senior Vice President of Shared Services at Dyno Nobel, Inc., a manufacturer and supplier of industrial explosives, from July 2011 to July 2012, and was Vice President, Human Resources for Federal Signal Corporation prior to that. From 2001 to 2010, Ms. Erfurth held positions of increasing responsibility at Schawk, Inc., most recently as Global Senior Vice President of Human Resources, a position she held from 2007 until her departure in 2010. Earlier in her career, she served as Director of Human Resources at CINTAS Corporation and World Color.

Roger E. George has served as our Vice President, Corporate and Legal Affairs and General Counsel since July 2002. 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.

Timothy A. Mack has served as our Vice President, Marketing and Business Development since May 2012. He served as Vice President, Business Development since our acquisition of Cadent Holdings, Inc. in April 2011. At Cadent, he was President and Chief Executive Officer since 2009. He joined Cadent in 2005, as Executive Vice President & General Manager where he led the introduction and adoption of Cadent's new 3D digital imaging technology into the market. Prior to Cadent, Mr. Mack was Vice President and General Manager of DENTSPLY Ceramco, a wholly-owned subsidiary of DENTSPLY International. Prior to

DENTSPLY, Mr. Mack held a series of management positions in the U.S. and Europe within Consumer Electronics and Medical Imaging Divisions at Eastman Kodak Company. Mr. Mack will be retiring in March 2016.

Raphael Pascaud was promoted to Chief Marketing Portfolio and Business Development Officer in July 2015. He joined Align in 2010 as Vice President and Managing Director for the Europe, Middle East and Africa Region, ("EMEA") and was promoted in January 2014 to Vice President, International. Prior to Align, Mr. Pascaud spent 14 years in various management positions within DePuy, a Johnson & Johnson family of companies, including Vice President Orthopedics of EMEA and Vice President Marketing of International.

Christopher C. Puco has served as our Vice President, North America since December 2012. He joined Align in 2006 as a sales director and in 2008 became senior director for the Eastern sales area. Most recently, as Vice President of Sales Strategy, he led Align's go-to-market strategy and managed the integration of the North American scanner and CAD/CAM services sales organization. Mr. Puco has more than 20 years of experience in the medical device industry, holding sales management positions in both starts-ups and established corporate environments. Prior to Align, he was with United States Surgical Corporation, General Surgical Innovations, Baxter BioSurgery and Fusion Medical Technologies.

Zelko Relic was appointed Vice President, Research & Development in December 2013. Prior to joining Align, 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, manufacturer of metrology tools from 1994 to 2000.

Julie Tay was appointed Vice President and Managing Director, Asia Pacific in March 2013. 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. He has been with us since March 2000, predominantly in manufacturing and operations roles. Previously, Mr. Wright served as Vice President, Manufacturing and, was General Manager of New Product Development. Prior to joining us, Mr. Wright was Senior Manufacturing Manager at Metrika, Inc. a medical device manufacturer, from May 1999 to March 2000. From July 1994 to May 1999, 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 Invisalign Full and Invisalign Teen, 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, our operating results would be harmed.

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 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 intra-oral 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.

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 introduce any price reductions or consumer rebate programs; if we expand our discount programs in the future or participation in these programs increases; if our product mix shifts to lower priced products or 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. In July 2015, we launched a new product policy called "Additional Aligners at No Charge" that addresses one of our customer's top complaints. With this product policy change, we no longer distinguish between mid-course correction and case refinements and allow doctors to order additional aligners to address either treatment need at no charge, subject to certain requirements. Based on this new product policy, beginning in the third quarter of 2015, we deferred more revenue as a result of providing free additional aligners for eligible treatments. Additionally, as we grandfathered over 1 million open cases, we will recognize lower revenues as additional aligners are shipped for at least the next two years until these cases complete.

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, beginning in September 2015, we began entering into currency hedging 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 at our existing 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. In addition, in order to meet the demands from expected volumes, we purchased a second manufacturing facility in Juarez, Mexico. We began manufacturing aligners in this second facility in September 2015 while continuing to manufacture Aligners at our existing facility in Juarez. Our ability to plan, construct and equip additional manufacturing facilities is subject to significant risk and uncertainty, including risks inherent in the establishment of a new manufacturing 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. If the transition into this additional facility 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 manufacturing 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. 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.

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 in the past not been and may in the future not be able to sustain our historical growth rates. If we do not increase profitability or 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 the level of activity in our customers' practices from quarter to quarter;
- weakness in consumer spending as a result of the slowdown in the U.S. economy and global economies;
- changes in relationships with our distributors;
- 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 revenue can be recognized;
- fluctuations in currency exchange rates against the U.S. dollar;
- changes in product mix;
- 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 intra-oral scanners;
- timing of industry tradeshows;
- changes in the timing of when revenue is recognized, including as a result of the introduction of new products 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;
- the development and marketing of directly competitive products by existing and new competitors;
- 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;
- the timing of new product introductions by us and our competitors, as well as customer order deferrals in anticipation of enhancements or new products;

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- 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; 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.

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

Our future success may depend on our ability to develop, manufacture, market, and obtain regulatory approval or clearance of new products. 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 future products 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 and technological innovations;
- differentiate our offerings from our competitors' offerings;
- 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 produce 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 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.

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 operating profits could materially decline. In a rising fuel cost environment, our freight costs will increase. 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.

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. At our facility in San Jose, Costa Rica, technicians use a sophisticated, internally developed computer-modeling program to prepare digital treatment plans, which are then transmitted electronically to Juarez, Mexico. These digital files form the basis of the ClinCheck treatment plan and are used to manufacture aligner molds. Our order acquisition, aligner fabrication and shipping operations are conducted in Juarez, Mexico. In addition to the research and development efforts conducted in our North America facilities, we also carry out research and development at locations in Moscow, Russia. In addition, our customer-care, accounts receivable, credit and collections and customer event registration organizations are located at our facility in San Jose, Costa Rica. We also have operations in Israel where the design and wand assembly and our intra-oral scanner are 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 located in Russia and Israel;
- fluctuations in currency exchange rates;
- increased income taxes, and other restrictions and limitations, if we were to decide to repatriate any of our foreign cash balances back to the U.S.;
- import and export license requirements and restrictions;
- controlling production volume and quality of the manufacturing process;
- political, social and economic instability, including as a result of 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;
- geopolitical risks around the Ukraine and the possibility of additional sanctions against Russia which continue to bring uncertainty to this region;
- interruptions and limitations in telecommunication services;
-

product or material transportation delays or disruption, including as a result of 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;

- trade restrictions and changes in tariffs; 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. As a result of these sales operations, we face a variety of risks, 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 UK Bribery Act of 2010 and export control laws, in spite of our policies and procedures designed to ensure compliance with these laws;
- although it is our intention to indefinitely reinvest earnings outside the U.S., restrictions on the transfer of funds held by our foreign subsidiaries, including with respect to restrictions on our ability to repatriate foreign cash to the U.S at favorable tax rates;
- fluctuations in currency exchange rates; and
- increased expense of developing, testing and making localized versions of our products.

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

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 timeframe 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 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 headquarters facility 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 in the process of implementing a multi-year, company-wide program to transform certain business processes or extend established processes, including the transition to a single enterprise resource planning ("ERP") software system to perform various functions. The implementation of additional functionality in the ERP system 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. During transitions we must continue to rely on legacy information systems, which may be costly or inefficient, while the implementation of new initiatives may not achieve the anticipated benefits and may divert management's attention from other operational activities, negatively affect employee morale, or have other unintended consequences. Additionally, if we are not able to accurately forecast expenses and capitalized costs related to the project, this may have an adverse impact on our financial condition and operating results.

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 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.

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 revenue 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.

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. 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.

Competition in the markets for our products is intense 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. Many of these manufacturers, including Danaher Corporation, 3M, Sirona Dental Systems, Inc. and Dentsply International, have substantially greater financial resources and manufacturing and marketing experience than we do and may, in

the future, attempt to develop an orthodontic system similar to ours or combine technologies that make our product economically unattractive. The expiration of certain key patents commencing in 2017 owned by us may result in additional competition. Large consumer product companies may also enter the orthodontic supply market. Furthermore, we may 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 you 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.

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 that our facilities and infrastructure are perceived by the marketplace and our customers to be secure. Despite the implementation of security measures, our infrastructure may be vulnerable to physical break-ins, computer viruses, programming errors, attacks by third parties or similar disruptive problems. If we fail to meet our clients' expectations regarding the security of healthcare information, we could be liable for damages and our reputation could be impaired. In addition, patient care could suffer, and we could be liable if our systems fail to deliver correct information in a timely manner. Our insurance may not protect us from this risk.

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, 2015, we had issued 384 U.S. patents, 276 foreign issued patents, and 236 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. 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 is subject to inherent uncertainties and unfavorable rulings could occur. 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, 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. 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. In addition, our ability to recognize revenue on the direct sales of our intra-oral scanners depends in part upon our ability to schedule and staff trainings. The loss of the services provided by these individuals or our ability to timely hire such personnel in sufficient numbers based on our volume growth, may harm our business. If we are unable to retain our trainers or replace such individuals with persons having equivalent technical expertise and qualifications, or if we are unable to successfully instill such technical expertise in newly hired personnel or accurately predict the number of such personnel needed, our net revenues 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.

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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 intra-oral 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 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 in the Czech Republic 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 intra-oral 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 North American 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. 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 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.

If our distributor relationships are not successful, our ability to market and sell our products would be harmed and our financial performance will be adversely affected.

We depend on relationships with distributors for the marketing and sales of our products in various geographic regions, and we have a limited ability to influence their efforts. Relying on distributors for our sales and marketing could harm our business for various reasons, including:

- agreements with distributors may terminate prematurely due to disagreements or may result in litigation between the partners;
- we may not be able to renew existing distributor agreements on acceptable terms;
- our distributors may not devote sufficient resources to the sale of products;
- our distributors may be unsuccessful in marketing our products;
- our existing relationships with distributors may preclude us from entering into additional future arrangements with other distributors; and
- we may not be able to negotiate future distributor agreements on acceptable terms.

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, the implementation of 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. In response to perceived increases in health care costs in recent years, Congress passed health care reform legislation that President Obama signed into law in March 2010. This legislation contains many provisions designed to generate the revenues necessary to fund the coverage expansions. The most relevant of these provisions are those that impose fees or taxes on certain health-related industries, including medical device manufacturers.

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.

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

Outside of North America, we currently sell our products in Europe, Asia Pacific, Latin America and the Middle East and may expand into other countries from time to time. For sales of our products outside the U.S., 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 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.

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 by us, our customers or competitors; 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.

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

Under Generally Accepted Accounting Principles in the United States ("U.S. GAAP"), we review our goodwill and 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.

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

We prepare our consolidated financial statements in conformity with U.S. GAAP. These principles are subject to interpretation by the SEC and various bodies formed to interpret and create appropriate accounting policies. A change in these policies 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.

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 a current unstable credit environment, we might incur significant realized, unrealized or impairment losses associated with these investments.

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, regulations and/or rates, 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 option deductions relating to incentive stock options and employee stock purchase plans, settlement of income tax audits, and changes in overall levels of pretax earnings.

In June 2009, the Costa Rica Ministry of Foreign Trade, an agency of the Government of Costa Rica, granted a twelve year extension of various income tax incentives, which were previously granted in 2002. The incentive tax rates will expire in various years beginning in 2017. Under these incentives, all of the income in Costa Rica during these twelve year incentive periods is subject to reduced rates of Costa Rica income tax. 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 2015, 2014 and 2013. As a result of these incentives, our income taxes were reduced by $32.7 million, $32.5 million, and

$27.7 million for the year ended December 31, 2015, 2014, and 2013, respectively, representing a benefit to diluted net income per share of $0.40, $0.40 and $0.34 in 2015, 2014 and 2013, respectively. Our subsidiary in Israel is under audit by the local tax authorities for calendar years 2006 through 2012. We are currently under audit by the California Franchise Tax Board for fiscal year 2011, 2012 and 2013.

ITEM 1B.UNRESOLVED STAFF COMMENTS
None.

ITEM 2.PROPERTIES
We occupy several leased and owned facilities with total office and manufacturing area of over 898,000 square feet. At December 31, 2015, the significant facilities were occupied as follows:

Location	Lease/Own	Primary Use	Segment	Expiration of lease
San Jose, California	Lease	Office for corporate headquarters, research & development and administrative personnel	Clear Aligner and Scanner	September 2017
San Jose, Costa Rica	Lease	Office for administrative personnel, manufacturing personnel, and customer care	Clear Aligner and Scanner	November 2017
Juarez, Mexico	Own	Manufacturing and office facilities for manufacturing and administrative personnel	Clear Aligner and Scanner	N/A
Or Yehuda, Israel	Lease	Manufacturing and office for manufacturing, administrative personnel, and research and development	Scanner	October 2017
Amsterdam, The Netherlands	Lease	Office for international headquarters, sales and marketing and administrative personnel	Clear Aligner	April 2017
Moscow, Russia	Lease	Office for research and development	Clear Aligner and Scanner	April 2017
Raleigh, North Carolina	Lease	Office for research & development and administrative personnel	Clear Aligner	August 2020

ITEM 3.LEGAL PROCEEDINGS

Securities Class Action Lawsuit

On November 28, 2012, plaintiff City of Dearborn Heights Act 345 Police & Fire Retirement System filed a lawsuit against Align, Thomas M. Prescott (“Mr. Prescott”), Align’s former President and Chief Executive Officer, and Kenneth B. Arola (“Mr. Arola”), Align’s former Vice President, Finance and Chief Financial Officer, in the United States District Court for the Northern District of California on behalf of a purported class of purchasers of our common stock (the “Securities Action”). On July 11, 2013, an amended complaint was filed, which named the same defendants, on behalf of a purported class of purchasers of our common stock between January 31, 2012 and October 17, 2012. The amended complaint alleged that Align, Mr. Prescott and Mr. Arola violated Section 10(b) of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder, and that Mr. Prescott and Mr. Arola violated Section 20(a) of the Securities Exchange Act of 1934. Specifically, the amended complaint alleged that during the purported class period defendants failed to take an appropriate goodwill impairment charge related to the April 29, 2011 acquisition of Cadent Holdings, Inc. in the fourth quarter of 2011, the first quarter of 2012 or the second quarter of 2012, which rendered our financial statements and projections of future earnings materially false and misleading and in violation of U.S. GAAP. The amended complaint sought monetary damages in an unspecified amount, costs and attorneys’ fees. On December 9, 2013, the court granted defendants’ motion to dismiss with leave for plaintiff to file a second amended complaint. Plaintiff filed a second amended complaint on January 8, 2014 on behalf of the same purported class. The second amended complaint states the same claims as the amended complaint. On August 22, 2014, the court granted our motion to dismiss without leave to amend. On September 22, 2014, Plaintiff filed a notice of appeal to the Ninth Circuit Court of Appeals. Align intends to vigorously defend itself against these allegations. Align is currently unable to predict the outcome of this amended complaint and therefore cannot determine the likelihood of loss nor estimate a range of possible loss, if any.

Shareholder Derivative Lawsuit

On February 1, 2013, plaintiff Gary Udis filed a shareholder derivative lawsuit against several of Align’s current and former officers and directors in the Superior Court of California, County of Santa Clara. The complaint alleges that our reported income and earnings were materially overstated because of a failure to timely write down goodwill related to the April 29, 2011 acquisition of Cadent Holdings, Inc., and that defendants made allegedly false statements

concerning our forecasts. The complaint asserts various state law causes of action, including claims of breach of fiduciary duty, unjust enrichment, and insider trading, among others. The complaint seeks unspecified damages on behalf of Align, which is named solely as nominal defendant against whom no recovery is sought. The complaint also seeks an order directing Align to reform and improve its corporate governance and internal procedures, and seeks restitution in an unspecified amount, costs, and attorneys' fees. On July 8, 2013, an Order was entered staying this derivative lawsuit until an initial ruling on our first motion to dismiss the Securities Action. On January 15, 2014, an Order was entered staying this derivative lawsuit until an initial ruling on our second motion to dismiss the Securities Action. On October 14, 2014, an Order was entered staying this derivative lawsuit until a ruling by the Ninth Circuit in the Securities Action discussed above. Align is currently unable to predict the outcome of this complaint and therefore cannot determine the likelihood of loss nor estimate a range of possible losses.

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.

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

Price Range of Common Stock

Our common stock is quoted on the NASDAQ Global Select Market under the symbol "ALGN." The following table sets forth the range of high and low per share sales prices as reported for each period indicated:

	High	Low
Year Ended December 31, 2015:		
Fourth quarter	$68.48	$54.69
Third quarter	$66.53	$52.01
Second quarter	$64.99	$51.65
First quarter	$64.75	$51.77
Year Ended December 31, 2014:		
Fourth quarter	$57.72	$43.27
Third quarter	$57.79	$51.29
Second quarter	$57.50	$47.22
First quarter	$65.10	$50.37

On February 19, 2016, the closing price of our common stock on the NASDAQ Global Market was $63.29 per share. As of February 19, 2016 there were approximately 101 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.

We have never declared or paid any cash dividends on our common stock. We currently intend to retain any future earnings to fund the development and growth of our business and do not anticipate paying any cash dividends in the foreseeable future.

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, 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, 2010 to December 31, 2015.

UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

Following is a summary of stock repurchases for the three months ended December 31, 2015:

Period	Total Number of Shares Repurchased	Average Price Paid per Share	Total Number of Shares Repurchased as Part of Publicly Announced Program [1]	Approximate Dollar Value of Shares that May Yet Be Repurchased Under the Program [1]
October 1, 2015 through October 31, 2015	103,000	$59.97	103,000	$104,989,100
November 1, 2015 through November 30, 2015	75,875	$66.04	75,875	$99,978,175
December 1, 2015 through December 31, 2015	—	$—	—	$99,978,175

[1] On April 23, 2014, we announced that our Board of Directors had authorized a stock repurchase program pursuant to which we may purchase up to $300.0 million of our common stock over three years, with $100.0 million of that amount authorized to be purchased during each twelve month period. Any purchases under this stock repurchase program may be made, from time-to-time, pursuant to open market purchases (including pursuant to Rule 10b5-1 plans), privately-negotiated transactions, accelerated stock repurchases, block trades or derivative contracts or otherwise in accordance with applicable federal securities laws, including Rule 10b-18 of the Securities Exchange Act of 1934.

As of December 31, 2015, we have approximately $100 million remaining under the April 2014 stock repurchase program. We expect to finance future stock repurchases with current cash on hand.

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, 2015. 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. We have derived the statement of operations data for the year ended December 31, 2015, 2014 and 2013 and the balance sheet data as of December 31, 2015 and 2014 from the consolidated audited financial statements included elsewhere in this Annual Report on Form 10-K. The statement of operations data for the year ended December 31, 2012 and 2011 and the balance sheet data as of December 31, 2013, 2012 and 2011 were derived from the consolidated audited financial statements that are not included in this Annual Report on Form 10-K.

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

	Year Ended December 31,				
	2015	2014	2013	2012	2011
Consolidated Statement of Operations Data:					
Net revenues [1]	$845,486	$761,653	$660,206	$560,041	$479,741
Gross profit [2]	$640,110	$578,443	$498,106	$416,388	$361,283
Income from operations [3]	188,634	193,576	94,212	85,592	90,360
Interest and other income (expense), net	(2,533)	(3,207)	(1,073)	(1,296)	(419)
Net income before provision for income taxes [3]	186,101	190,369	93,139	84,296	89,941
Provision for income taxes	42,081	44,537	28,844	25,605	23,225
Net income [3]	$144,020	$145,832	$64,295	$58,691	$66,716
Net income per share					
Basic	$1.80	$1.81	$0.80	$0.73	$0.86
Diluted	$1.77	$1.77	$0.78	$0.71	$0.83
Shares used in computing net income per share:					
Basic	79,998	80,754	80,551	80,529	77,988
Diluted	81,521	82,283	82,589	83,040	80,294

	December 31,				
	2015	2014	2013	2012	2011
Consolidated Balance Sheet Data:					
Working capital [4]	$460,338	$455,349	$369,338	$330,022	$236,699
Total assets	1,158,633	987,997	832,147	756,312	649,264
Total long-term liabilities	39,035	33,415	22,839	19,224	10,366
Stockholders' equity	$847,926	$752,771	$633,970	$581,317	$490,781

[1] Net revenues for the year ended December 31, 2011 include eight months of revenues from our Scanners segment of approximately $28.0 million as a result of our acquisition of Cadent Holdings, Inc. on April 29, 2011.

[2] Gross profit includes:

- $1.7 million out of period adjustment in 2013 (See Note 1 in the financial statements)
- $0.2 million acquisition and integration related costs, $0.9 million amortization of intangible assets, and $0.5 million of exit costs in 2012
- $0.4 million acquisition and integration related costs, $0.7 million amortization of intangible assets, and $0.8 million for exit costs in 2011

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[3] Income from operations, net income before provision for income taxes, and net income includes the following, net of taxes:

- $1.8 million out of period income tax adjustment in 2014 (see Note 1 in the financial statements)
- $40.7 million and $26.3 million of goodwill and long-lived asset impairment, respectively, in 2013
- $1.9 million, net of tax, out of period adjustment in 2013 (see Note 1 in the financial statements)
- $36.6 million of goodwill impairment, $1.3 million acquisition and integration related costs, $4.5 million of amortization of intangible assets, and $0.8 million of exit costs in 2012
- $10.0 million acquisition and integration related costs, $3.2 million of amortization of intangible assets, and exit costs of $1.1 million in 2011

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

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 our Annual Report on Form 10-K.

The successful execution of our business strategy and our results in 2015 and beyond may be affected by a number of other factors including:

- Additional Aligners at No Charge. In July 2015, we launched a new product policy called "Additional Aligners at No Charge" that addresses one of our customers' top complaints. Previously, we charged customers for additional aligners ordered beyond those covered by the initial treatment plan. With this product policy change, we no longer distinguish between mid-course corrections and case refinements and allow doctors to order additional aligners to address either treatment need at no charge, subject to certain requirements. These changes were effective for all new Invisalign Full, Teen, and Assist treatments shipped worldwide after July 18, 2015 as well as any open Invisalign Full, Teen and Assist cases as of that date.

Based on this new product policy, beginning in the third quarter of 2015, we deferred more revenue as a result of providing free additional aligners for eligible treatments. Additionally, since we grandfathered over 1 million open cases, we will recognize lower revenues as additional aligners are shipped. We expect lower amounts of revenue to be recognized for at least the next two years until these cases complete. In the fourth quarter of 2015, the new product policy decreased Clear Aligner net revenues by approximately $7.0 million and reduced operating margin by 2.2% and diluted earnings per share by $0.07 per share. We expect a decrease in Clear Aligner net revenues by approximately $7.0 million to $8.0 million in the first quarter of 2016, and by approximately $25.0 million to $30.0 million in fiscal year 2016. While this product policy change will impact the timing of our revenue recognition, we believe this policy change will result in a significant improvement in customer satisfaction and loyalty, and ultimately increase Invisalign utilization and volume over time.

- New Products, Feature Enhancements and Technology Innovation. Product innovation drives greater treatment predictability and clinical applicability, and ease of use for our customers, which supports adoption of Invisalign in their practices. Increasing applicability and treating more complex cases requires that we move away from individual features to more comprehensive solutions so that Invisalign providers can more predictably treat the whole case, such as with Invisalign G5 for deep bite treatment, Invisalign G6 for premolar extraction and ClinCheck Pro, the next generation Invisalign treatment software tool, designed to provide more precise control over final tooth position and to help Invisalign providers achieve their treatment goals. In addition, we began shipping the next generation iTero Element Intraoral Scanner in September 2015 and expect to ramp up our production over the next few quarters accordingly; however, if we are unable to scale production of our iTero Element scanner to meet customer demand, our financial results may be negatively impacted. 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.
- 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 quarterly utilization rates for the previous 9 quarters are as follows:

* Invisalign Utilization rates = # of cases shipped divided by # of doctors cases were shipped to

Total utilization in the fourth quarter of 2015 increased to 4.9 cases per doctor compared to 4.4 in the fourth quarter of 2014. Utilization among our North American orthodontist customers reached an all time high of 9.9 cases per doctor in the fourth quarter of 2015 compared to 8.6 in the fourth quarter of 2014. International doctor utilization increased to 5.0 cases in the fourth quarter of 2015 from 4.5 in the fourth quarter of 2014. North American GP doctor utilization increased to 3.1 cases in the fourth quarter of 2015 from 2.9 in the fourth quarter of 2014. The increase in North America orthodontist utilization reflects improvements in product and technology, which continues to strengthen our doctors' clinical confidence in the use of Invisalign such that they now utilize Invisalign more often and on more complex cases, including their teenage patients. Increased International utilization reflects growth in both the EMEA and Asia Pacific regions driven by go-to-market and sales coverage investments, improving clinical education and support as well as ongoing technology innovation. 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, however, we expect that our utilization rates 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 2015, Invisalign growth was driven primarily by increased utilization across all regions as well as by the continued expansion of our customer base as we trained a total of 9,795 new Invisalign doctors, of which 56% were trained internationally.

- International Clear Aligner Growth. We will continue to focus our efforts towards increasing adoption of our products by dental professionals in our direct international markets. International volume for 2015 increased 32.5% driven primarily by strong performance in the Asia Pacific region as well as growth in Europe. In 2016, 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 selected country markets. We expect international revenues to continue to grow at a faster rate than North America for the foreseeable future due to our continued investment in international market expansion, the size of the market opportunity, and our relatively low market penetration in this region. As our international revenues have increased from $219.7 million in 2014 to $250.1 million in 2015, we are increasingly subject to fluctuations in foreign currency exchange rates relative to the U.S. dollar. Although we have historically accepted the exposure to exchange rate movements without using derivative financial instruments to manage risk, in the third quarter of 2015 we initiated a foreign currency economic hedging program to mitigate

the foreign currency risk in countries where we have significant monetary assets and liabilities denominated in currencies other than the functional currency. The impact from these forward contracts was not material to our financial statements for the year ended December 31, 2015.

In addition, as we plan for further international expansion over the next several years, we must provide better support to our customers in these regions and be geographically closer to their practices. Accordingly, we intend to make further investments in our manufacturing over the next few years to enhance our regional capabilities.

- Establish Regional Order Acquisition and Treatment Planning facilities: We intend to establish additional Order Acquisition and Treatment Planning facilities closer to our International customers in order to improve our operational efficiency and provide doctors with a great experience to further improve their confidence in using Invisalign to treat more patients, more often. If demand for our product in 2016 exceeds our current expectations, or if the timing of receipt of case product orders during a given quarter is different from our expectations, we may not be able to fulfill orders in a timely manner, which may negatively impact our financial results and overall business. Conversely, if demand decreases or if we fail to forecast demand accurately, we could be required to record excess capacity charges, which would lower our gross margin.
- Operating Expenses. We expect operating expenses to increase in 2016 compared to 2015 due in part to:
  - investments in international expansion in new country markets such as India and Korea;
  - the increase in sales and customer support resources; and
  - product and technology innovation to address such things as treatment times, indications unique to teens, and predictability.

We believe that these investments will position us to increase our revenue and continue to grow our market share.

Results of Operations

Net revenues by Reportable Segment Comparison for Year Ended December 31, 2015, 2014 and 2013:

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

- Our Clear Aligner segment consists of our Invisalign system which includes Invisalign Full, Teen and Assist ("Full Products"), Express/Lite ("Express Products"),Vivera retainers, along with our training and ancillary products for treating malocclusion.
- Our Scanner segment consists of intra-oral scanning systems and additional services available with the intra-oral scanners that provide digital alternatives to the traditional cast models. This segment includes our iTero scanner and OrthoCAD services.

Net revenues for our Clear Aligner segment by region and our Scanner segment for the year ended December 31, 2015, 2014 and 2013 is as follows (in millions):

	Year Ended December 31, 2015	December 31, 2014	Change		Year Ended December 31, 2014	December 31, 2013	Change	
Clear Aligner Revenues:								
North America	$498.7	$446.6	$52.1	11.7 %	$446.6	$408.2	$38.4	9.4 %
International	250.1	219.7	30.4	13.8 %	219.7	161.7	58.0	35.9 %
Invisalign non-case net revenues	51.4	46.2	5.2	11.3 %	46.2	44.7	1.5	3.4 %
Total Clear Aligner net revenues	$800.2	$712.5	$87.7	12.3 %	$712.5	$614.6	$97.9	15.9 %
Total Scanner net revenues	$45.3	$49.1	$(3.8)	(7.7)%	$49.1	$45.6	$3.5	7.7 %
Total net revenues	$845.5	$761.6	$83.9	11.0 %	$761.6	$660.2	$101.4	15.4 %

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 Invisalign case shipments by region, for the year ended December 31, 2015, 2014 and 2013 is as follows (in millions):

Region	Year Ended December 31, 2015	December 31, 2014	Change			Year Ended December 31, 2014	December 31, 2013	Change		
North American Invisalign	398.4	338.5	59.9	17.7	%	338.5	313.9	24.6	7.8	%
International Invisalign	184.8	139.5	45.3	32.5	%	139.5	108.5	31.0	28.6	%
Total Invisalign case volume	583.2	478.0	105.2	22.0	%	478.0	422.4	55.6	13.2	%

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

Fiscal Year 2015 compared to Fiscal Year 2014

Total net revenues increased by $83.9 million in 2015 as compared to 2014 primarily as a result of Invisalign case volume growth across all regions and products as well as increased Invisalign non-case revenue.

Clear Aligner - North America

Clear Aligner North America net revenues increased by $52.1 million in 2015 compared to 2014 primarily due to Invisalign case volume growth of approximately $79.0 million across all channels and products. These increases were offset in part by lower average selling prices ("ASP"), which decreased net revenues by $26.9 million. The decrease in ASP was primarily as a result of higher net revenue deferrals of $16.0 million, which includes the impact of our new additional aligner product policy launched in July 2015 of $8.9 million and the impact of higher promotional discounts in 2015 as compared to 2014 of $11.7 million. These decreases in ASP were offset in part by the price increase on our Full Products, effective April 1, 2015.

Clear Aligner - International

Clear Aligner international net revenues increased by $30.4 million in 2015 compared to 2014 primarily driven by Invisalign case volume growth of $71.5 million across all products. This was partially offset by lower ASP which decreased net revenues by approximately $41.1 million. The decrease in ASP was primarily as a result of the unfavorable impact from foreign exchange rates primarily due to the weakening of the Euro compared to the U.S. dollar in 2015 compared to 2014 of $34.5 million, and to a lesser extent higher net revenue deferrals of $7.8 million which includes the impact of our new additional aligner product policy launched in July 2015 of $4.7 million, as well as higher promotional discounts of $6.3 million in 2015 compared to 2014. These decreases were partially offset by an increase in ASP as we transitioned to direct sales in certain Asia Pacific countries and Europe, Middle East and Africa regions, as well as the price increase on our Full Products effective July 1, 2015.

Clear Aligner - Invisalign Non-Case

Invisalign non-case net revenues, consisting of training fees and ancillary product revenues, increased by $5.2 million in 2015 as compared to 2014 primarily due to increased Vivera volume both in North America and International.

Scanner

Scanner net revenues decreased by $3.8 million in 2015 compared to 2014 primarily due to a decrease in scanner revenue, offset in part by a slight increase in services revenue. In March 2015, we announced our next generation scanner which began shipping in September 2015. Net revenues declined in 2015 primarily due to fewer scanners recognized and permanent price reductions on our previous generation scanner. The increase in services revenue was primarily due to an increase in the volume of CAD/CAM services resulting from a larger installed base of scanners.
Fiscal Year 2014 compared to Fiscal Year 2013

Total net revenues increased by $101.4 million in 2014 as compared to 2013 primarily as a result of Invisalign case volume growth across all regions and products as well as increased Invisalign non-case revenue.

Clear Aligner - North America

Clear Aligner North America net revenues increased by $38.4 million in 2014 compared to 2013 primarily due to Invisalign case volume growth of approximately $32.1 million across all channels and products, and, to a lesser extent, higher ASP which contributed approximately $6.3 million to the increase in net revenues. The increase in ASP was primarily a result of increased mid-course correction revenue from higher usage as well as a product mix shift towards higher priced Invisalign products in 2014 compared to 2013. This increase was offset in part by higher promotional discounts in 2014 as compared to 2013.

Clear Aligner - International

Clear Aligner international net revenues increased by $58.0 million in 2014 compared to 2013 primarily driven by Invisalign case volume growth of $46.2 million along with higher ASP which contributed approximately $11.8 million to the increase in net revenues. The increase in ASP was primarily due to the impact from acquiring our distributor in the Asia Pacific region on April 30, 2013 when we began recognizing direct sales of Invisalign products sold in that region at our full ASP rather than the discounted ASP under the distributor agreement, as well as the price increases which were effective July 2013 along with a favorable impact from foreign exchange rates. Foreign exchange rates had a favorable impact on revenues in 2014 as compared to 2013, despite the weakening of the Euro to the U.S. dollar in the last six months of 2014.

Clear Aligner - Invisalign Non-Case

Invisalign non-case net revenues, consisting of training fees and ancillary product revenues, increased by $1.5 million in 2014 as compared to 2013 primarily due to the consolidation of our Vivera product shipments in North America from four shipments per year to one shipment along with increased Vivera volume both in North America and international.

Scanner

Scanner net revenues increased by 7.7%, in 2014 compared to 2013 due to an increase in both services revenue as well as scanner revenue.

The increase in services revenue was primarily due to an increase in the volume of CAD/CAM services resulting from a larger installed base of scanners. The increase in scanner revenue was primarily due to an increase in the number of scanners recognized offset in part by lower scanner ASP as a result of promotional discounts as well as permanent price reductions. The increase was partially offset as 2013 had higher net revenues due to the release of $1.4 million of revenue previously reserved for the iTero upgrade program which was completed in the first quarter of 2013.

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

	Year Ended December 31, 2015		December 31, 2014		Change	Year Ended December 31, 2014		December 31, 2013		Change
Clear Aligner										
Cost of net revenues	$172.0		$149.7		$22.3	$149.7		$129.8		$19.9
% of net segment revenues	21.5	%	21.0	%		21.0	%	21.1	%	

Gross profit	$628.2		$562.9		$65.3		$562.9		$484.8		$78.1
Gross margin %	78.5	%	79.0	%			79.0	%	78.9	%	
Scanner											
Cost of net revenues	$33.4		$33.6		$(0.2	)	$33.6		$32.3		$1.3
% of net segment revenues	73.7	%	68.3	%			68.3	%	70.9	%	
Gross profit	$11.9		$15.6		$(3.7	)	$15.6		$13.3		$2.3
Gross margin %	26.3	%	31.7	%			31.7	%	29.1	%	
Total cost of net revenues	$205.4		$183.2		$22.2		$183.2		$162.1		$21.1
% of net revenues	24.3	%	24.1	%			24.1	%	24.6	%	
Gross profit	$640.1		$578.4		$61.7		$578.4		$498.1		$80.3
Gross margin %	75.7	%	75.9	%			75.9	%	75.4	%	

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 salaries for staff involved in the production process, the cost of materials, packaging, shipping costs, depreciation on capital equipment used in the production process, amortization of acquired intangible assets from Cadent, training costs and stock-based compensation.

Fiscal Year 2015 compared to Fiscal Year 2014

Clear Aligner

The gross margin percentage declined in 2015 compared to 2014 due to lower ASP which was partially offset by lower costs per unit.

Scanner

The gross margin percentage decreased in 2015 compared to 2014 due to lower ASP from permanent price reductions on our previous generation scanner and higher manufacturing costs from lower production volumes and higher inventory reserves. This was partially offset by a product mix shift to the lower cost Element scanner which commenced shipping in September.

Fiscal Year 2014 compared to Fiscal Year 2013

Clear Aligner

The gross margin percentage improved slightly in 2014 compared to 2013 due to higher ASP. The ASP improvement was mostly offset by increased manufacturing costs in 2014 when compared to 2013 which benefited from an out of period adjustment (see Note 1 in the financial statements).

Scanner

The gross margin percentage increased in 2014 compared to 2013 due to increased absorption of manufacturing spend from higher production volumes, lower product costs due to product mix and lower inventory reserves. These were partially offset by a lower ASP as a result of price reductions.

Selling, general and administrative (in millions):

	Year Ended December 31, 2015		December 31, 2014		Change	Year Ended December 31, 2014		December 31, 2013		Change
Selling, general and administrative	$390.2		$332.1		$58.1	$332.1		$292.8		$39.3
% of net revenues	46.2	%	43.6	%		43.6	%	44.3	%	

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, outside consulting services, legal expenses, depreciation and amortization expense, the medical device excise tax ("MDET") and allocations of

corporate overhead expenses including facilities and IT.

Selling, general and administrative expense increased in 2015 compared to 2014 primarily due to higher compensation related costs of $50.1 million as a result of increased headcount, which led to higher salaries, stock based compensation and commissions. In addition, consulting costs increased by $9.7 million primarily due to our enterprise resource planning ("ERP") project. Partially offsetting these increases was the MDET refund of $6.8 million received in the first quarter of 2015.

Selling, general and administrative expense increased in 2014 compared to 2013 primarily due to higher compensation costs of $24.1 million due to increased headcount, including the additional headcount from the acquisition of our APAC distributor and stock based compensation. In addition, we incurred higher advertising and marketing expenses as a result of increased advertising production and marketing campaigns combined with higher costs for trade shows and our Europe and APAC Summits as well as

increases in consulting expenses and credit card processing fees. These increases were offset by lower MDET of $6.8 million as our aligners were no longer subject to the excise tax in 2014 as well as lower outside litigation costs. In March 2014, the IRS informed us that our aligners are not subject to the MDET, which we had been paying and expensing in selling, general and administrative expense in the Consolidated Statements of Operations since January 1, 2013.

Research and development (in millions):

	Year Ended December 31, 2015		December 31, 2014		Change	Year Ended December 31, 2014		December 31, 2013		Change
Research and development	$61.2		$52.8		$8.4	$52.8		$44.1		$8.7
% of net revenues	7.2	%	6.9	%		6.9	%	6.7	%	

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 and outside consulting expenses associated with the research and development of new products and enhancements to existing products, corporate allocations, facility and facility related costs and stock-based compensation expense.

Research and development expense increased during 2015 compared to 2014 primarily as a result of our investment in obstructive sleep apnea which was terminated in the third quarter of 2015. While we continue to believe that the opportunities in the obstructive sleep apnea market are potentially interesting, we have decided to remain focused on our core business and organic growth opportunities.

Research and development expense increased during 2014 compared to 2013 almost entirely due to higher compensation costs as a result of higher bonuses, stock-based compensation and salaries primarily due to additional headcount.

Impairment of goodwill (in millions):

	Year Ended December 31, 2015		December 31, 2014		Change	Year Ended December 31, 2014		December 31, 2013		Change
Impairment of goodwill	$—		$—		$—	$—		$40.7		$(40.7)
% of net revenues	—	%	—	%		—	%	6.2	%	

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

There was no charge for impairment of goodwill recorded in the years ended December 31, 2015 or 2014.

During the first quarter of 2013, we determined that the goodwill for our Scanner reporting unit should be tested for impairment as a result of changes in the competitive environment for intra-oral scanners which caused us to lower our expectations for growth and profitability for our Scanner reporting unit. As a result of our analysis, we recorded a goodwill impairment charge of $40.7 million, none of which was deductible for tax purposes. Refer to Note 5 "Goodwill and Intangible Assets" of our consolidated financial statements for details of the impairment analysis.

Impairment of long-lived assets (in millions):

	Year Ended December 31, 2015	December 31, 2014	Change	Year Ended December 31, 2014	December 31, 2013	Change
Impairment of long-lived assets	$—	$—	$—	$—	$26.3	$(26.3)
% of net revenues	— %	— %		— %	4.0 %	

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

There was no charge for impairment of long-lived assets recorded in the year ended December 31, 2015 or 2014.

The impairment of our long-lived assets in 2013 was the result of changes in the competitive environment for intra-oral scanners which caused us to lower our expectations for growth and profitability for our Scanner reporting unit. As a result, we determined that the carrying value of the long-lived assets was not recoverable and therefore recorded an impairment charge of $26.3 million. Refer to Note 5 "Goodwill and Intangible Assets" of our consolidated financial statements for details of the impairment analysis.

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

	Year Ended December 31, 2015	December 31, 2014	Change	Year Ended December 31, 2014	December 31, 2013	Change
Interest and other income (expense), net	$(2.5)	$(3.2)	$0.7	$(3.2)	$(1.3)	$(1.9)

Interest and other income (expense), net, includes foreign currency translation gains and losses, interest income earned on cash, cash equivalents and investment balances and other miscellaneous charges.

Interest and Other income (expense), net, in 2015 increased mainly due to higher interest income on higher balances of cash, cash equivalents and investments offset in part by higher foreign exchange losses primarily due to the strengthening of the U.S. dollar to the Euro and Australian dollar.

Interest and Other income (expense), net, in 2014 decreased due to higher foreign exchange losses primarily as a result of the weakening of the Euro to the U.S. dollar offset slightly by increased interest income earned on higher balances of cash, cash equivalents and investments.

Provision for income taxes (in millions):

	Year Ended December 31, 2015	December 31, 2014	Change	Year Ended December 31, 2014	December 31, 2013	Change
Provision for income taxes	$42.1	$44.5	$(2.4)	$44.5	$28.8	$15.7
Effective tax rates	22.6%	23.4%		23.4%	31.0%	

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

Our provision for income taxes was $42.1 million, $44.5 million and $28.8 million for the year ended December 31, 2015, 2014 and 2013, respectively. This represents effective tax rates of 22.6%, 23.4% and 31.0%, respectively. Our effective tax rates in these fiscal years differ from the statutory federal income tax rate of 35% due to certain foreign earnings, primarily from Costa Rica, which are subject to a lower tax rate. The decrease in the effective rate for the year ended December 31, 2015 compared to 2014 is mainly due to an additional $1.8 million tax adjustment recorded in 2014 which related to prior periods. The effective tax rate for the year ended December 31, 2013 also reflects a non-deductible goodwill impairment charge of $40.7 million.

As of December 31, 2015, approximately $359.8 million of undistributed earnings from non-U.S. operations held by our foreign subsidiaries are designated as indefinitely reinvested outside the U.S. Accordingly, no additional U.S. income taxes or additional foreign withholding taxes have been provided thereon. We have sufficient cash reserves in the U.S. and do not intend to repatriate our foreign earnings. We intend to use the undistributed earnings for local operating expansions and to meet local operating working capital needs. If these earnings were distributed in the form of dividends or otherwise, or if the shares of the relevant foreign subsidiaries were sold or otherwise transferred, we would be subject to additional U.S. income taxes subject to an adjustment for foreign tax credits and foreign withholding taxes. Determination of the amount of unrecognized deferred tax liability related to these earnings is not practicable.

We assess the likelihood that we will be able to realize our deferred tax assets quarterly. 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 do not expect to 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, 2015 included historical operating profits, a projection of future income and other objectively verifiable evidence. As of December 31, 2015, we

believed, except for the items noted in the subsequent paragraph, that is was more likely than not that the amount of deferred tax assets recorded on the balance sheet will be realized.

As of December 31, 2015, we maintained a valuation allowance of $31.7 million against our deferred tax assets which primarily relate to Israel operating loss carryforwards and Australia capital loss carryforwards. These net operating and capital loss carryforwards would result in an income tax benefit if we were to conclude it is more likely than not that the related deferred tax assets will be realized. The valuation allowance decreased from December 31, 2014 by $0.8 million due to the decrease of foreign tax rate which resulted in lower tax impact on net operating and capital loss carryforwards. We are currently evaluating an internal restructuring which may result in a future reassessment of our need for a valuation allowance against these deferred tax assets. As a result it is possible that we may realize a tax benefit which may have a material impact on the financial statements within the next twelve months.

As of December 31, 2015, we have California net operating loss carryforwards of approximately $20.5 million, which, if not used, will begin to expire in 2016. In the event of a change in ownership, as defined under federal and state tax laws, our net operating loss and tax credit carryforwards may be subject to annual limitations. The annual limitations may result in the expiration of the net operating loss and tax credit carryforwards before utilization. As of December 31, 2015, we had California research credit carryforwards of approximately $3.9 million that can be carried forward indefinitely.

We account for uncertain tax positions 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. We first determine whether it is more likely than not that a tax position will be sustained upon audit based on its technical merits. If a tax position meets the more-likely-than-not recognition threshold it is then measured to determine the amount of benefit to recognize in the financial statements. The tax position is measured as the largest amount of benefit that is more than 50 percent likely to be realized upon ultimate settlement. We adjust 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 the final outcome of these matters is different than the amounts recorded, such differences will impact our tax provision in our Consolidated Statements of Operations in the period in which such determination is made.

Our total gross unrecognized tax benefits, excluding interest, was $39.4 million and $33.1 million as of December 31, 2015 and 2014, respectively, all of which would impact our effective tax rate if recognized. We have elected to recognize interest and penalties related to unrecognized tax benefits as a component of income taxes. The accrued interest as of December 31, 2015 was $0.7 million. We do not expect any significant changes to the amount of unrecognized tax benefit within the next twelve months.

In November 2015, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2015-17, Income Taxes (Topic 740), to simplify the presentation of deferred income taxes. Under the new standard, both deferred tax liabilities and assets are required to be classified as noncurrent in a classified balance sheet. ASU 2015-17 will become effective for fiscal years, and the interim periods within those years, beginning after December 15, 2016, with early adoption permitted. The new guidance has been adopted on a prospective basis by the Company for the year ended December 31, 2015, thus resulting in the reclassification of $30.1 million of current deferred tax assets to noncurrent on the accompanying Consolidated Balance Sheet. The prior reporting period was not retrospectively adjusted. The adoption of this guidance had no impact on our Consolidated Statements of Operations or Consolidated Statements of Comprehensive Income.

We file U.S. federal, U.S. state, and non-U.S. income tax returns. Our major tax jurisdictions are U.S. federal and the State of California. For U.S. federal and state tax returns, we are no longer subject to tax examinations for years before 2000. With few exceptions, we are no longer subject to examination by foreign tax authorities for years before 2007. Our subsidiary in Israel is under audit by the local tax authorities for calendar years 2006 through 2012. We are

currently under audit by the California Franchise Tax Board for fiscal year 2011, 2012 and 2013.

In June 2009, the Costa Rica Ministry of Foreign Trade, an agency of the Government of Costa Rica, granted a twelve year extension of certain income tax incentives, which were previously granted in 2002. The incentive tax rates will expire in various years beginning in 2017. Under these incentives, all of the income in Costa Rica during these twelve year incentive periods is subject to reduced rate of Costa Rica income tax. 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 2015, 2014 and 2013. As a result of these incentives, our income taxes were reduced by $32.7 million, $32.5 million and $27.7 million for the year ended December 31, 2015, 2014 and 2013, respectively, representing a benefit to diluted net income per share of $0.40, $0.40 and $0.34 in 2015, 2014 and 2013, respectively.

Liquidity and Capital Resources

We fund our operations from product sales. As of December 31, 2015 and 2014, we had the following cash and cash equivalents, and short-term and long-term investments (in thousands):

	Year Ended December 31,	
	2015	2014
Cash and cash equivalents	$167,714	$199,871
Short-term investments	359,581	254,787
Long-term investments	151,370	147,892
Total	$678,665	$602,550

Cash flows (in thousands):

	Year Ended December 31,		
	2015	2014	2013
Net cash flow provided by (used in):			
Operating activities	$237,997	$226,899	$185,976
Investing activities	(166,361)	(201,627)	(210,734)
Financing activities	(100,786)	(66,420)	(38,171)
Effects of exchange rate changes on cash and cash equivalents	(3,007)	(1,934)	(504)
Net decrease in cash and cash equivalents	$(32,157)	$(43,082)	$(63,433)

As of December 31, 2015, we had $678.7 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. dollar denominated foreign corporate bonds, U.S. government agency bonds, municipal bonds and asset-backed securities. Other uses of cash include our stock repurchase program, which is described below.

As of December 31, 2015, approximately $442.5 million of cash, cash equivalents and short-term and long-term marketable securities was held by our foreign subsidiaries. Amounts held by foreign subsidiaries are generally subject to U.S. income taxation on repatriation to the U.S. The costs to repatriate our foreign earnings to the U.S. would likely be material; however, our intent is to permanently reinvest our earnings from foreign operations, and our current plans do not require us to repatriate them to fund our U.S. operations as we generate sufficient domestic operating cash flow and have access to external funding under our current revolving line of credit.

Operating Activities

For the year ended December 31, 2015, cash flows from operations of $238.0 million resulted primarily from our net income of approximately $144.0 million as well as the following:

Significant non-cash activities

- Stock-based compensation was $52.9 million related to our equity incentive compensation granted to employees and directors.
- Depreciation and amortization of $18.0 million related to our fixed assets and acquired intangible assets.
- Excess tax benefits from our share-based compensation arrangements of $10.4 million.

Significant changes in working capital

- An increase of $41.9 million in deferred revenues corresponding to higher product sales along with the increased deferrals as a result of the change to our new additional aligner product policy in July 2015,
-

an increase of $19.5 million in accrued and other long-term liabilities primarily due to an increase in income tax payable along with other accruals due to timing of payment, and

- an increase of $40.8 million in accounts receivable which is a result of the increase in net revenues.

For the year ended December 31, 2014, cash flows from operations of $226.9 million resulted primarily from our net income of approximately $145.8 million as well as the following:

Significant non-cash activities

- Stock-based compensation was $39.8 million related to our equity incentive compensation granted to employees and directors.
- Deferred taxes of $25.5 million primarily due to the utilization of deferred tax assets.
- Excess tax benefits from our share-based compensation arrangements of $21.4 million.
- Depreciation and amortization of $17.9 million related to our fixed assets and acquired intangible assets.

Significant changes in working capital

- An increase of $27.2 million in accounts receivable which is a result of the increase in net revenues,
- an increase of $22.7 million in accrued and other long-term liabilities primarily due to an increase in income tax payable along with other accruals due to timing of payment, and
- an increase of $15.8 million in deferred revenues corresponding to the increases in revenues.

For the year ended December 31, 2013, cash flows from operations of $186.0 million resulted primarily from our net income of approximately $64.3 million as well as the following:

Significant non-cash activities

- Impairment of goodwill related to our Scanner reporting unit was $40.7 million.
- Impairment of long-lived assets related to our Scanner reporting unit was $26.3 million.
- Excess tax benefits from our share-based compensation arrangements of $27.1 million.
- Stock-based compensation was $26.4 million related to our equity incentive compensation granted to employees and directors.
- Depreciation and amortization of $16.8 million related to our fixed assets and acquired intangible assets.
- Deferred taxes of $21.2 million primarily due to the utilization of deferred tax assets.

Significant changes in working capital

- An increase of $12.0 million in accounts receivable due to the increase in net revenues,
- an increase of $9.7 million in accrued and other long-term liabilities due to compensation and bonuses accruals along with higher sales rebates, and
- an increase of $14.9 million in deferred revenue primarily due to higher product sales along with additional deferrals as a result of our mid-course correction policy change in June 2013.

Investing Activities

Net cash used in investing activities was $166.4 million for the year ended December 31, 2015, which primarily consisted of purchases of marketable securities of $447.1 million and property, plant and equipment purchases of $53.5 million for additional manufacturing capacity and infrastructure including a project to implement a new enterprise resource planning system which we started in late 2014. These uses were partially offset by $334.1 million of maturities and sales of our marketable securities.

For 2016, we expect to invest $55.0 million to $65.0 million on capital expenditures primarily for additional manufacturing capacity and to establish order acquisition and treatment planning facility and our ERP implementation. Although we believe our current investment portfolio has little risk of impairment, we cannot predict future market conditions or market liquidity and can provide no assurance that our investment portfolio will remain unimpaired.

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Net cash used in investing activities was $201.6 million for the year ended December 31, 2014, which primarily consisted of purchases of marketable securities of $437.2 million and property, plant and equipment purchases of $24.1 million. These uses were partially offset by $259.8 million of maturities and sales of our marketable securities.

Net cash used in investing activities was $210.7 million for the year ended December 31, 2013, which primarily consisted of our purchase of marketable securities of $303.9 million and property and equipment purchases of $19.4 million along with $7.7 million for the acquisition of our Asia Pacific distributor in April 2013. These uses were partially offset by $122.7 million of maturities and sales of our marketable securities.

Financing Activities

Net cash used by financing activities was $100.8 million for the year ended December 31, 2015 resulting from repurchases of our common stock of $101.8 million (Refer to Note 10 "Common Stock Repurchase Program", of the Notes to consolidated financial statements for details of the stock repurchase program) and $20.7 million of payroll taxes paid for our employees' vesting of restricted stock units ("RSUs") through share withholdings, partially off-set by proceeds from issuance of common stock of $11.3 million and $10.4 million from excess tax benefit from our share-based compensation arrangements.

Net cash used by financing activities was $66.4 million for the year ended December 31, 2014 resulting from repurchases of our common stock of $98.2 million and $7.6 million of payroll taxes paid for our employees' vesting of RSUs through share withholdings, partially off-set by proceeds from issuance of common stock of $18.0 million and $21.4 million from excess tax benefit from our share-based compensation arrangements.

Net cash used by financing activities was $38.2 million for the year ended December 31, 2013 resulting from repurchases of our common stock of $95.1 million and $4.4 million of payroll taxes paid for our employees' vesting of restricted stock units through share withholdings, partially off-set by proceeds from issuance of common stock of $34.2 million and $27.1 million from excess tax benefit from our share-based compensation arrangements.
Net proceeds from the issuance of our common stock related to the exercise of employee stock options have historically been a significant component of our liquidity; however, in 2006, we began granting RSUs which, unlike stock options, do not generate cash from exercises. As a result, we will continue to generate less cash from the proceeds of the sale of our common stock in future periods. In addition, because restricted stock units are taxable to the individuals when they vest, the number of shares we issue to each of our employees will be net of applicable withholding taxes which will be paid by us on their behalf. During 2015, 2014 and 2013, we paid $20.7 million, $7.6 million and $4.4 million, respectively, for taxes related to RSUs that vested during the periods. The cash paid for taxes related to RSUs in 2015 increased in comparison to 2014 due to the Company changing its policy in mid 2014 to pay for employees' payroll taxes related to their vesting RSUs instead of requiring employees to sell to cover for their payroll taxes.
Stock Repurchase

On April 23, 2014, we announced that our Board of Directors had authorized a stock repurchase program pursuant to which we may purchase up to $300.0 million of our common stock over three years, with $100.0 million of that amount authorized to be purchased during each twelve month period. Any purchases under this stock repurchase program may be made, from time-to-time, pursuant to open market purchases (including pursuant to Rule 10b5-1 plans), privately-negotiated transactions, accelerated stock repurchases, block trades or derivative contracts or otherwise in accordance with applicable federal securities laws, including Rule 10b-18 of the Securities Exchange Act of 1934.

As part of our $300.0 million stock repurchase program, we entered into an accelerated share repurchase agreement ("ASR") with Goldman, Sachs & Co. on April 28, 2014 to repurchase $70.0 million of our common stock. We paid

$70.0 million on April 29, 2014 and received an initial delivery of approximately 1.0 million shares. The ASR was completed on July 29, 2014 with a final delivery of approximately 0.4 million shares. We received a total of approximately 1.4 million shares under the ASR for an average purchase price per share of $51.46, which all shares were retired. The final number of shares repurchased was based on our volume-weighted average stock price during the term of the transaction, less an agreed upon discount. During 2014, we repurchased on the open market approximately 0.6 million shares of our common stock at an average price of $50.93 per share, including commissions, for an aggregate purchase price of approximately $28.2 million. All repurchased shares were retired.

In January 2015, our Board of Directors authorized the repurchase of the next $100.0 million under the repurchase program which we anticipate completing within twelve months. On April 28, 2015, we entered into an accelerated stock repurchase agreement ("2015 ASR") to repurchase $70.0 million of our common stock. The 2015 ASR was completed on July 23, 2015. We received a total of approximately 1.2 million shares for an average share price of $60.52 under the 2015 ASR, which were all retired. The

final number of shares repurchased was based on our volume-weighted average stock price during the term of the transaction, less an agreed upon discount. In addition, during the year ended December 31, 2015, we repurchased on the open market approximately 0.5 million shares of our common stock at an average price of $58.89 per share, including commissions, for an aggregate purchase price of $31.8 million. All repurchased shares were retired. As of December 31, 2015, we have approximately $100.0 million remaining under the April 2014 stock repurchase program. We expect to finance future stock repurchases with current cash on hand.

Credit Facility

On March 22, 2013, we entered into a credit facility for a $50.0 million revolving line of credit, with a $10.0 million letter of credit sublimit, and has a maturity date on March 22, 2016. (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, 2015 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	$19,750	$10,236	$8,553	$853	$108
Unconditional purchase obligations	74,569	74,569	—	—	—
Total contractual cash obligations	$94,319	$84,805	$8,553	$853	$108

Our contractual obligations table above excludes approximately $40.1 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, 2015. 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 off-balance sheet arrangements as defined in Regulation S-K Item 303(a) (4) as of December 31, 2015.

We believe that our current cash and cash equivalents and marketable debt securities combined with our positive cash flows from operations will be sufficient to fund our operations for at least the next 12 months. If we are unable to generate adequate operating cash flows, we may need to 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.

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, 2015, 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

We enter into sales arrangements that may consist of multiple deliverables of our products and services where certain elements of the sales arrangement are not delivered in one reporting period. We measure and allocate revenue according to the accounting guidance for multiple-deliverable revenue arrangements in Accounting Standards Update ("ASU") 2009-13, Multiple-Deliverable Revenue Arrangements-a consensus of the Financial Accounting Standard Board ("FASB") Emerging Issues Task Force.

Each element within a multiple-element arrangement is accounted for as a separate unit of accounting provided the following criteria are met: the delivered products or services have value to the customer on a standalone basis; and for an arrangement that includes a general right of return relative to the delivered products or services, delivery or performance of the undelivered product or service is considered probable and is substantially controlled by us. We consider a deliverable to have standalone value if the product or service is sold separately by us or another vendor or could be resold by the customer. Further, our revenue arrangements generally do not include a general right of return relative to the delivered products. The arrangement consideration is then allocated to each element, delivered or undelivered, based on the relative selling price of each unit of accounting based first on vendor-specific objective evidence ("VSOE") if it exists, second on third-party evidence ("TPE") if it exists, or on best estimated selling price ("BESP") if neither VSOE nor TPE exist (a description as to how we determine VSOE, TPE, and BESP is provided below).

- VSOE - In most instances, this applies to products and services that are sold separately in stand-alone arrangements. We determine VSOE based on pricing and discounting practices for the specific product or service when sold separately, considering geographical, customer, and other economic or marketing variables, as well as renewal rates or stand-alone prices for the service element(s).
- TPE - If we cannot establish VSOE of selling price for a specific product or service included in a multiple-element arrangement, we use third-party evidence of selling price. We determine TPE based on sales of comparable amount of similar products or service offered by multiple third parties considering the degree of customization and similarity of product or service sold.
- BESP - The best estimated selling price represents the price at which we would sell a product or service if it were sold on a stand-alone basis. When VSOE or TPE do not exist for all elements, we determine BESP for the arrangement element based on sales, cost and margin analysis, as well as other inputs based on our pricing practices. Adjustments for other market and Company-specific factors are made as deemed necessary in determining BESP. We regularly

review our estimates of selling price and maintain internal controls over the establishment and update of these estimates.

Judgment is required to properly identify the accounting units of the multiple deliverable transactions, to determine the best estimated selling price for each accounting unit, and to determine the manner in which revenue should be allocated among the accounting units. Further, while changes in the allocation of the best estimated selling price between the accounting units will not affect the amount of total revenue recognized for a particular arrangement, any material changes in these allocations could impact the timing of revenue recognition, which could have a material effect on our financial position and results of operations.

Clear Aligner

We enter into arrangements (“treatment plans”) that involve multiple future product deliverables. Invisalign Full, Invisalign Teen, and Invisalign Assist products include optional Additional Aligners at no charge for a period of up to five years after initial shipment. Invisalign Teen also includes up to six optional replacement aligners in the price of the product and may be ordered by the dental professional any time throughout treatment. Invisalign Lite includes one optional case refinement in the price of the

product. Case refinement is a finishing tool used to adjust a patient's teeth to the desired final position and may be elected by the dental professional at any time during treatment, however, it is generally ordered in the last stages of orthodontic treatment.

We determined that our treatment plans, except Invisalign Assist with progress tracking, comprise the following deliverables which also represent separate units of accounting: single-batched aligners, additional aligners, case refinement, and replacement aligners. We allocate revenue for each treatment plan based on each unit's relative selling price based on BESP and recognize the revenue upon the delivery of each unit in the treatment plan.

For Invisalign Assist with the progress tracking feature, aligners and services are provided to the dental professional every nine stages (“a batch”). We are able to reliably estimate the number of batches which are expected to be shipped for each case based upon our historical experience. The amounts allocated to this deliverable are recognized on a prorated basis as each batch is shipped.

Scanners and Services

We sell intra-oral scanners and CAD/CAM services through both our direct sales force and distribution partners. The intra-oral scanner sales price includes one year of warranty, and unlimited scanning services. The customer may, for additional fees, also select extended warranty and unlimited scanning services for periods beyond the initial year. When intra-oral scanners are sold with an unlimited scanning service agreement and/or extended warranty, we allocate revenue based on each element's relative selling price.We estimate the selling price of each element, as if it is sold on a stand-alone basis, taking into consideration historical prices as well as our discounting strategies.

Stock-based Compensation Expense

We recognize stock-based compensation cost for only those shares ultimately expected to vest on a straight-line basis over the requisite service period of the award. We use the Black-Scholes option pricing model to determine the fair value of stock options 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 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.

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 reporting units based on relative synergies generated.

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.
Impairment of goodwill, finite-lived acquired intangible assets 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 circumstances changes that 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 5 "Goodwill and Intangible Assets" of Notes to consolidated financial statements for details of the impairment analysis.

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 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 5 "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 Sheets.

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

We assess the likelihood that we will be able to realize our deferred tax assets. Should there be a change in our ability to realize our deferred tax assets, our tax provision would increase in the period in which we determine that it is more likely than not that we cannot realize our deferred tax assets. We consider all available evidence, both positive and negative, including historical levels of income, expectations and risks associated with estimates of future taxable

income and ongoing prudent and feasible tax planning strategies in assessing the need for a valuation allowance. If it is more likely than not that we will not realize our deferred tax assets, we will increase our provision for taxes by recording a valuation allowance against the deferred tax assets that we estimate will not ultimately be realized.

Recent Accounting Pronouncements

See Note 1 “Summary of Significant Accounting Policies” in the Notes to consolidated financial statements in Item 8 for a full description 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 cash equivalents and investments are fixed-rate short-term and long-term securities. Fixed-rate securities may have their fair market value adversely impacted due to a rise in interest rates, and as a result, our future investment income may fall short of expectations due to changes in interest rates or we may suffer losses in principal if forced to sell securities which have declined in market value due to changes in interest rates. As of December 31, 2015, we had approximately $511.0 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 have interest bearing liabilities as of December 31, 2015, and, therefore, we are not subject to risks from immediate interest rate increases.

Currency Rate Risk

We operate in North America, Europe, Asia Pacific, Costa Rica and Israel. 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 as discussed further below. Regardless of this natural hedging, our results of operations may be adversely impacted by exchange rate fluctuations.

In September 2015, we entered 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 hedging activities could have on our results of operations. The fair value of foreign exchange forward contracts outstanding as of December 31, 2015 was not material.

Although we will continue to monitor our exposure to currency fluctuations, and, where appropriate, may use financial hedging techniques in the future 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							
	2015				2014			
	December 31, 2015	September 30, 2015	June 30, 2015	March 31, 2015	December 31, 2014	September 30, 2014	June 30, 2014	March 31, 2014
	(in thousands, except per share data) (unaudited)							
Net revenues	$230,276	$207,636	$209,488	$198,086	$198,600	$189,876	$192,531	$180,646
Gross profit	172,810	157,576	158,634	151,090	150,662	145,054	145,476	137,251
Income from operations [1]	59,339	38,046	42,325	48,924	51,493	51,547	48,732	41,804
Net income [1]	48,877	27,616	31,350	36,177	39,541	38,247	35,600	32,444
Net income per share:								
Basic	$0.61	$0.35	$0.39	$0.45	$0.49	$0.47	$0.44	$0.40
Diluted	$0.60	$0.34	$0.39	$0.44	$0.48	$0.47	$0.43	$0.39
Shares used in computing net income per share:								
Basic	79,481	79,808	80,257	80,459	80,266	80,629	81,027	81,120
Diluted	81,051	81,092	81,394	81,824	81,691	82,014	82,341	82,817

[1] In the three months ended June 30, 2014, we recorded an out of period correction that resulted in an increase in the provision for income taxes of $2.1 million, which $1.8 million related to prior years and $0.3 million related to the three months ended March 31, 2014. The out of period correction was not material to the consolidated financial statements for any quarter within 2014.

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, 2015. 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 its assessment, management has concluded that, as of December 31, 2015, 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, 2015 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report which is included herein.

/S/ JOSEPH M. HOGAN
Joseph M. Hogan
President and Chief Executive Officer
February 25, 2016

/S/ DAVID L. WHITE
David L. White
Chief Financial Officer
February 25, 2016

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

In our opinion, the consolidated financial statements listed in the index appearing under Item 15(a) (1), present fairly, in all material respects, the financial position of Align Technology, Inc. and its subsidiaries at December 31, 2015 and December 31, 2014, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2015 in conformity with accounting principles generally accepted in the United States of America. In addition, in our opinion, the financial statement schedule listed in the index appearing under Item 15(a)(2) presents fairly, in all material respects, the information set forth therein when read in conjunction with the related consolidated financial statements. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2015, based on criteria established in Internal Control—Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for these financial statements and financial statement schedule, 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 these financial statements, on the financial statement schedule, and on the Company's internal control over financial reporting based on our integrated audits. We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. 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.

As discussed in Note 1 to the consolidated financial statements, the Company changed the manner in which it classifies deferred income tax assets and liabilities in 2015.

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 25, 2016

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

	Year Ended December 31,		
	2015	2014	2013
Net revenues	$845,486	$761,653	$660,206
Cost of net revenues	205,376	183,210	162,100
Gross profit	640,110	578,443	498,106
Operating expenses:			
Selling, general and administrative	390,239	332,068	292,798
Research and development	61,237	52,799	44,083
Impairment of goodwill	—	—	40,693
Impairment of long lived assets	—	—	26,320
Total operating expenses	451,476	384,867	403,894
Income from operations	188,634	193,576	94,212
Interest and other income (expense), net	(2,533)	(3,207)	(1,073)
Net income before provision for income taxes	186,101	190,369	93,139
Provision for income taxes	42,081	44,537	28,844
Net income	$144,020	$145,832	$64,295
Net income per share:			
Basic	$1.80	$1.81	$0.80
Diluted	$1.77	$1.77	$0.78
Shares used in computing net income per share:			
Basic	79,998	80,754	80,551
Diluted	81,521	82,283	82,589

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,		
	2015	2014	2013
Net income	$144,020	$145,832	$64,295
Net change in cumulative translation adjustment	(154)	(196)	62
Change in unrealized gains (losses) on available-for sale securities, net of tax	(686)	(238)	29
Other comprehensive income (loss)	(840)	(434)	91
Comprehensive income	$143,180	$145,398	$64,386

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, 2015	2014
ASSETS		
Current assets:		
Cash and cash equivalents	$167,714	$199,871
Marketable securities, short-term	359,581	254,787
Accounts receivable, net of allowance for doubtful accounts and returns of $2,472 and $1,563, respectively	158,550	129,751
Inventories	19,465	15,928
Prepaid expenses and other current assets	26,700	19,770
Deferred tax assets	—	37,053
Total current assets	732,010	657,160
Marketable securities, long-term	151,370	147,892
Property, plant and equipment, net	136,473	90,125
Goodwill and intangible assets, net	79,162	82,056
Deferred tax assets	51,416	3,099
Other assets	8,202	7,665
Total assets	$1,158,633	$987,997
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$34,354	$23,247
Accrued liabilities	107,765	87,880
Deferred revenues	129,553	90,684
Total current liabilities	271,672	201,811
Income tax payable	37,512	30,483
Other long-term liabilities	1,523	2,932
Total liabilities	310,707	235,226
Commitments and contingencies (Notes 6 and 8)		
Stockholders' equity:		
Preferred stock, $0.0001 par value (5,000 shares authorized; none issued)	—	—
Common stock, $0.0001 par value (200,000 shares authorized; 79,500 and 80,205 issued and outstanding at 2015 and 2014, respectively)	8	8
Additional paid-in capital	821,507	783,410
Accumulated other comprehensive income (loss), net	(980)	(140)
Accumulated surplus (deficit)	27,391	(30,507)
Total stockholders' equity	847,926	752,771
Total liabilities and stockholders' equity	$1,158,633	$987,997

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

ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
For the year ended December 31, 2015, 2014 and 2013
(in thousands)

	Common Stock		Additional Paid in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Surplus (Deficit)	Total
	Shares	Amount				
Balances at December 31, 2012	80,611	$8	$670,732	$ 203	$ (89,626)	$581,317
Net income	—	—	—	—	64,295	64,295
Net change in unrealized gain from available-for sale securities	—	—	—	29	—	29
Net change in cumulative translation adjustment	—	—	—	62	—	62
Issuance of common stock relating to employee equity compensation plans	2,694	—	34,196	—	—	34,196
Tax withholdings related to net share settlement of restricted stock units	—	—	(4,363)	—	—	(4,363)
Common stock repurchased and retired	(2,722)	—	(24,528)	—	(70,579)	(95,107)
Tax benefits from stock-based awards	—	—	27,103	—	—	27,103
Stock based compensation	—	—	26,438	—	—	26,438
Balances at December 31, 2013	80,583	8	729,578	294	(95,910)	633,970
Net income	—	—	—	—	145,832	145,832
Net change in unrealized gain from available-for sale securities	—	—	—	(238)	—	(238)
Net change in cumulative translation adjustment	—	—	—	(196)	—	(196)
Issuance of common stock relating to employee equity compensation plans	1,536	—	18,028	—	—	18,028
Tax withholdings related to net share settlements of restricted stock units	—	—	(7,608)	—	—	(7,608)
Common stock repurchased and retired	(1,914)	—	(17,804)	—	(80,429)	(98,233)
Tax benefits from stock-based awards	—	—	21,393	—	—	21,393
Stock based compensation	—	—	39,823	—	—	39,823
Balances at December 31, 2014	80,205	8	783,410	(140)	(30,507)	752,771
Net income	—	—	—	—	144,020	144,020
Net change in unrealized gain from available-for sale securities	—	—	—	(686)	—	(686)
Net change in cumulative translation adjustment	—	—	(10)	(154)	—	(164)
Issuance of common stock relating to employee equity compensation plans	991	—	11,325	—	—	11,325
Tax withholdings related to net share settlements of restricted stock units	—	—	(20,716)	—	—	(20,716)
Common stock repurchased and retired	(1,696)	—	(15,669)	—	(86,122)	(101,791)
Tax (shortfalls) benefits from stock-based awards	—	—	10,224	—	—	10,224
Stock based compensation	—	—	52,943	—	—	52,943

Balances at December 31, 2015	79,500	$8	$821,507	$ (980)	$ 27,391	$847,926

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,		
	2015	2014	2013
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net income	$144,020	$145,832	$64,295
Adjustments to reconcile net income to net cash provided by operating activities:			
Deferred taxes	(11,424)	4,088	(5,899)
Depreciation and amortization	18,004	17,856	16,825
Stock-based compensation	52,943	39,823	26,438
Tax (shortfalls) benefits from stock-based awards	10,224	21,393	27,103
Excess tax benefit from share-based payment arrangements	(10,396)	(21,393)	(27,103)
Impairment of goodwill	—	—	40,693
Impairment of long-lived assets	—	—	26,320
Other non-cash operating activities	13,799	10,106	4,142
Changes in assets and liabilities, excluding the effects of business combinations:			
Accounts receivable	(40,775)	(27,229)	(11,981)
Inventories	(3,563)	(1,999)	1,158
Prepaid expenses and other assets	(3,726)	(2,924)	(392)
Accounts payable	7,575	2,887	(186)
Accrued and other long-term liabilities	19,462	22,692	9,662
Deferred revenues	41,854	15,767	14,901
Net cash provided by operating activities	237,997	226,899	185,976
CASH FLOWS FROM INVESTING ACTIVITIES:			
Acquisition, net of cash acquired	—	—	(7,652)
Purchase of property, plant and equipment	(53,451)	(24,092)	(19,412)
Purchase of marketable securities	(447,092)	(437,152)	(303,917)
Proceeds from maturities of marketable securities	304,125	176,810	90,917
Proceeds from sales of marketable securities	30,011	82,990	31,741
Other investing activities	46	(183)	(2,411)
Net cash used in investing activities	(166,361)	(201,627)	(210,734)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from issuance of common stock	11,325	18,028	34,196
Common stock repurchase	(101,791)	(98,233)	(95,107)
Excess tax benefit from share-based payment arrangements	10,396	21,393	27,103
Employees' taxes paid upon the vesting of restricted stock units	(20,716)	(7,608)	(4,363)
Net cash used in financing activities	(100,786)	(66,420)	(38,171)
Effect of foreign exchange rate changes on cash and cash equivalents	(3,007)	(1,934)	(504)
Net decrease in cash and cash equivalents	(32,157)	(43,082)	(63,433)
Cash and cash equivalents, beginning of year	199,871	242,953	306,386
Cash and cash equivalents, end of year	$167,714	$199,871	$242,953

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

ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
Note 1. Summary of Significant Accounting Policies

Business Description

Align Technology, Inc. (“We”, “Our”, or “Align”) was incorporated in April 1997 in Delaware and focuses on designing, manufacturing and marketing innovative, technology-rich products to help dental professionals achieve the clinical results they expect and deliver effective, convenient cutting-edge dental treatment options to their patients. We are headquartered in San Jose, California with offices worldwide. Our international headquarters are located in Amsterdam, the Netherlands. We have two operating segments, (1) Clear Aligner, known as the Invisalign System, and (2) Scanners and Services ("Scanner"), known as the iTero intra-oral 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.

In connection with the preparation of the consolidated financial statements, we evaluated events subsequent to the balance sheet date through the financial statement issuance date and determined that all material transactions have been recorded and disclosed properly.

Out of period adjustment

In 2013, we recorded an out of period correction that resulted in decreases in cost of net revenues of approximately $1.7 million and operating expense of $0.7 million offset in part by an increase in the provision for income taxes of $0.5 million. We do not believe the increase of $1.9 million to net income related to the out of period adjustment is material to the consolidated financial statements for the fiscal year ended December 31, 2013 or to any prior years' consolidated financial statements.

In 2014, we recorded an out of period correction that resulted in an increase in the provision for income taxes of $1.8 million. We do not believe the decrease to net income related to the out of period adjustment is material to the consolidated financial statements for the fiscal year ended December 31, 2014 or to any prior years' consolidated financial statements.

Use of estimates

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

The carrying amounts of our cash, accounts receivable, accounts payable and other current liabilities approximate their fair value.

We measure our cash equivalents, marketable securities, and our Israeli severance fund at fair value. Fair value is 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.

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ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

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 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

Our restricted cash balance as of December 31, 2015 was $3.5 million, of which $3.3 million was classified as a long term asset and $0.2 million as a current asset. Our restricted cash balance as of December 31, 2014 was $3.8 million, of which $3.6 million was classified as a long term asset and $0.2 million as a current asset. The restricted cash primarily consisted of funds reserved for legal requirements.

Marketable securities

We invest primarily in money market funds, commercial paper, corporate bonds, U.S. government agency bonds, asset-backed securities, municipal securities, U.S. dollar dominated foreign corporate bonds, U.S. government treasury bonds and certificates of deposits.

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, 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 Interest and other income (expense), net as incurred. We periodically evaluate these investments for other-than-temporary impairment.

Derivative Financial Instruments

In September 2015, we began 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. We do not enter into foreign currency forward contracts for trading or speculative purposes. These instruments are marked to market through earnings every period and generally are one month in original maturity. The net gain or loss from the settlement of these foreign currency forward contracts is recorded in Interest and other income (expense), net in the Consolidated Statements of Operations.

Foreign currency

For our international subsidiaries where the U.S. dollar is the functional currency, we analyze on an annual basis or more often if necessary, if a significant change in facts and circumstances indicate that the primary economic currency has changed. Adjustments from translating certain European and Asia Pacific subsidiaries' financial statements from the local currency to the U.S. dollar 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. As of December 31, 2015 and 2014, there were no material amounts in accumulated other comprehensive income, net related to the translation of our foreign subsidiaries' financial statements.

Some of our international entities operate in a U.S. dollar functional currency environment, and therefore, the foreign currency assets and liabilities are remeasured into the U.S. dollar at current exchange rates except for non-monetary assets and liabilities which are remeasured at historical exchange rates. Revenues and expenses are generally remeasured at an average exchange rate in effect during each period. Gains or losses from foreign currency remeasurement are included in Interest and other income (expense), net. For the year ended December 31, 2015 and 2014, we had foreign currency net losses of $4.0 million and $3.8 million.

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ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

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 two financial institutions. Financial instruments which potentially expose us to concentrations of credit risk consist primarily of cash equivalents, marketable securities and accounts receivable. We invest excess cash primarily in money market funds of major financial institutions, U.S. government agencies, U.S. dollar dominated foreign corporate bonds and domestic corporate bonds. 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. 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, 2015 or 2014, or net revenues for the year ended December 31, 2015, 2014, or 2013.

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 operations located outside the U.S. We currently rely on our manufacturing facility in Costa Rica to prepare digital treatment plans using a sophisticated, internally developed computer-modeling program. In addition, we manufacture our clear aligners and distribute our intra-oral scanners at our facility in Juarez, Mexico, and we produce our handheld scanner wand in Or Yehuda, Israel. 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, particularly as a result of increased levels of violence in Juarez, Mexico and Or Yehuda, Israel; 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 market, 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 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, generally three to ten years. We amortize leasehold improvements over the shorter of the remaining

lease term or the estimated useful lives of the assets. We depreciate buildings over periods up to 20 years. Land is not depreciated. 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 general ledger and any related gains or losses are reflected in expenses. Maintenance and repairs are expensed as incurred.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

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 the Cadent acquisition. 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 circumstances changes that 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.

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). 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.

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 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 cashflow ("DCF") approach includes numerous uncertainties which require our significant judgment when making assumptions of expected growth rates and the selection of discount rates, as well as assumptions regarding general economic and business conditions, and the structure that would yield the highest economic value, among other factors. Refer to Note 5 for details of the impairment analysis.

There were no further triggering events in 2015 that would cause further impairments of our long-lived assets.

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ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES
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Development costs for internal use software

Internally developed software includes enterprise-level business software that we are customizing 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. In 2014, we started an ERP project which we have capitalized $25.4 million of costs as of December 31, 2015 which is included in construction in progress ("CIP"). When the ERP is placed into production, these costs will be amortized over 10 years.

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 Invisalign case is complete. We accrue for warranty costs in cost of net revenues upon shipment of products. The amount of accrued estimated warranty costs 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 the accrued balances and update these balances based on historical warranty cost trends.
Scanners and Services
We warrant our intra-oral 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 and Returns

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

Revenue Recognition

We measure and allocate revenue according to the accounting guidance for multiple-deliverable revenue arrangements in Accounting Standards Update ("ASU") 2009-13, Multiple-Deliverable Revenue Arrangements-a consensus of the Financial Accounting Standard Board ("FASB") Emerging Issues Task Force.

Multiple-Element Arrangements ("MEAs"): Arrangements with customers may include multiple deliverables, including any combination of products/equipment and services. The deliverables included in the MEAs are separated into more than one unit of accounting when (i) the delivered product/equipment has value to the customer on a stand-alone basis, and (ii) delivery of the undelivered service element(s) is probable and substantially in our control. Arrangement consideration is then allocated to each unit, delivered or undelivered, based on the relative selling price of each unit of accounting based first on vendor-specific objective evidence ("VSOE") if it exists, second on third-party evidence ("TPE") if it exists, or on best estimated selling price ("BESP") if neither VSOE or TPE exist.

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VSOE - In most instances, this applies to products and services that are sold separately in stand-alone arrangements. We determine VSOE based on pricing and discounting practices for the specific product or service when sold separately, considering geographical, customer, and other economic or marketing variables, as well as renewal rates or stand-alone prices for the service element(s).

- TPE - If we cannot establish VSOE of selling price for a specific product or service included in a multiple-element arrangement, we use third-party evidence of selling price. We determine TPE based on sales of comparable amount of

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similar products or service offered by multiple third parties considering the degree of customization and similarity of product or service sold.

- BESP - The best estimated selling price represents the price at which we would sell a product or service if it were sold on a stand-alone basis. When VSOE or TPE do not exist for all elements, we determine BESP for the arrangement element based on sales, cost and margin analysis, as well as other inputs based on our pricing practices. Adjustments for other market and Company-specific factors are made as deemed necessary in determining BESP. We regularly review our estimates of selling price and maintain internal controls over the establishment and update of these estimates.

Revenue is recognized when persuasive evidence of the arrangement exists, the price is fixed or determinable, collectability is reasonably assured, title and risk of loss has passed to customers based on the shipping terms, and allowances for discounts, returns, and customer incentives can be reliably estimated. Provisions for discounts and rebates to customers are provided for in the same period that the related product sales are recorded.

Clear Aligner

We enter into arrangements (“treatment plans”) that involve multiple future product deliverables. Invisalign Full, Invisalign Teen, and Invisalign Assist products include optional Additional Aligners at no charge for a period of up to five years after initial shipment. Invisalign Teen also includes up to six optional replacement aligners in the price of the product and may be ordered by the dental professional any time throughout treatment. Invisalign Lite includes one optional case refinement in the price of the product. Case refinement is a finishing tool used to adjust a patient's teeth to the desired final position and may be elected by the dental professional at any time during treatment, however, it is generally ordered in the last stages of orthodontic treatment.

We determined that our treatment plans, except Invisalign Assist with progress tracking, comprise the following deliverables which also represent separate units of accounting: single-batched aligners, additional aligners, case refinement, and replacement aligners. We allocate revenue for each treatment plan based on each unit's relative selling price based on BESP and recognize the revenue upon the delivery of each unit in the treatment plan.

For Invisalign Assist with the progress tracking feature, aligners and services are provided to the dental professional every nine stages (“a batch”). We are able to reliably estimate the number of batches which are expected to be shipped for each case based upon our historical experience. The amounts allocated to this deliverable are recognized on a prorated basis as each batch is shipped.

Scanners and Services

We recognize revenues from the sales of iTero intra-oral scanners and CAD/CAM services. CAD/CAM services include scanning services, extended warranty for the intra-oral scanners, a range of iTero restorative services, and OrthoCAD services such as OrthoCAD iRecord. We sell intra-oral scanners and services through both our direct sales force and distribution partners. The intra-oral scanner sales price includes one year of warranty, and for additional fees, the customer may select an unlimited scanning service agreement over a fixed period of time or extended warranty periods. When intra-oral scanners are sold with either an unlimited scanning service agreement and/or extended warranty, we allocate revenue based on each element's relative selling price. We estimate the selling price of each element, as if it is sold on a stand-alone basis, taking into consideration historical prices as well as our discounting strategies.

Scanner revenue, net of related discounts and allowances, is recognized when products or equipment have been shipped and no significant obligations for installation or training remain. For certain distributors who provide installation and training to the customer, we recognize scanner revenue when the intra-oral scanner is shipped to the distributor assuming all of the other revenue recognition criteria have been met. Discounts are deducted from revenue at the time of sale. Returns of products, excluding warranty related returns, are infrequent and insignificant.

Service revenue, including iTero restorative and all OrthoCAD services are recognized upon delivery or ratably over the contract term as the specified services are performed. If a customer selects a pay per use basis for scanning service fees, the revenue is recognized as the service is provided.

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We offer customers an option to purchase extended warranties on certain products. We recognize revenue on these extended warranty contracts ratably over the life of the contract. The costs associated with these extended warranty contracts are recognized when incurred.

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 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 liability in our financial statements. If only a range of estimated losses can be determined, we accrue an amount within the range that, in our judgment, reflect 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 compensation costs, including stock-based compensation expense, outside consulting expenses, costs associated with conducting clinical and pre-commercialization trial and testing, allocations of corporate overhead expenses including facilities and IT costs, equipment costs and depreciation and amortization.

Advertising costs

The cost of advertising and media is expensed as incurred. For the year ended December 31, 2015, 2014 and 2013 advertising costs totaled $23.4 million, $26.9 million and $26.0 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 are in excess over par between additional paid in capital and retained earnings. All shares repurchased are retired.

Operating leases

We currently lease office spaces, automobiles and equipment under operating leases with original lease periods of up to 9 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 as certain leases have adjustments for market provisions.

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 Sheets.

We account for uncertainty in income taxes pursuant to authoritative guidance based on a two-step approach to recognize and measure uncertain tax positions taken or expected to be taken in a tax return. The first step is to determine if the weight of available evidence indicates that it is more likely than not that the tax position will be sustained on audit based on its technical

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merits, including resolution of any related appeals or litigation processes. The second step is to measure the tax benefit as the largest amount that is more than 50% likely to be realized upon ultimate settlement. We adjust reserves for our uncertain tax positions due to changing facts and circumstances, such as the closing of a tax audit, or refinement of estimates due to new information. To the extent that the final outcome of these matters is different than the amounts recorded, such differences will impact our tax provision in our Consolidated Statements of Operations in the period in which such determination is made.

We assess the likelihood that we will be able to realize our deferred tax assets. Should there be a change in our ability to realize our deferred tax assets, our tax provision would increase in the period in which we determine that it is more likely than not that we cannot realize our deferred tax assets. We consider all available evidence, both positive and negative, including historical levels of income, expectations and risks associated with estimates of future taxable income and ongoing prudent and feasible tax planning strategies in assessing the need for a valuation allowance. If it is more likely than not that we will not realize our deferred tax assets, we will increase our provision for taxes by recording a valuation allowance against the deferred tax assets that we estimate will not ultimately be realizable. The available positive evidence at December 31, 2015 included historical operating profits and a projection of future income sufficient to realize most of our remaining deferred tax assets. As of December 31, 2015, 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.

As of December 31, 2015, U.S. income taxes and foreign withholding taxes associated with the repatriation of undistributed earnings of foreign subsidiaries were not provided for on a cumulative total of $359.8 million. We intend to reinvest these earnings indefinitely in our foreign subsidiaries. If these earnings were distributed in the form of dividends or otherwise, or if the shares of the relevant foreign subsidiaries were sold or otherwise transferred, we would be subject to additional U.S. income taxes subject to an adjustment for foreign tax credit, and foreign withholding taxes. Determination of the amount of unrecognized deferred income tax liability related to these earnings is not practicable.

Accounting guidance for stock-based compensation prohibits recognition of a deferred income tax asset for excess tax benefits due to stock option exercises that have not yet been realized through a reduction in income taxes payable. We follow the tax law ordering method to determine when excess tax benefits have been realized and consider only the direct impacts of awards when calculating the amount of windfalls or shortfalls.

Stock-based compensation

We recognize stock-based compensation cost for only those shares ultimately expected to vest on a straight-line basis over the requisite service period of the award. We use the Black-Scholes option pricing model to determine the fair value of 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.

Medical Device Excise Taxes

In accordance with the Patient Protection and Affordable Care Act, effective January 1, 2013, we began to incur an excise tax on sales of medical devices in the U.S. In March 2014, we were informed by IRS that our aligners are not subject to the medical device excise tax ("MDET") which we had been paying and expensing in selling, general and administrative expenses in the Consolidated Statements of Operations since January 1, 2013; however, our scanners are still subject to the MDET. Beginning in March 2014, we ceased expensing and paying the MDET for aligners. In the first quarter of 2015, the IRS approved our MDET refund claim of $6.8 million refund of MDET paid in 2013 related to our aligners; reducing expense for the year ended December 31, 2015.

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Comprehensive income

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

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (" FASB") released Accounting Standards Update ("ASU") 2014-9 "Revenue from Contracts with Customers" 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. The new standard defines a five step process to achieve this core principle and, in doing so, it is possible more judgment and estimates may be required within the revenue recognition process than required under existing GAAP including identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligation. In addition, the new standard requires that reporting companies disclose the nature, amount, timing, and uncertainty of revenue and cash flows arising from contracts with customers.

In August 2015, the FASB deferred the effective date of the update by one year, with early adoption on the original effective date permitted. We are required to adopt this standard starting in the first quarter of fiscal year 2018 using either of two methods: (i) retrospective to each prior reporting period presented with the option to elect certain practical expedients as defined within the standard; or (ii) retrospective with the cumulative effect of initially applying the standard recognized at the date of initial application and providing certain additional disclosures as defined per the standard. We have not yet selected a transition method, and are in the process of determining the impact that the new standard will have on our consolidated financial statements.

In April 2015, the FASB issued ASU No. 2015-05, "Customer's Accounting for Fees Paid in a Cloud Computing Arrangement." providing guidance to entities about whether a cloud computing arrangement includes a software license. If a cloud computing arrangement includes a software license, the entity should account for the software license element of the arrangement consistent with the acquisition of other software licenses. If a cloud computing arrangement does not include a software license, the entity should account for the arrangement as a service contract. The new guidance does not change the accounting for an entity's accounting for service contracts. The updated standard becomes effective for interim and annual reporting periods beginning after December 15, 2015. We adopted this ASU in January, 2016, and we do not expect it to have a material impact on our consolidated financial statements and related disclosures.

In November 2015, the FASB issued ASU 2015-17, "Income Taxes" (Topic 740), to simplify the presentation of deferred income taxes. Under the new standard, both deferred tax liabilities and assets are required to be classified as noncurrent in a classified balance sheet. ASU 2015-17 will become effective for fiscal years, and the interim periods within those years, beginning after December 15, 2016, with early adoption permitted. The new guidance has been adopted on a prospective basis by the Company for the year ended December 31, 2015, thus resulting in the reclassification of $30.1 million of current deferred tax assets to noncurrent on the accompanying Consolidated Balance Sheets. The prior reporting period was not retrospectively adjusted. The adoption of this guidance had no impact on our Consolidated Statements of Operations or Consolidated Statements of Comprehensive Income.

In February 2016, the FASB issued ASU No. 2016-02, “Leases” (topic 842). The FASB issued this update 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. Early adoption of the update is permitted. The Company is evaluating the impact of the adoption of this update on our consolidated financial statements and related disclosures.

Note 2. Marketable Securities and Fair Value Measurements

As of December 31, 2015 and 2014, the estimated fair value of our short-term and long-term investments, classified as available for sale, are as follows (in thousands):

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ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES
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Short-term

December 31, 2015	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Commercial paper	$38,537	$—	$—	$38,537
Corporate bonds	179,765	6	(251)	179,520
U.S. dollar dominated foreign corporate bonds	510	—	(2)	508
Municipal securities	14,209	7	(2)	14,214
U.S. government agency bonds	75,172	—	(53)	75,119
U.S. government treasury bonds	51,763	1	(81)	51,683
Total Marketable Securities, Short-Term	$359,956	$14	$(389)	$359,581

Long-term

December 31, 2015	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. government agency bonds	$43,853	$—	$(178)	$43,675
Corporate bonds	64,012	9	(217)	63,804
U.S. government treasury bonds	37,673	—	(107)	37,566
Municipal securities	3,993	—	(2)	3,991
Asset-backed securities	2,338	—	(3)	2,335
Total Marketable Securities, Long-Term	$151,869	$9	$(507)	$151,371

Short-term

December 31, 2014	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Commercial paper	$33,998	$—	$—	$33,998
Corporate bonds	152,055	27	(116)	151,966
U.S. dollar dominated foreign corporate bonds	901	—	—	901
Municipal securities	9,147	13	—	9,160
U.S. government agency bonds	41,574	14	(1)	41,587
U.S.government treasury bonds	15,770	7	—	15,777
Asset-backed securities	1,398	—	—	1,398
Total Marketable Securities, Short-Term	$254,843	$61	$(117)	$254,787

Long-term

December 31, 2014	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. government agency bonds	$48,233	$12	$(28)	$48,217
Corporate bonds	57,195	6	(112)	57,089
U.S. dollar dominated foreign corporate bonds	523	—	(2)	521
U.S. government treasury bonds	20,814	5	(6)	20,813
Municipal securities	9,552	5	(6)	9,551
Asset-backed securities	11,713	—	(12)	11,701
Total Marketable Securities, Long-Term	$148,030	$28	$(166)	$147,892

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ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

For the year ended December 31, 2015 and 2014, realized losses were immaterial. Cash and cash equivalents were not included in the table above as the gross unrealized gains and losses were not material. We have no material short-term or long-term investments that have been in continuous unrealized loss positions for greater than twelve months as of December 31, 2015. Amounts reclassified to earnings from unrealized gain or losses were immaterial in 2015 and 2014.

Our fixed-income securities investment portfolio consists of corporate bonds, U.S. dollar dominated foreign corporate bonds, commercial paper, municipal securities, U.S. government agency bonds, U.S. government treasury bonds and asset-backed securities that have a maximum maturity of two years. 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 9 months and 10 months as of December 31, 2015 and 2014, 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 maturity as of December 31, 2015 and 2014 (in thousands):

	December 31, 2015	December 31, 2014
One year or less	$359,581	$254,787
Due in greater than one year	151,370	147,892
Total available for short-term and long-term marketable securities	$510,951	$402,679

Fair Value Measurements

We measure the fair value of our cash equivalents and marketable securities 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 U.S. 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.

Our Level 1 assets consist of money market funds and U.S government treasury bonds. We did not hold any Level 1 liabilities as of December 31, 2015 or 2014.

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.

Our Level 2 assets consist of commercial paper, corporate bonds, U.S. dollar denominated foreign corporate bonds, municipal securities, U.S. government agency bonds, asset-backed securities, and our Israeli funds that are mainly invested in insurance policies and foreign currency forward contracts. We obtain these fair values for level 2 investments from our asset manager for each of our portfolios. 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. The foreign currency forward contracts are valued using observable inputs such as quotations on forward foreign exchange rates.

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 ("DCF") methodologies or similar valuation techniques, as well as significant management judgment or estimation.
We did not hold any Level 3 assets or liabilities as of December 31, 2015 and 2014.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

The following tables summarizes our financial assets measured at fair value on a recurring basis as of December 31, 2015 and 2014 (in thousands):

Description	Balance as of December 31, 2015	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)
Cash equivalents:			
Money market funds	$ 70,148	$70,148	$—
Commercial paper	36,887	—	36,887
U.S. government Agency bonds	3,599		3,599
Corporate bonds	625	—	625
Short-term investments:			
Commercial paper	38,537	—	38,537
Corporate bonds	179,520	—	179,520
U.S. dollar denominated foreign corporate bonds	508	—	508
Municipal securities	14,214	—	14,214
U.S. government agency bonds	75,119	—	75,119
U.S. government treasury bonds	51,683	51,683	—
Long-term investments:			
Corporate bonds	63,804	—	63,804
U.S. government agency bonds	43,675	—	43,675
U.S. government treasury bonds	37,566	37,566	—
Municipal securities	3,991	—	3,991
Asset-backed securities	2,335	—	2,335
Long-term other assets:			
Israeli funds	2,436	—	2,436
	$ 624,647	$159,397	$465,250

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ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Description	Balance as of December 31, 2014	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)
Cash equivalents:			
Money market funds	$80,786	$80,786	$—
Commercial paper	21,997	—	21,997
Corporate bonds	1,745		1,745
Short-term investments:			
Commercial paper	33,998	—	33,998
Corporate bonds	151,966	—	151,966
U.S. dollar denominated foreign corporate bonds	901	—	901
Municipal securities	9,160	—	9,160
U.S. government agency bonds	41,587	—	41,587
U.S. government treasury bonds	15,777	15,777	—
Certificate of Deposits	1,398		1,398
Long-term investments:			
Corporate bonds	57,089	—	57,089
U.S. government agency bonds	48,217	—	48,217
U.S. dollar denominated foreign corporate bonds	521	—	521
U.S. government treasury bonds	20,813	20,813	—
Municipal securities	9,551	—	9,551
Asset-backed securities	11,701	—	11,701
Long-term other assets:			
Israeli funds	2,307	—	2,307
	$509,514	$117,376	$392,138

Derivative Financial Instruments

In September 2015, 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, which are classified within level 2 of the fair value hierarchy. The net loss on these forward contracts was immaterial for the year ended December 31, 2015. As of December 31, 2015, the fair value of foreign exchange forward contracts outstanding was immaterial.

The following table presents the gross notional value of all our foreign exchange forward contracts outstanding as of December 31, 2015 (in thousands):

	As of December 31, 2015	
	Local Currency Amount	Notional Contract Amount (USD)
US dollar	$ 20,700	$20,700
Euro	€22,100	24,222
Japanese yen	¥583,000	4,839

Australian dollar	A$4,700	3,426
Hong Kong dollar	HK$51,000	6,579
		$59,766

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ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Note 3. Balance Sheet Components

Inventories

Inventories consist of the following (in thousands):

	December 31,	
	2015	2014
Raw materials	$9,950	$8,143
Work in process	7,067	2,970
Finished goods	2,448	4,815
Total Inventories	$19,465	$15,928

Work in process includes costs to produce our clear aligner and intra-oral scanner products. Finished goods primarily represent our intra-oral scanners and ancillary products that support our clear aligner products.

Property, plant and equipment

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

	December 31,	
	2015	2014
Clinical and manufacturing equipment	$128,044	$107,707
Computer hardware	25,843	24,092
Computer software	21,451	22,044
Furniture and fixtures	8,855	7,386
Leasehold improvements	20,172	15,358
Building	4,227	1,868
Land	3,072	1,162
CIP	42,846	18,310
Total	254,510	197,927
Less: Accumulated depreciation and amortization and impairment charges	(118,037)	(107,802)
Total Property, plant and equipment, net	$136,473	$90,125

As of December 31, 2015, CIP consists primarily of costs for capital equipment to be placed in service in the next year. In late 2014, we started an ERP project and have capitalized $25.4 million as of December 31, 2015, which we anticipate will be placed in service in 2016. Depreciation and amortization was $18.0 million, $17.9 million, and $16.8 million, for the year ended December 31, 2015, 2014 and 2013, respectively.

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ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Accrued liabilities

Accrued liabilities consist of the following (in thousands):

	December 31, 2015	2014
Accrued payroll and benefits	$55,430	$44,610
Accrued accounts payable	13,834	5,736
Accrued sales rebate	8,486	11,110
Accrued sales and marketing expenses	7,071	5,979
Accrued sales tax and value added tax	4,801	5,456
Accrued professional fees	2,775	2,494
Accrued income taxes	2,646	2,027
Accrued warranty	2,638	3,148
Other accrued liabilities	10,084	7,320
Total Accrued Liabilities	$107,765	$87,880

Warranty

We regularly review the accrued balances and update these balances 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.

Clear Aligner

We warrant our Invisalign products against material defects until the Invisalign case is complete. We accrue for warranty costs in cost of net revenues upon shipment of products. The amount of accrued estimated warranty costs is primarily based on historical experience as to product failures as well as current information on replacement costs.

Scanners

We warrant our scanners for a period of one year from the date of training and installation. We accrue for these warranty costs which includes materials and labor based on estimated historical repair costs. Extended service packages may be purchased for additional fees.

Warranty accrual as of December 31, 2015 and 2014 consists of the following activity (in thousands):

Warranty accrual, December 31, 2013	$3,104
Charged to cost of revenues	1,990
Actual warranty expenditures	(1,946)
Warranty accrual, December 31, 2014	3,148
Charged to cost of revenues	1,796
Actual warranty expenditures	(2,306)
Warranty accrual, December 31, 2015	$2,638

Note 4. Business Combinations

ICA Holdings Pty Limited

On April 30, 2013, we completed the acquisition of ICA Holdings Pty Limited ("ICA") upon the expiration of the distribution agreement between certain subsidiaries of ICA and Align Technology B.V., for a total cash consideration of approximately $8.6 million, of which $7.4 million was attributed to assets acquired, $2.4 million in liabilities assumed and $3.6 million to goodwill.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Goodwill as a result of this acquisition represents the excess of the purchase price over the fair value of the underlying net assets acquired and represents the knowledge and experience of the workforce in place. None of this goodwill will be deductible for tax purposes. Under the applicable accounting guidance, goodwill will not be amortized but will be tested for impairment on an annual basis or more frequently if certain indicators are present.

Pro forma results of operations for this acquisition have not been presented as it is not material to our results of operations, either individually or in aggregate, for the year ended 2013.

Note 5. Goodwill and Intangible Assets

Goodwill
The change in the carrying value of goodwill for the year ended December 31, 2015 for the Clear Aligner segment, which are also our reporting units, are as follows (in thousands):

	Total
Balance as of December 31, 2013	$61,623
Adjustments [1]	(254)
Balance as of December 31, 2014	61,369
Adjustments [1]	(295)
Balance as of December 31, 2015	$61,074

[1] The adjustments to goodwill were a result of foreign currency translation.

Impairment of Goodwill

We evaluate goodwill for impairment at least annually on November 30th or more frequently if indicators are present, an event occurs or circumstances changes that 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.

2013 Impairment

During March 2013, changes in the competitive environment for intra-oral scanners, including announcements from our competitors of new low-priced scanners targeted at orthodontists and general practitioner dentists in North America, caused us to lower our expectations for growth and profitability for our Scanner reporting unit. As a result, we determined that goodwill related only to our Scanner reporting unit should be tested for impairment as of March 2013. There was no triggering event related to the Clear Aligner goodwill.

We performed a step one analysis for our Scanner reporting unit which consists of a comparison of the fair value of the Scanner reporting unit against its carrying amount, including the goodwill allocated to it. In deriving the fair value of the Scanner reporting unit, we utilized the income approach which is classified as Level 3 within the fair value hierarchy. As a result of our step one analysis, we concluded that the fair value of the Scanner reporting unit was less than its carrying value; therefore, we proceeded to step two of the goodwill impairment analysis. We use a discounted cash flow (“DCF”) approach to estimate the fair value of a reporting unit, utilizing the harvest model, which we believe is the most reliable indicator of fair value of this business, and is most consistent with the approach a market place participant would use. Based on our analysis, there was no implied goodwill for the Scanner reporting unit; therefore, we recorded a goodwill impairment charge of $40.7 million in March, 2013, which represents the remaining goodwill balance in the Scanner reporting unit. None of the goodwill impairment charge was deductible for tax purposes.

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ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Annual Impairment Test

The remaining goodwill is entirely attributable to our Clear Aligner reporting unit. During the fourth quarter of fiscal 2015, we performed the annual goodwill impairment testing and found no impairment events as the fair value of our Clear Aligner reporting unit was significantly in excess of the carrying value.

Acquired Intangible 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 intra-oral scanning business.

During March 2013, changes in the competitive environment for intra-oral scanners, including announcements from our competitors of new low-priced scanners targeted at orthodontists and general practitioner dentists in North America, that caused us to lower our expectations for growth and profitability for our Scanner reporting unit. As a result, we determined that the carrying value of the Scanner long-lived assets was not recoverable as compared to the value of the undiscounted cash flows of our revised projections for the asset group. In order to determine the impairment amount of our long-lived assets, we fair valued each key component of our long-lived assets within the asset group, which involved the use of significant estimates and assumptions including replacement costs, revenue growth rates, operating margins, and plant and equipment cost trends. Upon completion of this analysis, we recorded a total impairment charge of $26.3 million of which $19.3 million represented the impairment related to our Scanner intangible assets and $7.0 million related to plant and equipment. There was no triggering event related to the Clear Aligner asset group.

There were no triggering events in 2015 that would cause further impairments of our long-lived assets.

Intangible assets arising either as a direct result from the Cadent acquisition or individually acquired are being amortized as follows (in thousands):

	Weighted Average Amortization Period (in years)	Gross Carrying Amount as of December 31, 2015	Accumulated Amortization	Impairment Charge	Net Carrying Value as of December 31, 2015
Trademarks	15	$7,100	$ (1,492)	$(4,179)	$1,429
Existing technology	13	12,600	(3,577)	(4,328)	4,695
Customer relationships	11	33,500	(10,957)	(10,751)	11,792
Other	8	285	(113)	—	172
Total Intangible Assets		$53,485	$ (16,139)	$(19,258)	$18,088

	Weighted Average Amortization Period (in	Gross Carrying Amount as of December 31, 2014	Accumulated Amortization	Impairment Charge	Net Carrying Value as of December 31, 2014

	years)				
Trademarks	15	$7,100	$ (1,354)	$(4,179)	$1,567
Existing technology	13	12,600	(3,015)	(4,328)	5,257
Customer relationships	11	33,500	(9,095)	(10,751)	13,654
Other	8	285	(76)	—	209
Total Intangible Assets		$53,485	$ (13,540)	$(19,258)	$20,687

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The total estimated annual future amortization expense for these acquired intangible assets as of December 31, 2015 is as follows (in thousands):

Fiscal Year	
2016	$2,600
2017	2,600
2018	2,600
2019	2,592
2020	2,582
Thereafter	5,114
Total	$18,088

Note 6. Legal Proceedings

Securities Class Action Lawsuit

On November 28, 2012, plaintiff City of Dearborn Heights Act 345 Police & Fire Retirement System filed a lawsuit against Align, Thomas M. Prescott ("Mr. Prescott"), Align's former President and Chief Executive Officer, and Kenneth B. Arola ("Mr. Arola"), Align's former Vice President, Finance and Chief Financial Officer, in the United States District Court for the Northern District of California on behalf of a purported class of purchasers of our common stock (the "Securities Action"). On July 11, 2013, an amended complaint was filed, which named the same defendants, on behalf of a purported class of purchasers of our common stock between January 31, 2012 and October 17, 2012. The amended complaint alleged that Align, Mr. Prescott and Mr. Arola violated Section 10(b) of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder, and that Mr. Prescott and Mr. Arola violated Section 20(a) of the Securities Exchange Act of 1934. Specifically, the amended complaint alleged that during the purported class period defendants failed to take an appropriate goodwill impairment charge related to the April 29, 2011 acquisition of Cadent Holdings, Inc. in the fourth quarter of 2011, the first quarter of 2012 or the second quarter of 2012, which rendered our financial statements and projections of future earnings materially false and misleading and in violation of U.S. GAAP. The amended complaint sought monetary damages in an unspecified amount, costs and attorneys' fees. On December 9, 2013, the court granted defendants' motion to dismiss with leave for plaintiff to file a second amended complaint. Plaintiff filed a second amended complaint on January 8, 2014 on behalf of the same purported class. The second amended complaint states the same claims as the amended complaint. On August 22, 2014, the court granted our motion to dismiss without leave to amend. On September 22, 2014, Plaintiff filed a notice of appeal to the Ninth Circuit Court of Appeals. Align intends to vigorously defend itself against these allegations. Align is currently unable to predict the outcome of this amended complaint and therefore cannot determine the likelihood of loss nor estimate a range of possible loss, if any.

Shareholder Derivative Lawsuit

On February 1, 2013, plaintiff Gary Udis filed a shareholder derivative lawsuit against several of Align's current and former officers and directors in the Superior Court of California, County of Santa Clara. The complaint alleges that our reported income and earnings were materially overstated because of a failure to timely write down goodwill related to the April 29, 2011 acquisition of Cadent Holdings, Inc., and that defendants made allegedly false statements concerning our forecasts. The complaint asserts various state law causes of action, including claims of breach of fiduciary duty, unjust enrichment, and insider trading, among others. The complaint seeks unspecified damages on behalf of Align, which is named solely as nominal defendant against whom no recovery is sought. The complaint also seeks an order directing Align to reform and improve its corporate governance and internal procedures, and seeks

restitution in an unspecified amount, costs, and attorneys' fees. On July 8, 2013, an Order was entered staying this derivative lawsuit until an initial ruling on our first motion to dismiss the Securities Action. On January 15, 2014, an Order was entered staying this derivative lawsuit until an initial ruling on our second motion to dismiss the Securities Action. On October 14, 2014, an Order was entered staying this derivative lawsuit until a ruling by the Ninth Circuit in the Securities Action discussed above. Align is currently unable to predict the outcome of this complaint and therefore cannot determine the likelihood of loss nor estimate a range of possible losses.

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 7. Credit Facility

On March 22, 2013, we entered into a credit facility with Wells Fargo Bank. The credit facility provides for a $50.0 million revolving line of credit, with a $10.0 million letter of credit sublimit, and has a maturity date on March 22, 2016. The credit facility also requires us to maintain a minimum unrestricted cash balance of $50.0 million and comply with specific financial conditions and performance requirements. The loans bear interest, at our option, at a fluctuating rate per annum equal to the daily one-month adjusted LIBOR rate plus a spread of 1.75% or an adjusted LIBOR rate (based on one, three, six or twelve-month interest periods) plus a spread of 1.75%. As of December 31, 2015, we had no outstanding borrowings under this credit facility and were in compliance with the conditions and performance requirements.

Note 8. 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 2022 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 and accrue for any rent expense incurred but not paid. Total rent expense was $8.2 million, $7.6 million and $7.3 million, for the year ended December 31, 2015, 2014 and 2013, respectively.

Minimum future lease payments for non-cancelable leases as of December 31, 2015, are as follows (in thousands):

Fiscal Year	Operating leases
2016	$10,236
2017	6,078
2018	2,475
2019	527
2020	326
Thereafter	108
Total minimum lease payments	$19,750

Off-balance Sheet Arrangements

As of December 31, 2015, we had no 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.

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 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

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a particular period. As of December 31, 2015, we did not have any material indemnification claims that were probable or reasonably possible.

Note 9. Stockholders' Equity

Common Stock

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

Stock-based Compensation Plans

Our 2005 Incentive Plan, as amended, provides for the granting of incentive stock options, non-statutory stock options, restricted stock 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. Full value awards granted prior to May 16, 2013 were counted against the authorized share reserve as one and one half (1 1/2) share for every one (1) share subject to the award, and any shares canceled that were counted as one and one half against the plan reserve will be returned at this same ratio.

As of December 31, 2015, the 2005 Incentive Plan (as amended) has a total reserve of 23,283,379 shares for issuance of which 4,869,639 shares are available for issuance. No shares were added to the plan in 2015 or 2014. 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, 2015, 2014 and 2013 is as follows (in thousands):

	For the Year Ended December 31,		
	2015	2014	2013
Cost of net revenues	$3,938	$3,616	$2,565
Selling, general and administrative	40,813	29,625	20,354
Research and development	8,192	6,582	3,519
Total stock-based compensation	$52,943	$39,823	$26,438

Stock Options

We have not granted options since 2011, thus all options outstanding are fully vested. Activity for the year ended December 31, 2015, under the stock option plans are set forth below (in thousands, except years and per share amounts):

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	Stock Options Number of Shares Underlying Stock Options	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding as of December 31, 2014	668	15.57		
Granted	—	—		
Exercised	(172)	16.82		
Cancelled or expired	—	—		
Outstanding as of December 31, 2015	496	$15.14	2.05	$25,163
Vested and expected to vest at December 31, 2015	496	$15.14	2.05	$25,163
Exercisable at December 31, 2015	496	$15.14	2.05	$25,163

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 2015 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 December 31, 2015. 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, 2015, 2014 and 2013 was $7.4 million, $24.5 million and $46.7 million, respectively. The total fair value of the options vested during the year ended December 31, 2015, 2014 and 2013 was $0.1 million, $0.7 million, $3.7 million, respectively.

All compensation costs relating to stock options have been recognized as of December 31, 2015, the total recognized tax effect from exercised options was $0.5 million.

Restricted Stock Units

The fair value of nonvested restricted stock units (“RSUs”) is based on our closing stock price on the date of grant. A summary for the year ended December 31, 2015, is as follows (in thousands, except years and per share amounts):

	Shares Underlying RSUs	Weighted Average Grant Date Fair Value	Weighted Remaining Vesting Period (in years)	Aggregate Intrinsic Value
Nonvested as of December 31, 2014	2,124	$42.08		
Granted	843	57.78		
Vested and released	(781)	38.41		
Forfeited	(107)	49.42		
Nonvested as of December 31, 2015	2,079	$49.45	1.16	$136,857

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 2015 by the number of nonvested RSUs) that would have been received by the unit holders had all RSUs been vested and released on December 31, 2015. This amount will fluctuate based on the fair market value of our stock. During 2015, of the 781,232 shares vested and released, 269,634 vested shares were withheld for employee minimum statutory tax obligations, resulting in a net issuance of 511,598 shares.

The total intrinsic value of RSUs vested and released during 2015, 2014 and 2013 was $45.9 million, $38.9 million and $20.3 million, respectively. The total fair value RSUs vested during the year ended December 31, 2015, 2014 and 2013 was $30.0 million, $22.0 million, $13.2 million, respectively. As of December 31, 2015, there was $65.2 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 2.0 years.

On an annual basis, we grant market-performance based restricted stock units (“MSUs”) to our executive officers. Each MSU represents the right to one share of Align’s common stock and will be issued through our amended 2005 Incentive Plan. 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

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performance of the NASDAQ Composite Index over the vesting period, generally two to three years, up to 150% of the MSUs initially granted.

The following table summarizes the MSU performance as of December 31, 2015:

	Number of Shares Underlying MSUs (in thousands)	Weighted Average Grant Date Fair Value