ALIGN TECHNOLOGY INC
Form 10-K
March 01, 2013

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, 2012

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 $2,641,311,855 as of June 30, 2012 based on the closing sale price of the registrant’s common stock on the NASDAQ Global Market on such date. Shares held by persons who may be deemed affiliates have been excluded. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

On February 22, 2013, 81,758,299 shares of the registrant’s common stock were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant’s definitive Proxy Statement relating to its 2013 Annual Stockholders’ Meeting to be filed pursuant to Regulation 14A within 120 days after the registrant’s fiscal year end of December 31, 2012 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 G3 and G4 and SmartTrack material, 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, including our expectations that revenue will continue to increase after we revert to a direct sales model in the Asia-Pacific region, the anticipated number of new doctors trained and their impact on volumes, 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 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 CAD/CAM Services ("SCCS"), known as the iTero intra-oral scanner and OrthoCAD services. For the year ended December 31, 2012, Clear Aligner revenues represent approximately 92 percent of worldwide revenue, while Scanners and CAD/CAM Services represent the remaining 8 percent of worldwide revenues. We distribute the vast majority of our products directly to our customers: orthodontists and general practitioner dentists, or ("GPs") sell as to restorative dentists, including prosthodontists, periodontists, and oral surgeons.

We received the United States Food and Drug Administration (“FDA”) clearance to market the Invisalign system in 1998. The Invisalign system is regulated by the FDA as a Class II medical device. In order to provide Invisalign treatment to their patients, orthodontists and GPs must initially complete an Invisalign training course. The Invisalign system is sold in North America, Europe, Asia-Pacific, Latin America and Japan. We use a distributor model for the sale of our products in non-core country markets in the Asia Pacific, Europe, the Middle East and Africa (EMEA), and Latin America regions.

On April 29, 2011, we acquired Cadent Holdings, Inc. (“Cadent”), a leading provider of 3D digital scanning solutions for orthodontics and dentistry. Since this acquisition, we manufacture the iTero digital intra-oral scanner and provide CAD/CAM restorative models for use by dental professionals and/or labs and services for orthodontic digital procedures. Scanners and CAD/CAM Services are sold through our direct sales force and distribution partners.

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 United States ("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. Options available to attempt to improve treatment aesthetics include using 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 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 dental professional can also submit an intra-oral scan or "digital impression" through an iTero intra-oral scanner instead of a physical PVS impression.

Preparation of 3D computer models of the patient's initial malocclusion. Upon receipt, we use the treatment data to construct digital models of the patient's dentition. Using computed tomography, known as CT scanning, we scan the PVS impression 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.

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.

Scanners and CAD/CAM Services Segment

Although advancements have been made in materials used for taking dental impressions since their introduction one hundred years ago, the overall impression process has remained relatively unchanged. Shortcomings such as voids, pulls, and the general margin for error have remained inherent in conventional impressions, and subsequent retakes create unnecessary cost increase for a clinical practice. 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.

As the only intra-oral scanner system in the market based on parallel confocal imaging, the iTero and iOC intra-oral scanners utilize laser and optical scanning to capture the contours of the patient's dentition, gingival structures and the bite. The intra-oral scanners capture 100,000 points of laser light in perfect focus without the use of powder to coat the teeth, allowing for contact of the wand and tooth. The benefit of contact scanning for the clinician is it eliminates the challenge of hovering over the teeth at a specific distance which can be complicated. For the patient, they enjoy a more comfortable powder free experience which allows the clinician to provide a very comfortable patient centric experience. Within minutes, an accurate 3D digital impression can be viewed on the screen. 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 computer aided placement of traditional braces; and orthodontic retainers and appliances.

Both iTero and iOC intra-oral scanners consist of a mobile computer unit, display screen, a control foot pedal and scanning wand to scan and capture a patient's dentition (full or partial dental arch). System software features include occlusal map, eraser tool, edge trim tool, real-time modeling and an option to submit scans for Invisalign treatment. The systems provide doctors and labs with an open choice to export generic digital files of their digital impression to use with other third party dental service providers. This allows the digital impression to integrate with cone beam CT images for implant and orthodontic treatment planning. OrthoCAD services are additional services available with our scanners. In-office training on the system and features is provided after the unit is delivered to the practice.

Our Products and Services

Our revenues are generated from the sale of the following product offerings.

Percentage of Revenues by Product	Fiscal Year 2012		Fiscal Year 2011		Fiscal Year 2010	
Invisalign Full	61	%	63	%	68	%
Invisalign Express/Lite	9		9		9	
Invisalign Teen	12		11		14	
Invisalign Assist	5		6		4	
Invisalign Non-case*	5		5		5	
Scanners**	4		3		—	
CAD/CAM Services**	4		3		—	
Total	100	%	100	%	100	%

* Non-case revenue includes the retainer business, training revenues, and ancillary offerings under our Clear Aligner product lines

** As the acquisition of Cadent closed on April 29, 2011, the fiscal year 2011 percentages for Scanners and CAD/CAM Services only reflect eight months of revenues.

Clear Aligner Products

Invisalign Full. Used for a wide range of malocclusion, Invisalign Full consists of the number of aligners necessary to achieve the doctor's treatment goals. For Invisalign Full, 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.

Invisalign Express (10 and 5) and Invisalign Lite/i7. Invisalign Express, Invisalign Lite and Invisalign i7 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. 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.

Invisalign Teen. Invisalign Teen includes all the features of Invisalign Full, plus additional features that address the orthodontic needs of teenage patients such as eruption compensation and six free single arch replacement

aligners. This product is predominantly marketed to orthodontists who treat the vast majority of malocclusion in teenage patients. For Invisalign Teen, 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.

Invisalign Assist. Intended for use for anterior alignment and aesthetically-oriented cases Invisalign Assist 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.

Retention. In addition to a traditional single retainer product, we also offer Vivera retainers, where we deliver four new replacement retainers to orthodontic patients which is intended to 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. Beginning in late 2009, we began introducing enhanced features across the Invisalign system. Referred to as Invisalign 1.5 (launched in September 2009), Invisalign G3 (launched in October 2010) and Invisalign G4 (launched in November of 2011), these feature enhancements are a collection of clinical innovations designed to address some of the most significant treatment challenges doctors encounter. Features 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; and
- SmartForce features engineered to achieve more predictable tooth movements using custom optimized attachments and Power Ridge.

SmartTrack™ Aligner Material. In October 2012, we announced SmartTrack, the next generation of Invisalign clear aligner material. SmartTrack is a proprietary, custom-engineered 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. SmartTrack became the new standard aligner material for Invisalign clear aligner products in North America beginning January 21, 2013 and in February 2013 for Europe, and other international markets where we have obtained regulatory approval.

Scanners and CAD/CAM Services Products

Scanners

iTero Scanner. On January 2013, we announced the new iTero scanner system available as a single hardware platform with software options for restorative or orthodontic procedures. Previously, we sold two hardware platforms, the iTero scanner for GPs, prosthodontists, periodontists, and oral surgeons and the iOC scanner for orthodontists. The new iTero scanner system replaces these two scanner platforms which will no longer be sold after February 2013. The newly redesigned iTero scanner system maintains its innovative powderless technology and features a modern design with enhanced wand optics for a smaller, more ergonomic fit, easy-to-use keyboard design and a larger working surface. Additionally, full color model rendering is available and enables clinicians to show patients a life-like final model of their scanned dentition. The new iTero delivers substantially reduced capture time through improved optics and enhanced algorithms while maintaining a high standard of digital imaging accuracy, the efficiency of open source imaging and streamlined workflow. We will begin marketing and selling the new iTero in North America beginning February 2013 and soon thereafter in select international markets.

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 exclusive Invisalign interoperability to support clear aligner orthodontic treatment.

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 ABO (American Board of Orthodontics) 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. The iRecord is available exclusively from an iTero scan.

Chair Side Applications

Invisalign Outcome Simulator. In January 2013, we announced the commercial availability of the Invisalign Outcome Simulator, our first Invisalign chair-side application powered by the iTero scanner. The interactive application provides GPs and orthodontists an enhanced platform for patient eduction 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.

Proprietary software mentioned in this Annual Report on Form 10-K such as ClinCheck software, the Invisalign Doctor Site, and enhanced features such as Invisalign G3 and Invisalign G4 are included as part of the Invisalign system and are not sold separately nor do they contribute as individual items of revenue.

Our iTero scanners include 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.

Business Strategy

Our goal is to establish Invisalign treatment as the standard method for treating malocclusion and to establish our intra-oral scanning platform as the preferred scanning protocol for 3D digital scans, ultimately driving increased product adoption by dental professionals. We intend to achieve this by focusing on the following key strategic initiatives:

1. Product innovation and clinical effectiveness. We believe that product performance and innovation is a cornerstone to our long-term goal to drive and sustain product adoption, which includes introducing new products along with significant evolution in features and functionality.
2. Enhancing the customer experience. We are committed to enhancing the customer experience through the evolution of our customer facing systems and programs making it easier for our customers to adopt our products into their practice and increase utilization.
3. Increasing the effectiveness of our consumer demand creation and extending Invisalign brand awareness. As an established and known brand within the dental industry, efficiently marketing to the consumer and creating demand is one of our key strategic objectives for driving long-term growth.
4. Growth of international markets. We will continue to focus our efforts towards increasing adoption of our products by dental professionals in our core European markets as well as expansion into new markets.

Manufacturing and Suppliers

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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 digital planning of the Invisalign system 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 solutions, CT scanning, stereolithography and automated aligner fabrication. To increase the efficiency of our manufacturing processes, we will 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 the efficiency and increase the scale of our operations, we will 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, our direct sales organization consists of approximately 200 people, which includes quota carrying sales representatives, sales management, and sales administration. Internationally, we have approximately 60 people engaged in sales and sales support for the Invisalign system. Our direct sales organization in North America is comprised of a team of territory managers and to a lesser extent, territory specialists. These territory specialists are used to enhance coverage in larger territories, especially with our lower volume GP customers. Due to the success of this sales coverage model, we expect to add approximately 20 sales representatives in 2013, predominantly in North America. In addition, when we transition our Asia-Pacific distributor to a direct sales model in May 2013, as described in the paragraph below, we will acquire approximately 15 additional sales representatives in that region.

Currently, we have three distribution partners that sell the Invisalign system in smaller non-core country markets in the Asia-Pacific, EMEA, 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. Based on the continued progress in the Asia-Pacific distributor region, we expect to revert to a direct sales model in this region in the second quarter of 2013 and therefore will not renew the Asia-Pacific distribution agreement when it expires in April 2013. As a result, on May 1, 2013, four of the largest indirect country markets of Australia, New Zealand, Hong Kong and Singapore will revert back to a direct sales region and we will begin to recognize direct sales of Invisalign products sold in that region at our full average selling price ("ASP") rather than at the discounted average sales price under the distribution agreement. In 2012, this distributor accounted for approximately 3% of worldwide revenues, and we expect them to become an even more meaningful contributor to revenue growth beginning in May 2013. In the near term, however, the assumption of the direct operating costs will offset the uplift to ASPs. Although we expect volumes and revenues will increase, we may experience

difficulties in achieving the anticipated financial benefits. The remaining eight indirect country markets in Brunei, Indonesia, Macau, Malaysia, Philippines, South Korea, Taiwan, Thailand and Vietnam will likely continue under a distribution model.

For our intra-oral scanners, we have approximately 21 direct sales representatives in North America. Our smaller intra-oral scanner sales team also leverages leads generated by our Invisalign sales and marketing resources, including customer events and industry trade-shows. We also have distribution partners that sell our iTero intra-oral scanner in North America. Effective October 2012, we terminated our agreement with Straumann as our exclusive distribution partner for iTero intra-oral scanners in Europe and our non-exclusive distribution partner North America. As a result, in the near term, we expect to have very few scanner sales internationally as we evaluate the most effective sales model to re-stage growth in this market.

We market Invisalign by communicating the benefits of the Invisalign system to dental professionals through our training programs, online and traditional mail campaigns, trade shows, trade journals and print. We also promote the benefits of Invisalign through our integrated consumer marketing platform which combines traditional print and broadcast media with a balanced mix of public relations, event marketing, and social media. The goal of this platform is to raise awareness of Invisalign and Invisalign Teen as the best options for a healthy, beautiful smile among adults and teenagers. In addition, our consumer marketing platform enables us to help prospective patients find a great Invisalign treatment practice that can meet their needs. For intra-oral scanners, in addition to leveraging Invisalign customer events and industry trade-shows to communicate the benefits of digital scanning to dental professionals, we also have training programs, educational websites and limited print advertising.

We provide training, marketing and clinical support to orthodontists and GPs. In 2012, we had more than 34,230 active Invisalign providers and more than 3,200 intra-oral scanner installed based worldwide.

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 $42.9 million for 2012, $37.2 million for 2011, and $26.0 million for 2010.

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 are also undertaking pre-commercialization trial and testing as well as making additional 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, 2012, we had 280 issued U.S. patents, 141 pending U.S. patent applications, and 224 foreign issued patents, as well as 134 pending foreign 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 SCCS 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 nature of Invisalign treatment which is prescribed by a doctor and therefore no two cases are alike, we maintain relatively low levels of backlog. The period from which treatment data (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, 2012 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. and Dentsply International, Inc. 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

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.

U.S.

U.S. Food and Drug Administration. In the U.S., we must comply with applicable FDA Quality System, dental, and medical device regulations identified in the Code of Federal Regulations (CFR). Our Invisalign products and intra-oral scanners are classified as Class II medical devices. The Invisalign system has received premarket clearance from the FDA

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pursuant to the 510(k) pre-market notification procedure, allowing us to market the Invisalign family of products in the U.S. Our intra-oral scanners are 510(k) Exempt with Special Controls, which allows us to market this product in the U.S. without submitting a 510(k) pre-market notification. We are subject to routine inspections by the FDA and state of California Food and Drug Branch (FDB) for compliance with Quality System Regulations. We maintain applicable City, State, and Federal licenses and registrations for each of our facilities.

If the FDA determines that we do not comply with the applicable FDA regulations, it can institute a wide variety of enforcement actions against us, ranging from a public Warning Letter to more severe sanctions, including but not limited to financial penalties, withdrawal of our right to market our products and/or criminal prosecution.

Health Insurance Portability and Accountability Act of 1996. Under the Health Insurance Portability and Accountability Act of 1996, or HIPAA, Congress mandated a package of interlocking administrative simplification rules to establish standards and requirements for electronic transmission of patient health information. Confidentiality and security of patient medical records and the circumstances under which these records may be used and released by healthcare professionals and their Business Associates are subject to substantial regulations under the HIPAA Standards for Privacy of Individually Identifiable Health Information, referred to as the Privacy Standard, and the Security Standard, and other state laws and regulations. The Privacy Standard governs both the disclosure and the use of confidential patient medical information, and the Security Standard governs the technical, physical, and administrative safe guards used to ensure the availability of patient records and to protect the unauthorized release or disclosure of patient information. The Privacy and Security Standards apply to healthcare providers, health insurance plans and healthcare clearinghouses, (referred to as “Covered Entities”) as well as Business Associates who perform services for Covered Entities and have access to protected patient information. We believe we have designed our product and service offerings to be compliant with the requirements of the Privacy and Security standards under HIPAA and applicable corresponding state 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 patients. Additionally, our success may be dependent on the success of healthcare participants in dealing with HIPAA requirements.

Other Federal and State Laws. As a participant in the health care industry, we are subject to extensive and frequently changing regulation under many other 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. We are a medical device manufacturer subject to FDA regulations. These regulations, among other things, require that we maintain device and facilities registrations and listings as well as promote our products consistent with our FDA 510(k) clearances. Furthermore, our health care service 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. Laws regulating medical device manufacturers and health care providers cover a broad array of subjects. For example, the confidentiality of patient medical information and the circumstances under which such information may be used by us, released for inclusion in our databases, or released by us to third parties, are subject to substantial regulation by state governments. These state laws and regulations govern both the disclosure and the use of confidential patient medical information and are evolving rapidly. In addition, provisions under the federal anti-kickback statutes prohibit, among other things, paying or offering to pay any remuneration in exchange for the referral of patients to a person participating in, or for the order, purchase or recommendation of items or services that are subject to reimbursement by, Medicare, Medicaid and other similar federal or state health care programs. Most states have also enacted illegal remuneration laws that are similar to the federal laws. These laws, which are evolving at the federal and state levels, are applicable to our financial relationships with, and any marketing or other promotional activities involving, our dental professional customers. Violations of any of these laws or regulations could subject us to a variety of civil and criminal sanctions. Furthermore, various state laws require us to report payments and other transfers of value made to dental professionals and teaching hospitals to state regulatory bodies.

Canada

In Canada, we must comply with Health Canada’s Medical Device Regulations (SOR/98-282). Our Invisalign system family of products is classified as a Class II medical device and we maintain a Medical Device License for this product. Our intra-oral scanners are classified as Class I medical device in Canada.

European Union

In the European Union, the Invisalign system is regulated as a custom device and we must comply with the requirements of the Medical Device Directives (MDD 93/42/EEC). Also, our intra-oral scanners are classified as Class I medical devices by the MDD and bear the CE mark showing that such products adhere to the European regulations. Our Quality Management System is ISO 13485:2003 certified, which facilitates commercialization of our products in Europe.

China

In 2010, we received a "Registration Certificate for Medical Device" from China's State Food and Drug Administration to market and sell the Invisalign system family of products for the treatment of malocclusion, as a Class I medical device. Currently, we do not sell our intra-oral scanners in China.

Employees

As of December 31, 2012, we had 3,176 employees, including 2,086 in manufacturing and operations, 466 in sales and marketing which includes customer care, 234 in research and development and 390 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 March 1, 2013:

Name	Age	Position
Thomas M. Prescott	57	President and Chief Executive Officer
Kenneth B. Arola (1)	57	Vice President, Finance and Chief Financial Officer
Jennifer M. Erfurth	43	Vice President, Global Human Resources
Roger E. George (1)	47	Vice President, Legal and Corporate Affairs General Counsel
Timothy A. Mack	54	Senior Vice President, Marketing and Business Development
Christopher C. Puco	52	Vice President, North American Sales
Richard Twomey	48	Vice President, International
Emory M. Wright	43	Vice President, Operations

(1) On January 30, 2013, we announced that Mr. Arola was stepping down from his position as Vice President, Finance and Chief Financial Officer, effective March 4, 2013. Mr. Arola will remain an employee until June 28, 2013. As of March 4, 2013, Mr. George will serve as Interim Chief Financial Officer.

Thomas M. Prescott has served as our President and Chief Executive Officer and as a member of our Board of Directors since March 2002. Prior to joining us, Mr. Prescott was President and Chief Executive Officer of Cardiac Pathways, Inc., a publicly-traded medical device company, from May 1999 until its acquisition by Boston Scientific in August 2001. Mr. Prescott then worked as a consultant for Boston Scientific Corporation until January 2002. Prior to working at Cardiac Pathways, Mr. Prescott held various sales, general management and executive roles at Nellcor Puritan Bennett, Inc. from April 1994 to May 1999.

Kenneth B. Arola has served as our Vice President of Finance and Chief Financial Officer since December 2007. He joined us as Vice President of Finance and Corporate Controller in August 2005. Prior to joining us, Mr. Arola served for fourteen years at Adaptec, Inc, an electronic data storage equipment company, where he held various senior finance management positions, most recently as Vice President of Finance and Corporate Controller. His experience also includes positions of increasing responsibility in various financial roles at Varian Associates and Cooper Labs.

Jennifer M. Erfurth joined Align as our Vice President of Global Human Resources in 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. 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, Legal and Corporate Affairs, General Counsel and Corporate Secretary 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 was appointed Senior Vice President, Marketing and Business Development in May 2012. He served as Senior 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.

Christopher C. Puco was appointed Vice President of North America Sales in 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.

Richard Twomey has served as our Vice President, International since May 2010. Prior to joining us, Mr. Twomey spent the past 13 years in senior management positions within divisions of Johnson & Johnson, having served most recently as president of DePuy, International Ltd., part of the DePuy Orthopaedics, a global leader in the provision of surgical implants for orthopaedic applications, as well as diversified interests in spinal, sports medicine and neurology sectors. Mr. Twomey also served as managing director and director of marketing for Johnson & Johnson Bone Tissue Management Group. Prior to Johnson & Johnson, Mr. Twomey held various sales and marketing positions at Biomet Ltd, Howmedica International Ltd., and Stafford Millar.

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 most recently 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, a continued weakness in general economic conditions, 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 continued 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 the 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. Continued 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 treatment of malocclusion, but a number of dental professionals believe that 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.

In response to challenges in our business, including increased competition, we have in the past reduced the list price of our products. We also 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; or if sales by our distributors grows at a faster pace than our direct sales, our average selling price would be adversely affected and our net revenues, gross margin and net income may be reduced. Furthermore, although the U.S. dollar is our reporting currency, a portion of our net revenues and income are generated in foreign currencies. Net revenues and income generated by subsidiaries operating outside of the United States 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 average selling price and consequently the amount of net revenues and profits in our consolidated financial statements.

As we continue to grow, we are subject to growth related risks, including risks related to capacity constraints at our existing facilities.

We are subject to growth related risks, including capacity constraints 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 and continued international expansion, we opened a new manufacturing facility in Juarez, Mexico at the end of 2011. We completed the transition of virtually all our scanner distribution, repair and CAD/CAM services from our New Jersey facility to this facility in Juarez, Mexico in the third quarter of 2012. In addition, in October 2012, we transitioned our intra-oral scanner research and development and manufacturing operations in Or Yehuda, Israel into a new, larger facility in the same city. Expansion can inherently include additional costs and start-up inefficiencies, as well as the inability to successfully integrate additional facilities or incremental capacity and to realize anticipated synergies, economies of scale or other value. Periods of contraction or reduced net sales, or other factors affecting particular sites, create other challenges.

Because we cannot always 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.

We may never achieve the anticipated benefits from our acquisitions which may have an adverse effect on our business.

We acquired Cadent Holdings, Inc. in April 2011. We acquired Cadent for their people, their technology and their existing revenue streams such as, OrthoCAD iRecord and OrthoCAD iCast in addition to their intra-oral scanning technology. This acquisition is expected to strengthen our ability to drive adoption of the Invisalign system by integrating Invisalign treatment more fully with mainstream tools and procedures in doctors' practices. In addition, we believe that the combination of the two companies will help accelerate the use of intra-oral scanning in the dental industry by leveraging Align's global sales reach, extensive professional and consumer marketing capabilities and large customer base. We also expect to complete the acquisition of our Asia-Pacific distributor in the second quarter of 2013. We may experience difficulties in achieving the anticipated financial or strategic benefits of these acquisitions. Potential risks include:

- slower adoption or lack of acceptance for intra-oral scanning products in general or our chairside features;
- our inability to increase utilization by integrating Invisalign treatment more fully with intra-oral scanners;
- difficulty in integrating the technology, operations, internal accounting controls or work force of the acquired business with our existing business;
- diversion of management resources and focus from ongoing business matters;
- retention of key employees following the acquisition;
- aggressive competition from other manufacturers of intra-oral scanners could lengthen the customer evaluation process and result in price reductions and loss of sales;
- difficulty dealing with tax, employment, logistics, and other related issues unique to international operations in Israel and the Asia-Pacific region;
- possible impairment of relationships with employees and customers as a result of the integration;
- possible inconsistencies in standards, controls, procedures and policies among the acquired businesses and Align, which may make it more difficult to implement and harmonize worldwide financial reporting, accounting, billing, information technology and other systems;
- a large portion of Cadent's operations are located in Israel, accordingly, any increase in hostilities in the Middle East involving Israel may cause interruption or suspension of business operations without warning; and
- negative impact on our results of operations and financial condition from acquisition-related charges, further impairment of goodwill, impairment of intangible assets and/or asset impairment charges.

If we cannot successfully integrate the acquired business with our existing business, our results of operations and financial condition could be adversely affected.

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 United States economy and global economies;
- changes in relationships with our distributors;
- changes in the timing of receipt of 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 predict from period to period the number of trainers or the availability of doctors required to complete intra-oral scanner installations, which may impact the timing of when revenue is recognized;
- if participation in our customer rebate program 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 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;
- 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; and
- investments in research and development to develop new products and enhancements.

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 the Invisalign system. 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 United States Food and Drug Administration ("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 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 San Jose, California facility, we also carry out research and development at locations in San Jose, Costa Rica and Moscow, Russia. In addition, our customer-care, accounts receivable, credit and collections and customer event registration organizations are located at our facility in Costa Rica. We also have operations in Israel where the design and wand assembly, intra-oral scanner manufacturing and digital modeling of our intra-oral scanners occurs. 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;
- fluctuations in currency exchange rates;

- 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;
- acts of terrorism and acts of war;
- interruptions and limitations in telecommunication services;
- product or material transportation delays or disruption, including as a result of 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.

A key step in our manufacturing process relies on sophisticated computer technology that requires new technicians to undergo a relatively long training process. 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.

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 profits 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 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 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.

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 United States. 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 key certain 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 (losses) 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.

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. 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 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.

We are currently focused on adding more functionality into our business enterprise systems to more efficiently integrate these systems with our other system applications, such as customer facing and manufacturing tools, and intend to continue this effort for the foreseeable future. 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.

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, 2012, we had issued 280 U.S. patents, 141 pending U.S. patent applications, and 224 foreign issued patents, and 134 pending foreign 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 to 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 policies or procedures may deteriorate. 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 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 valuations used to determine the fair values used to test goodwill and the undiscounted cash flows used to evaluate the recoverability of the asset group 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.

During the third quarter of 2012, we determined that sufficient indicators of potential impairment existed to require an interim goodwill impairment analysis for our Scanner and CAD/CAM Services reporting unit. As a result, we performed a goodwill impairment test as of September 30, 2012 for our Scanner and CAD/CAM Services reporting unit and concluded that the goodwill within this reporting unit was impaired. Based on our step one analysis, we concluded that the implied fair value of goodwill was substantially lower than the carrying value of the goodwill for the SCCS reporting unit. We recorded a preliminary goodwill impairment charge during the third quarter of 2012 of $24.7 million and an additional $11.9 million during the fourth quarter of 2012, representing a change in estimate, for a total impairment charge of $36.6 million. None of the goodwill impairment charge was deductible for tax purposes. As of December 31, 2012, the remaining amount of goodwill associated with our SCCS reporting unit is $40.7 million.

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. We had two executive departures in fiscal 2012 and we recently announced the departure of our Chief Financial Officer effective March 4, 2013. While we have since hired replacements for the 2012 departures and are currently conducting a search for a new CFO, there is always risk of uncertainty and instability relating to our ability to find highly qualified successors for certain executive positions and to transition the duties and responsibilities of any departing key executive in an orderly manner. 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.

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 all 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 Israel to assemble our iTero scanner. As a result, if this third party manufacturer fails to deliver its components or if we lose its services, 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. As of December 31, 2012, our North American sales organization consisted of approximately 200 people. Internationally, we had approximately 80 people engaged in sales and sales support as of December 31, 2012. 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 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 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;
- 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.

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 recently passed health care reform legislation that President Obama signed into law in March 2010. The enacted 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. Beginning in 2013, each medical device manufacturer will have to

pay an excise tax in an amount equal to 2.3 percent of the price for which

such manufacturer sells its medical devices in the U.S. This tax applies to all medical devices, including our products, which could have a material, negative impact on our results of operations and our cash flows.

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.

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 Securities and Exchange Commission ("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 are as follows:

- revenue recognition; and
- leases.

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

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

We have adopted a shareholders rights' plan to limit the possibility that we are acquired, which may mean that a transaction that shareholders are in favor of or are benefited by may be prevented.

Our board of directors has the authority to issue up to 5,000,000 shares of preferred stock and to determine the rights, preferences, privileges and restrictions of such shares without any further vote or action by our shareholders. To date, our board of directors has designated 200,000 shares as Series A participating preferred stock in connection with our shareholder rights' plan. The issuance of preferred stock under certain circumstances could have the effect of delaying

or preventing an acquisition of Align or otherwise adversely affecting the rights of the holders of our stock. The shareholder rights' plan may have the effect of rendering more difficult or discouraging an acquisition of our company which is deemed undesirable by our board of directors. The shareholder rights' plan may cause substantial dilution to a person or group attempting to acquire us on terms or in a manner not approved by our board of directors, except pursuant to an offer conditioned on the negation, purchase or redemption of the rights issued under the shareholder rights' plan.

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. During 2012, we incurred a $36.6 million impairment of goodwill which was not deductible for tax purposes.

In June 2009, the Costa Rica Ministry of Foreign Trade, an agency of the Government of Costa Rica, granted a twelve year extension of the tax incentives which were previously granted in 2002. Under these incentives, all of the income we earn in Costa Rica during these twelve year incentive periods is subject to reduced rates of Costa Rica income tax. The incentive tax rates will expire in various years beginning in 2017. The Costa Rica corporate income tax rate that would apply, absent the incentives, is 30% for 2012. As a result of these incentives, income taxes were reduced by $21.8 million in 2012. In order to receive the benefit of the incentives, we must hire specified numbers of employees and maintain 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. Our subsidiary in Israel is under audit by the local tax authority for calendar years 2006 through 2011.

ITEM 1B.UNRESOLVED STAFF COMMENTS
None.

ITEM 2.PROPERTIES
We occupy several facilities with a total office and manufacturing area of over 750,000 square feet of leased and owned properties. At December 31, 2012, the significant facilities were occupied as follows:

Location	Use	Segment	Expiration of lease
San Jose, California	Leased office for headquarters, research & development, administrative personnel	Clear Aligner and SCCS	September 2017
San Jose, Costa Rica	Leased office for administrative personnel, manufacturing personnel, and customer care	Clear Aligner and SCCS	September 2013
Juarez, Mexico	Purchased manufacturing and office facility for manufacturing and administrative personnel	Clear Aligner and SCCS	N/A
Juarez, Mexico	Leased manufacturing and office for manufacturing and administrative personnel	Clear Aligner and SCCS	July 2013
Or Yehuda, Israel	Leased manufacturing and office for manufacturing, administrative personnel, and research and development	SCCS	October 2017

We believe that our existing facilities are adequate to meet current requirements and that additional or substitute space will be available as needed to accommodate any expansion of operations.

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 President and Chief Executive Officer, and Kenneth B. Arola (“Mr. Arola”), Align's 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 between April

23, 2012 and October 17, 2012 (the "Securities Action"). The complaint alleges 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 complaint alleges that during the purported class period 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 seeks monetary damages in an unspecified amount, costs and attorney's fees. The hearing on the motion for

appointment of lead plaintiff is currently scheduled for May 30th, 2013. Align intends to vigorously defend itself against these allegations. 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 loss.

Shareholder Derivative Lawsuit

On February 1, 2013, plaintiff Gary Udis filed a shareholder derivative lawsuit against several of Align's officers and directors in the Superior Court of California, County of Santa Clara. The allegations in the complaint are similar to those presented in the Securities Action, but 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 attorney's fees. Align intends to vigorously defend itself against these allegations. 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, 2012:		
Fourth quarter	$39.39	$23.45
Third quarter	$39.82	$30.02
Second quarter	$35.15	$26.06
First quarter	$28.69	$22.39
Year Ended December 31, 2011:		
Fourth quarter	$25.58	$14.25
Third quarter	$24.06	$14.65
Second quarter	$25.94	$20.41
First quarter	$21.93	$19.10

On February 22, 2013, the closing price of our common stock on the NASDAQ Global Market was $31.88 per share. As of January 31, 2013 there were approximately 127 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.

Issuer Purchases of Equity Securities

Following is a summary of stock repurchases for the three months ended December 31, 2012 (1):

Period	Total Number of Shares Repurchased	Average Price Paid per Share	Total Number of Shares Repurchased as Part of Publicly Announced Program	Approximate Dollar Value of Shares that May Yet Be Repurchased Under the Program
October 1, 2012 through October 31, 2012	286,935	$ 26.98	286,935	$ 124,710,787
November 1, 2012 through November 30, 2012	1,127,975	$ 26.30	1,127,975	$ 95,052,512

On October 27, 2011, we announced that our Board of Directors approved a stock repurchase program pursuant to which we may repurchase up to $150.0 million of common stock. Purchases under the stock repurchase program may be made from time to time in the open market. During the fourth quarter of 2012, we repurchased approximately 1.4 million shares of common stock at an average price of approximately $26.41 per share for an aggregate purchase price of approximately $37.4 million including commissions. The common stock repurchases reduced additional paid-in capital by approximately $12.6 million and increased accumulated deficit by $24.8 million. All repurchased shares were retired.

(1) All shares were repurchased pursuant to the publicly announced repurchase program described above. We did not repurchase any shares in December 2012.

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 12/31/2007 to 12/31/2012.

COMPARISON OF 5 YEAR CUMULATIVE TOTAL RETURN
Among Align Technology, Inc., the NASDAQ Composite Index
and the S&P 1500 Composite Health Care Equipment & Supplies

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, 2012. 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 years ended December 31, 2012, 2011 and 2010 and the balance sheet data as of December 31, 2012 and 2011 from the consolidated audited financial statements included elsewhere in this Annual Report on Form 10-K. The statement of operations data for the years ended December 31, 2009 and 2008 and the balance sheet data as of December 31, 2010, 2009 and 2008 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)

	Years Ended December 31,				
	2012	2011	2010	2009	2008
Consolidated Statement of Operations Data:					
Net revenues(1)	$560,041	$479,741	$387,126	$312,333	$303,976
Gross profit(2)	$416,388	$361,283	$303,417	$233,492	$225,126
Income (loss) from operations(3)	85,592	90,360	102,734	(34,012)	15,514
Other income (expense), net	(1,296)	(419)	(731)	119	1,562
Net income (loss) before provision for (benefit from) income taxes(3)	84,296	89,941	102,003	(33,893)	17,076
Provision for (benefit from) income taxes	25,605	23,225	27,750	(2,624)	(62,911)
Net income (loss)(3)	$58,691	$66,716	$74,253	$(31,269)	$79,987
Net income (loss) per share					
Basic	$0.73	$0.86	$0.98	$(0.45)	$1.20
Diluted	$0.71	$0.83	$0.95	$(0.45)	$1.18
Shares used in computing net income (loss) per share:					
Basic	80,529	77,988	75,825	69,094	66,812
Diluted	83,040	80,294	78,080	69,094	68,064
	December 31,				
	2012	2011	2010	2009	2008
Consolidated Balance Sheet Data:					
Working capital(4)	$326,758	$236,699	$295,637	$180,056	$117,335
Total assets	756,312	649,264	476,943	355,240	279,341
Total long-term liabilities	19,224	10,366	6,222	961	229
Stockholders' equity	$581,317	$490,781	$377,747	$273,036	$218,540

(1)Net revenues for the year ended December 31, 2011 include eight months of revenues from our Scanners and CAD/CAM Services segment of approximately $28.0 million as a result of our acquisition of Cadent on April 29, 2011. Net revenues for the year ended December 31, 2010 includes a $14.3 million release of previously deferred revenue for Invisalign Teen replacement aligners.

(2)Gross profit for the year ended December 31, 2012 included acquisition and integration related costs of $0.2 million, amortization of intangible assets of $0.9 million, and exit costs of $0.5 million. Gross profit for the year ended December 31, 2011 included acquisition and integration related costs of $0.4 million, amortization of intangible assets of $0.7 million, and exit costs of $0.8 million. For years ended December 31, 2010 and 2009, gross profit included amortization of prepaid royalties of $0.8 million and $6.2 million, respectively, related to the litigation settlement with Ormco. In addition, 2010 gross profit also included the $14.3 million release of previously deferred revenue for Invisalign Teen replacement aligners.

(3)Income (loss) from operations, net income (loss) before provision for (benefit from) income taxes, and net income (loss) included:

$14.3 million release of previously deferred revenue for Invisalign Teen replacement aligners in 2010.

$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.

$0.8 million and $6.2 million of amortization of prepaid royalties related to the litigation settlement with Ormco in 2010 and 2009, respectively.

$4.5 million related to the class action litigation settlement with Leiszler in 2010.

$8.7 million benefit related to an insurance settlement over a disputed coverage under our general liability umbrella that was not previously reimbursed by our insurer related to the OrthoClear litigation in 2010.

Litigation settlement charge of $69.7 million related to Ormco in 2009.
Restructuring charges of $1.3 million and $6.2 million in 2009 and 2008, respectively.

$64.6 million benefit to income taxes as a result of the release of a tax valuation allowance on most of our deferred tax assets in 2008.

(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

Align Technology, Inc. is a global medical device company that pioneered the invisible orthodontics market with the introduction of the Invisalign system in 1999. Today, we are focused 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. Align Technology was founded in March 1997 and is 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) Scanner and CAD/CAM Services ("SCCS"), known as the iTero intra-oral scanners and OrthoCAD services. We received FDA clearance in 1998 and began our first commercial sales of Invisalign to U.S. orthodontists in 1999 followed by U.S General Practitioner Dentists (GPs) in 2002. Over the next decade, we introduced Invisalign to the European market and Japan, added distribution partners in Asia-Pacific, Latin America, and EMEA, and introduced a full range of treatment options including Invisalign Express 10, Invisalign Teen, Invisalign Assist, and Vivera retainers. By 2011, we launched Invisalign G3 and Invisalign G4, which includes significant new aligner and software features across all Invisalign products that make it easier for doctors to use Invisalign on more complex cases, and introduced Invisalign to the People's Republic of China. Most recently, we launched SmartTrack, the next generation of Invisalign clear aligner material which became the new standard aligner material for Invisalign clear aligner products in North America and Europe beginning January 21, 2013 and for other international markets where we have received regulatory approval in the first quarter of 2013.

In 2011, we acquired Cadent Holdings, Inc., a leading provider of 3D digital scanning solutions for orthodontics and dentistry, and makers of the iTero intra-oral scanner and OrthoCAD services. We believe that the combination of Align's and Cadent's technologies and capabilities creates greater growth opportunities for Align by bringing innovative new Invisalign treatment tools to customers and by extending the value of intra-oral scanning in dental practices. Intra-oral scanners provide a dental "chair-side" platform for accessing valuable digital diagnosis and treatment tools, with potential for enhancing accuracy of records, treatment efficiency, and the overall patient experience. We believe there are numerous benefits for customers and the opportunity to accelerate the adoption of Invisalign through interoperability with our intra-oral scanners. The use of digital technologies such as CAD/CAM for restorative dentistry or in-office restorations has been growing rapidly and intra-oral scanning is a critical part of enabling these new digital technologies and procedures in dental practices. Since the acquisition, we have launched significant product options and software enhancements to the scanner product line. In late 2012, we commercially launched the Invisalign Outcome Simulator, the first Invisalign chair-side application powered by the iTero scanner. The interactive application provides dentists 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. The new iTero scanner was available in North America beginning in February 2013 and will be available soon thereafter in select international markets as a single hardware platform with software options for restorative or orthodontic procedures.

The Invisalign system is offered in more than 45 countries and has been used to treat more than 2.0 million patients. Our iTero intra-oral scanner is available in over 25 countries and provide dental professionals with an open choice to send digital impressions to any laboratory-based CAD/CAM system or to any of the more than 1,800 dental labs worldwide.

Our goal is to establish the Invisalign system as the standard method for treating malocclusion and to establish our intra-oral scanning platform as the preferred scanning protocol for 3D digital scans, ultimately driving increased product adoption by dental professionals. We intend to achieve this by focusing on the key strategic initiatives set forth in the Business Strategy section in this Annual Report on Form 10-K.

In addition to the successful execution of our business strategy, there are a number of other factors which may affect our results in 2013 and beyond, which are described below:

- Product innovation and clinical effectiveness. We recently announced the introduction of SmartTrack, a proprietary, custom engineered, aligner material, designed to deliver gentle, more constant force to improve control of tooth movements with Invisalign clear aligner treatment, will build on the success we have seen with Invisalign G3/G4 and encourage even greater confidence and adoption in our customers' practices. Although the introduction of SmartTrack will result in higher cost of goods sold and reduction in gross margins in our clear aligner segment due to higher material costs, we believe these innovations are important contributors to increase utilization across our channels worldwide. Additionally, we recently introduced the new iTero scanner, which is a single hardware platform with software options for restorative or orthodontic procedures, Invisalign interoperability, as well as the Invisalign Outcome Simulator, our first chair-side application powered by our iTero scanner. We believe that over the long-term these types of product and clinical innovations will increase adoption of Invisalign and increase sales of our intra-oral scanners. However, it is difficult to predict the rate of adoption which may vary by region and channel.
- Invisalign Utilization rates. 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, or utilization. Our quarterly utilization rates for the previous 11 quarters are as follows:

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

Total utilization in the fourth quarter of 2012 decreased slightly to 4.1 cases per doctor compared to 4.2 cases in the third quarter driven primarily by the decrease in utilization by our North American Orthodontic customers from 7.7 to 7.3 cases per doctor as well as expansion of our submitting International customers. This decrease by our North American Orthodontic customers reflects a decline in the number of teen-aged cases shipped as teen case starts are down in the fourth quarter following the seasonally busier summer months. Although we expect that over the long-term our utilization rates will gradually improve, we expect that period over period comparisons of our utilization rates will fluctuate.

- Number of new Invisalign doctors trained. We continue to expand our Invisalign customer base through training new doctors. In 2012, Invisalign growth was driven primarily by the continued expansion of our customer base as we trained a total of 6,845 new orthodontists and GPs in North America and internationally. We expect to train approximately 7,220 doctors in 2013.

International Clear Aligner. We will continue to focus our efforts towards increasing adoption of our products by dental professionals in our core European markets as well as expansion into new markets. On a year over year basis, international volume increased 23%, driven primarily by growth in our direct business in Europe as well as by continued strong performance by our distribution partners. Although sales through our distribution partners represented 8% of total worldwide case shipments in 2012, sales through our distributors, particularly our partner covering the Asia-Pacific region, continued to grow at a faster rate than direct sales in other international geographic regions and we expect this trend to continue in the near term. Based on the continued progress in the Asia-Pacific region, we expect to revert to a direct sales model in this region beginning in the second quarter of 2013. Therefore, we will not renew our distribution agreement when it expires in April 2013. As a result, on May 1, 2013, four of the largest indirect country markets of Australia, New Zealand, Hong Kong and Singapore will revert back to a direct sales region and we will begin to recognize direct sales of Invisalign products sold in that region at our full average selling price ("ASP") rather than at the discounted average sales price under the distribution agreement. In 2012, this distributor accounted for approximately 3% of worldwide revenues, and we expect them to become an even more meaningful contributor to revenue growth beginning in May 2013. In the near term, however, the assumption of the direct operating costs will offset the uplift to ASPs. Although we expect volumes and revenues will increase, we may experience difficulties in achieving the anticipated financial benefits. We expect the remaining eight indirect country markets in Brunei, Indonesia, Macau, Malaysia, Philippines, South Korea, Taiwan, Thailand and Vietnam as well as the EMEA and Latin America regions will continue under a distribution model.

- Increased Sales Force Coverage. Our direct sales organization in North America is comprised of a team of territory managers and to a lesser extent, territory specialists. These territory specialists are used to enhance coverage in larger territories, especially with our lower volume GP customers. Due to the success of this sales coverage model, in 2013 we expect to add approximately 20 sales representatives in 2013, predominantly in North America. In addition, when we transition our Asia-Pacific distributor to a direct sales model in May 2013, we will acquire approximately 15 additional sales representatives in that region.
- Vivera Retainer Shipment Consolidation in North America. In the first quarter of 2013, we began consolidating Vivera retainer product shipments into one shipment per year rather than four shipments per year as had been our practice. As a result, our first quarter results will reflect approximately $4 million benefit to revenue associated with our Vivera product as we will recognize nine additional months of the subscription revenue in the first quarter instead of recognizing it ratably every quarter for one year. In addition, we will also begin to reduce freight costs as we make this change.
- International Scanner and CAD/CAM Services.In October 2012, we reached a mutual agreement to terminate the exclusive distribution arrangement with Straumann for iTero intra-oral scanners in Europe, as well as the non-exclusive distribution agreement for iTero intra-oral scanners in North America effective December 31, 2012. The global market for restorative dentistry is far more fragmented and complex than orthodontics with hundreds of thousands of labs, suppliers, general dentists and specialists. In Europe, adoption of digital restorative technology has been slowed due to challenging economic conditions and reluctance to invest in capital equipment. In view of these conditions, we expect to have very few scanner sales internationally in the near term as we determine the most effective way to re-stage growth in this market. Our direct sales model remains unchanged in North America where most of the scanner and CAD/CAM services revenue is generated.
- Increase in Invisalign Selling Price. In recent years, we have significantly increased investment in research and development resulting in product innovations, such as Invisalign G3, Invisalign G4 and SmartTrack clear aligner material. We have also continued to increase our consumer advertising spending to drive more patient demand. In addition, beginning January 1, 2013, the Federal Government imposed a new excise tax on medical device manufacturers, and Invisalign clear aligners are considered a taxable medical device. As a result of this new tax and our continued investments in research and development and consumer advertising, we increased our Invisalign pricing by adding $26.00 to $50.00 per case compared to 2012 prices, effective January 1, 2013. For 2013, we expect that the impact on our average sales price from this price increase will be offset somewhat by an expected increases in our rebate program due to the anticipated increase in utilization by our customers, increased volume from our lower price products, including Invisalign Express 5 and Invisalign i7, as well as slightly higher material costs for the SmartTrack

clear aligner material. The prices for Invisalign Teen, Invisalign retainers, and Vivera retainers will remain unchanged.

- 2013 Operating expenses. We expect operating expenses to increase in 2013 compared to 2012 due to the increase in North American sales force coverage, the acquisition of the direct sales force in Asia-Pacific, and the inclusion

of the medical device excise tax, which was enacted into law as part of the comprehensive healthcare reform legislation in March 2010.

- Balance sheet reclassification. Subsequent to our Results of Operations and Financial Conditions on Form 8-K filed with the SEC on January 30, 2013, we have made a $3.2 million reclassification of deferred revenues, which is a short-term liability to long-term deferred revenues which is included in other long-term liabilities in our consolidated balance sheet presented in this Form 10-K. This reclassification was not considered to be material and did not have an impact to our consolidated statement of cash flows or operations for 2012.
- Foreign exchange rates. Although the U.S. dollar is our reporting currency, a portion of our net revenues and income are generated in foreign currencies. Net revenues and 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 as a result are affected by changes in exchange rates. We have generally accepted the exposure to exchange rate movements without using derivative financial instruments to manage this risk. Therefore, both positive and negative movements in currency exchange rates against the U.S. dollar will continue to affect the reported amount of net revenues and income in our consolidated financial statements.

Results of Operations

Net revenues by Reportable Segment Comparison for Years Ended December 31, 2012, 2011 and 2010:

We group our operations into two reportable segments: Clear Aligner segment and Scanners and CAD/CAM Services segment.

- Our Clear Aligner segment consists of our Invisalign system which includes Invisalign Full, Express/Lite, Teen, Assist, Vivera retainers, along with our training and ancillary products for treating malocclusion.
- Our Scanners and CAD/CAM Services 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.

The below represents net revenues for our Clear Aligner segment by region, channel, and product and our Scanner and CAD/CAM Services segment by region and product for the years ended December 31, 2012, 2011 and 2010 as follows (in millions):

	Years Ended December 31,							
Clear Aligner	2012	Net Change	% Change		2011	Net Change	% Change	2010
Region and Channel								
North America								
Ortho	$172.5	$25.0	16.9	%	$147.5	$30.1	25.6 %	$117.4
GP	188.6	20.7	12.3	%	167.9	22.8	15.7 %	145.1
Total North America	361.1	45.7	14.5	%	315.4	52.9	20.2 %	262.5
International	124.8	13.3	11.9	%	111.5	21.4	23.8 %	90.1
Invisalign Teen deferred revenue release	—	—	N/A		—	(14.3)	N/A	14.3
Invisalign non-case revenues	30.7	6.0	24.3	%	24.7	4.5	22.3 %	20.2
Total (1)	$516.6	$65.0	14.4	%	$451.6	$64.5	16.7 %	$387.1
Product								
Invisalign Full	$338.6	$36.3	12.0	%	$302.3	$37.5	14.2 %	$264.8
Invisalign Express/Lite	51.5	8.9	20.9	%	42.6	8.0	23.1 %	34.6
Invisalign Teen(2)	67.1	12.6	23.1	%	54.5	1.7	3.2 %	52.8
Invisalign Assist	28.7	1.3	4.7	%	27.4	12.7	86.4 %	14.7
Invisalign non-case revenues	30.7	5.9	23.8	%	24.8	4.6	22.8 %	20.2
Total	$516.6	$65.0	14.4	%	$451.6	$64.5	16.7 %	$387.1
Scanners and CAD/CAM Services (3):								
Region								
North America	$42.2	$18.2	75.8	%	$24.0	$24.0	N/A	$—
International	1.2	(2.9)	(70.7)	%	4.1	4.1	N/A	—
Total	$43.4	$15.3	54.4	%	$28.1	$28.1	N/A	$—
Product								
Scanners	$20.0	$6.7	50.4	%	$13.3	$13.3	N/A	$—
CAD/CAM Services	23.4	8.6	58.1	%	14.8	14.8	N/A	—
Total	$43.4	$15.3	54.4	%	$28.1	$28.1	N/A	$—
Total Revenue	$560.0	$80.3	16.7	%	$479.7	$92.6	N/A	$387.1

(1) In the fourth quarter of 2012, we identified an error that the actual case refinement usage rate was lower than our estimate and, as a result, we recorded a net revenue release of $4.9 million previously deferred for case refinement of which $5.2 million was a correction of an error of which $4.5 million relates to the first three quarters for the fiscal year 2012 and $0.7 million relates to the fiscal year 2011. The adjustment was not material to any quarter within 2012. The net amount of $4.9 million is not material to the results of operations for twelve months ended December 31, 2012.

(2 Net revenues for the year ended December 31, 2010 includes a $14.3 million release of revenue previously deferred for Invisalign Teen replacement aligners. Excluding the $14.3 million for the Invisalign Teen replacement aligners, the percentage change from 2010 to 2011 was approximately 41.6%.

(3) As the acquisition of Cadent closed on April 29, 2011, the year ended December 31, 2011 balances for Scanners and CAD/CAM Services only reflect eight months of revenues.

Clear Aligner Case Volume by Channel and Product

Case volume data which represents Invisalign case shipments by channel and product, for the years ended December 31, 2012, 2011 and 2010 as follows (in thousands):

	Years Ended December 31,							
Region and Channel	2012	Net Change	% Change		2011	Net Change	% Change	2010
North America:								
Ortho	137.0	21.6	18.7	%	115.4	25.1	27.8	% 90.3
GP	139.7	16.5	13.4	%	123.2	14.1	12.9	% 109.1
Total North American Invisalign	276.7	38.1	16.0	%	238.6	39.2	19.7	% 199.4
International Invisalign	86.8	16.0	22.6	%	70.8	9.3	15.1	% 61.5
Total Invisalign case volume	363.5	54.1	17.5	%	309.4	48.5	18.6	% 260.9
Product								
Invisalign Full	235.0	28.7	13.9	%	206.3	26.6	14.8	% 179.7
Invisalign Express/Lite	58.7	14.5	32.8	%	44.2	6.8	18.2	% 37.4
Invisalign Teen	48.3	10.3	27.1	%	38.0	9.3	32.4	% 28.7
Invisalign Assist	21.5	0.6	2.9	%	20.9	5.8	38.4	% 15.1
Total Invisalign case volume	363.5	54.1	17.5	%	309.4	48.5	18.6	% 260.9

Fiscal Year 2012 compared to Fiscal Year 2011

Total net revenues increased $80.3 million in 2012 primarily as a result of volume growth of 17.5% across all regions and customer channels in our Clear Aligner segment and the inclusion of a full year of Scanner and CAD/CAM Services (SCCS) segment activity in 2012 compared to eight months in 2011.

Clear Aligner

Revenue from our Clear Aligner segment, increased by 14.4% due to increased case volumes across all products partially offset by lower ASP. Additionally, in the fourth quarter of 2012, we determined that the actual case refinement usage rate was lower than our estimate and, as a result, Invisalign revenue includes the release of $4.9 million of revenue previously deferred for case refinement (refer to Item 8 on this Form 10-K for further discussion).

North American revenue growth of 14.5% was driven by increased volumes of 16% in the Ortho Channel and GP channels due to higher utilization and an increased number of doctors submitting cases. ASP's were slightly lower due to increased discounting from our volume rebate program and a product mix shift towards our lower priced products.

International revenue growth of 11.9% was mainly due to volume increases of 22.6% across all products offset by lower ASP's due to higher discounts, unfavorable foreign exchange rates and a product mix shift towards distributor sales and lower priced products.

Invisalign non-case revenues, consisting of training fees and sales of ancillary products, were higher in 2012 compared to 2011 primarily due to increased sales of our Vivera product and training.

Scanner and CAD/CAM Services

Revenue from our Scanner and CAD/CAM Services segment, consisting of scanner and CAD/CAM services, increased by $15.3 million as a result of $18.2 million increase in North America revenue related to higher scanner volume from a full year of activity in 2012 compared to eight months in 2011. This is partially offset by a $2.9 million decrease in international revenue due to lower scanner volume as a result of the termination of our exclusive distribution agreement with Straumann for iTero intra-oral scanners. The financial results of Cadent have been included in this segment since the acquisition date on April 29, 2011.

Fiscal Year 2011 compared to Fiscal Year 2010

Total net revenues increased $92.6 million in 2011 as a result of worldwide volume growth across all customer channels and the inclusion of our Scanner and CAD/CAM Services segment.

Geographically, both North America and International revenue increased by $102.3 million due to an 18.6% growth in case volume, favorable foreign exchange rates, and the inclusion of eight months of Scanner and CAD/CAM Service revenues.

Invisalign case volume growth was driven by both improved utilization and an increase in the number of doctors submitting cases.

Revenue from our Clear Aligner segment, consisting of our Invisalign products, increased by 16.7% as a result of additional case volumes across all products. The most significant volume percentage increases were in the Invisalign Teen and Assist products. Although Invisalign Teen case volume increased 32.4%, revenue for Invisalign Teen was comparable to the prior year primarily because of the $14.3 million release of deferred revenue in 2010. Invisalign Assist revenue growth was comprised of both an increase in case volume and additional revenue being recognized as each batch is shipped over the course of treatment instead of deferring until the final batch shipment. Additionally, Invisalign non-case revenues, consisting of training fees and sales of ancillary products, were higher in 2011 compared to 2010 primarily due to increased sales of our Vivera product.

Since date of the acquisition until the end of the 2011 fiscal year end, the Scanner and CAD/CAM services segment generated $28.1 million of revenue from sales of iTero and iOC scanners and OrthoCad Services.

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

	Years Ended December 31,					
	2012	Change		2011	Change	2010	
Clear Aligner							
Cost of revenues	$110.6	$13.5		$97.1	$13.4	$83.7	
% of net segment revenues	21.4	%		21.5	%	21.6	%
Gross profit	$406.0	$51.3		$354.7	$51.3	$303.4	
Gross margin %	78.6	%		78.5	%	78.4	%
Scanners and CAD/CAM Services (1)							
Cost of revenues	$33.0	$11.6		$21.4	$21.4	$—	
% of net segment revenues	75.9	%		76.3	%	—	
Gross profit	$10.4	$3.9		$6.5	$6.5	$—	
Gross margin %	24.1	%		23.7	%	—	
Total cost of revenues	$143.6	$25.1		$118.5	$34.8	$83.7	
% of net revenues	25.7	%		24.7	%	21.6	%
Gross profit	$416.4	$55.2		$361.2	$57.8	$303.4	
Gross margin %	74.3	%		75.3	%	78.4	%

(1) The Scanners and CAD/CAM services segment was created as a result of our acquisition of Cadent on April 29, 2011 and the financial results for that segment reflect the activity since that date.

Cost of net revenues for our Clear Aligner and SCCS 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 expense.

Fiscal Year 2012 compared to Fiscal Year 2011

Clear Aligner

Gross margin remained fairly consistent 2012 compared to 2011 largely benefiting from higher sales volume that resulted in a decrease in cost per case offset by lower ASPs.

Scanner and CAD/CAM Services

Gross margin improved slightly in 2012 compared to 2011 primarily resulting from lower acquisition, integration, and exit costs partially offset by lower ASPs from our scanners as well as higher training costs.

Fiscal Year 2011 compared to Fiscal Year 2010

Gross margin decreased in 2011 compared to 2010 primarily due to the acquisition of our Scanner and CAD/CAM Services segment from Cadent, which carries a lower margin at approximately 23.5% compared to 78.5% for our Clear Aligner segment. Compared to 2010, our 2011 Clear Aligner gross margin remained flat due to higher cost per case resulting from higher material costs which was partially offset by higher case volumes. We also incurred amortization costs related to the acquired technology from Cadent of approximately $0.7 million and exit costs related to the consolidation of our New Jersey operations of approximately $0.8 million for the year ended December 31, 2011.

Sales and marketing (in millions):

	Years Ended December 31,							
	2012		Change		2011		Change	2010
Sales and marketing	$152.0		$9.8		$142.2		$28.2	$114.0
% of net revenues	27.1	%			29.6	%		29.5 %

Sales and marketing expense includes sales force and marketing compensation (including travel-related costs), media and advertising, clinical education, expenses for trade shows and industry events, product marketing and stock-based compensation expense.

Sales and marketing expense increased in 2012 compared to 2011 due primarily due to higher payroll and payroll-related costs of approximately $5.0 million which was largely attributable to the inclusion of Cadent's headcount for the full twelve months of 2012 as compared to only eight months in 2011. We also incurred higher costs related to advertising and industry events of approximately $4.4 million.

Sales and marketing expense increased in 2011 compared to 2010 due to compensation costs of approximately $15.2 million that were related to an increase in headcount as well as the inclusion of Cadent sales and marketing personnel. Additionally, we incurred higher clinical education costs primarily related to our international launch of Invisalign G3, media and advertising related target TV advertising, and travel-related costs of approximately $9.2 million.

General and administrative (in millions):

	Years Ended December 31,							
	2012		Change		2011		Change	2010
General and administrative	$95.8		$6.6		$89.2		$24.4	$64.8
% of net revenues	17.1	%			18.6	%		16.7 %

General and administrative expense includes salaries for administrative personnel, outside consulting services, legal expenses and stock-based compensation expense.

General and administrative expense for 2012 increased compared to 2011 largely due to higher legal and consulting fees of approximately $10.8 million related to ongoing litigation. We also incurred higher facility related expenses of approximately $2.5 million as a result of the inclusion of Cadent's operations for a full twelve months in 2012 compared to only eight months during 2011. Our payroll and payroll-related expenses were also higher by $2.1 million mainly due to our annual compensation adjustments and an increase in headcount. These costs were partially offset by lower consulting, accounting and legal fees of approximately $7.4 million that were directly related to the acquisition of Cadent in 2011 and lower amortization expense of approximately $2.1 million related to our non-compete agreements which were fully amortized in 2011.

General and administrative expense for 2011 increased compared to 2010 primarily due to compensation costs of approximately $12.3 million resulting from compensation and related benefits and increased in headcount due to the Cadent acquisition. We also incurred higher consulting, accounting, legal, and travel costs of approximately $11.2 million which was primarily related to the acquisition and integration of Cadent into our business operations.

Research and development (in millions):

	Years Ended December 31,				
	2012	Change	2011	Change	2010
Research and development	$42.9	$5.7	$37.2	$11.2	$26.0
% of net revenues	7.7 %		7.7 %		6.7 %

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, conducting clinical and pre-commercialization trials and testing and stock-based compensation expense.

Research and development expense increased in 2012 compared to 2011 primarily due to payroll and payroll-related costs of approximately $5.5 million which was largely attributed to the inclusion of Cadent's headcount for the full twelve months of 2012 compared to only eight months in 2011.

Research and development expense increased in 2011 compared to 2010 primarily due to higher compensation costs of approximately $6.6 million as a result of increased headcount due to the Cadent acquisition. In addition, we paid $2.0 million related to the Cadent Joint Development agreement that we entered into in January 2011 before the completion of the acquisition in April 2011. We also incurred higher travel and outside service costs of approximately $1.1 million.

Impairment of goodwill (in millions):

	Years Ended December 31,				
	2012	Change	2011	Change	2010
Impairment of goodwill	$36.6	$36.6	$—	$—	$—
% of net revenues	6.5 %		— %		— %

During the third quarter of 2012, we determined that the goodwill for our SCCS reporting unit should be tested for impairment between annual tests since an event occurred or circumstances changed that would more likely than not reduce the fair value of our SCCS reporting unit below its carrying amount. As a result of our analysis, we recorded a preliminary goodwill impairment charge during the third quarter of 2012 of $24.7 million and an additional $11.9 million during the fourth quarter of 2012, representing a change in estimate upon finalizing our 2013 annual budget process, for a total impairment charge of $36.6 million. None of the goodwill impairment charge was deductible for tax purposes, and there was no additional impairment that resulted from our annual goodwill impairment test during the fourth quarter of 2012. Refer to Note 5 for details of the impairment analysis.

Litigation settlement costs (in millions):

	Years Ended December 31,				
	2012	Change	2011	Change	2010
Litigation settlement costs	$—	$—	$—	$(4.5)	$4.5

On October 19, 2010, we entered into a memorandum of understanding to resolve a complaint filed by Dr. Leiszler. As a result, we recorded a total litigation settlement charge of $4.5 million in 2010 for settlement costs. There were no litigation settlement costs in 2012 and 2011.

Insurance settlement (in millions):

	Years Ended December 31,				
	2012	Change	2011	Change	2010
Insurance settlement	$—	$—	$—	$8.7	$(8.7)

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In June 2010, we received an $8.7 million insurance settlement over a disputed coverage under our general liability umbrella that was not previously reimbursed by our insurer related to the OrthoClear litigation. There were no insurance settlements in 2012 or 2011.

Amortization of acquired intangible assets (in millions):

	Years Ended December 31,				
	2012	Change	2011	Change	2010
Amortization of acquired intangible assets	$3.5	$1.1	$2.4	$2.4	$—

Amortization of acquired intangible assets increased in 2012 compared to 2011 reflecting a full twelve months of amortization expense for 2012 related to the Cadent acquisition in April 2011 compared to only eight months in 2011. Amortization of acquired intangibles for 2011 was approximately $2.4 million which were related to trademarks and customer relationships that were acquired as part of the Cadent acquisition in 2011.

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

	Years Ended December 31,				
	2012	Change	2011	Change	2010
Interest income	$0.8	$0.2	$0.6	$—	$0.6
Other expense, net	(2.1)	(1.1)	(1.0)	0.3	(1.3)
Total interest income and other expense, net	$(1.3)	$(0.9)	$(0.4)	$0.3	$(0.7)

Interest income and other expense, net, include interest income earned on cash balances, interest expense, foreign currency translation gains and losses and other miscellaneous charges.

Interest income in 2012 was largely consistent with 2011. Other expense, net increased in 2012 compared to 2011 by $1.1 million reflecting increase in foreign exchange losses during 2012.

Interest income in 2011 was consistent with 2010. Other expense, net decreased in 2011 compared to 2010 by $0.3 million reflecting increase in foreign exchange gain during 2011.

Provision for income taxes (in millions):

	Years Ended December 31,				
	2012	Change	2011	Change	2010
Provision for income taxes	$25.6	$2.4	$23.2	$(4.6)	$27.8
Effective tax rates	30.4%		25.8%		27.2%

The effective tax rate was 30.4%, 25.8%, and 27.2%, in fiscal years 2012, 2011, and 2010, 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, and foreign tax credits, partially offset by state income tax expense, the tax impact of certain stock-based compensation charges and, in fiscal year 2012, impairment of goodwill which is not deductible for tax purposes.

As of December 31, 2012, approximately $109.2 million of undistributed earnings from non-U.S. operations held by our foreign subsidiaries are designated as permanently reinvested outside the U.S. Accordingly, no additional U.S. income taxes or additional foreign withholding taxes have been provided thereon. 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 recover our deferred tax assets. Should there be a change in our ability to recover 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 recover 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

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feasible tax planning strategies in assessing the need for a valuation allowance. If it is not more likely than not that we expect to recover 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 recoverable. The available positive evidence at December 31, 2012 included historical operating profits and a projection of future income. As of December 31, 2012, we had a valuation allowance of approximately $27.1 million, mostly related to foreign net operating loss carryforward deferred tax assets because we cannot forecast sufficient future foreign source income to realize these deferred tax assets. These net operating loss carryforwards will result in an income tax benefit if and when we conclude it is more likely than not that the related deferred tax assets will be realized at some point in the future.
At December 31, 2012, we had federal net operating loss carryforwards of approximately $78.7 million, which, if not used, will begin to expire in 2026. These net operating loss carryforwards are subject to an annual limitation under Internal Revenue Code § 382, but are expected to be fully realized. Furthermore, we have California net operating loss carryforwards of approximately $62.1 million, which, if not used, will begin to expire in 2013. At December 31, 2012, we had research credit carryforwards of approximately $5.0 million for federal purposes and $3.4 million for California state tax purposes. If not utilized, the federal credit carryforwards will begin to expire in 2021. The California state credit can be carried forward indefinitely.
On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which would retroactively extend the federal research tax credit for two years through December 31, 2013. As a result, we expect to record a favorable benefit of approximately $0.5 million during the first quarter of 2013.

Liquidity and Capital Resources
We fund our operations from product sales and the proceeds from the sale of our common stock. As of December 31, 2012, 2011 and 2010, we had the following cash and cash equivalents, and short-term and long-term investments (in thousands):

	Years Ended December 31,		
	2012	2011	2010
Cash and cash equivalents	$306,386	$240,675	$294,664
Short-term investments	28,485	7,395	8,615
Long-term investments	21,252	—	9,089
Total	$356,123	$248,070	$312,368

Cash flows (in thousands):

	Years Ended December 31,		
	2012	2011	2010
Net cash flow provided by (used in):			
Operating activities	$133,778	$130,469	$129,529
Investing activities	(78,300)	(211,606)	(15,920)
Financing activities	10,205	27,241	14,707
Effects of exchange rate changes on cash and cash equivalents	28	(93)	(139)
Net increase (decrease) in cash and cash equivalents	$65,711	$(53,989)	$128,177

As of December 31, 2012, we had $356.1 million in cash, cash equivalents, and marketable securities. Cash equivalents and marketable securities are comprised of money market funds and highly liquid debt instruments which include corporate bonds, U.S. dollar denominated foreign corporate bonds, and U.S. government agency bonds.
As of December 31, 2012, approximately $135.1 million of cash was held by our foreign subsidiaries. We have not provided additional U.S. income taxes or additional foreign withholding taxes on approximately $109.2 million of undistributed foreign subsidiary earnings that are intended to be permanently reinvested outside the U.S. $105.4 million of the total undistributed foreign earnings relate to Costa Rica. In the event such earnings are repatriated to the U.S., the earnings would be subject to additional U.S. income taxes reduced by any foreign taxes

paid.
Operating Activities

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For the year ended December 31, 2012, cash flows from operations of $133.8 million resulted primarily from our net income of approximately $58.7 million million as well as the following:

Non-cash activities

- Impairment of goodwill related to our SCCS reporting unit was $36.6 million.
- Stock-based compensation was $21.5 million related to our equity incentive compensation granted to employees.
- Depreciation and amortization were $17.8 million related to our fixed assets and acquired intangible assets.
- Deferred taxes were $17.8 million primarily due to the utilization of deferred tax assets.
- Excess tax benefit from our share-based payments were $17.2 million.
- Other non-cash activities were $2.0 million.

Changes in working capital

- Accounts receivable increased by $9.1 million due to the increase in revenues during 2012, reducing our cash inflow from operating activities.
- Inventories increased by $5.7 million which was primarily due to increased production volumes for our intra-oral scanner products for the move to our new facility in Israel as well as procuring the new SmartTrack material for our clear aligners, increasing our cash outflow from operating activities.
- Prepaid expenses and other assets increased $3.9 million primarily due to the timing of software license and insurance policy renewals, increasing our cash outflow from operations.
- Accrued and other long-term liabilities increased by $2.9 million primarily due to higher deferred tax liabilities, decreasing our cash outflow from operations.
- Deferred revenue increased by $12.4 million primarily due to higher sales with deferred revenue components in 2012, increasing our cash inflow from operations.

For the year ended December 31, 2011, cash flows from operations of $130.5 million resulted primarily from our net income of approximately $66.7 million and the following reasons:

Non-cash activities

- Stock-based compensation of $19.1 million.
- Other non-cash activities including depreciation and amortization, deferred taxes, provision for doubtful accounts, amortization of intangible assets, benefits from tax provision for our share-based payments, and loss on the retirement/disposal of our fixed assets of $12.0 million.

Changes in working capital

- Accrued and other long-term liabilities increased by $37.1 million primarily due to the an increase of compensation and related employee benefits, income tax payable and other sales and marketing costs, decreasing our cash outflow from operations.
- Deferred revenue increased by $16.3 million primarily due to higher sales with deferred revenue components in 2011, increasing our cash inflow from operations.
- Accounts receivable increased by $21.7 million due to the increase in revenues during 2011, reducing our cash inflow from operating activities.
- Other working capital comprising of inventories, prepaid expenses and other assets, and accounts payable, resulted in a net decrease of $0.8 million, increasing our cash inflow from operations.

For the year ended December 31, 2010, cash flows from operations of $129.5 million resulted primarily from our net income of approximately $74.3 million and the following reasons:

Non-cash activities

- Deferred taxes increased by $17.3 million primarily due to the utilization of our deferred tax assets.

- Other non-cash activities including depreciation and amortization, stock-based compensation, provision for doubtful accounts, benefits from tax provision for our share-based payments, and loss on the retirement/disposal of our fixed assets resulted in a net increase of $27.4 million.

Changes in working capital

- Accounts receivable increased by $12.2 million due to the increase in revenues during 2010, reducing our cash inflow from operating activities.
- Accrued and other long-term liabilities increased by $19.7 million primarily due to the Leiszler class action settlement and an increase of our income tax payable and other sales and marketing costs, decreasing our cash outflow from operations.
- Deferred revenue increased by $2.2 million primarily due to higher sales with deferred revenue components in 2010, increasing our cash inflow from operations.
- Other working capital comprising of inventories, prepaid expenses and other assets, and accounts payable, resulted in a net decrease of $0.9 million, increasing our cash inflow from operations.

Investing Activities

Net cash used in investing activities was $78.3 million for the year ended December 31, 2012, primarily consisted of our purchase of marketable securities of $67.5 million and property and equipment purchases of $38.3 million. These costs were partially offset by net maturities of marketable securities of $25.2 million and the release of $2.5 million of funds related to unclaimed merger consideration for the acquisition of Cadent on April 29, 2011.

Net cash used in investing activities was $211.6 million for the year ended December 31, 2011, primarily consisted of our cash paid for the acquisition of Cadent of approximately $187.6 million and approximately $30.4 million of property, plant, and equipment purchases. We also had restricted cash of approximately $4.0 million which primarily represents funds we hold as unclaimed merger consideration related to the acquisition of Cadent on April 29, 2011. These costs were partially offset by net maturities of marketable securities and the proceeds from the sale of equipment of approximately $10.4 million.

Net cash used in investing activities was $15.9 million for the year ended December 31, 2010, primarily consisted of approximately $36.4 million for purchases of marketable securities and property and equipment which was partially offset by net maturities of our marketable securities of $20.6 million. Although we believe our current investment portfolio has very 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.

Financing Activities

Net cash provided by financing activities was $10.2 million for the year ended December 31, 2012 resulting from approximately $42.3 million in proceeds from the issuance of our common stock and approximately $17.2 million from excess tax benefit from our share-based compensation arrangements. These proceeds were partially offset by approximately $47.2 million common stock repurchases and $2.1 million of taxes paid for our employees' vesting of restricted stock units.

Net cash provided by financing activities was $27.2 million for the year ended December 31, 2011 primarily resulting from approximately $25.5 million in proceeds from the issuance of our common stock and approximately $11.4 million from excess tax benefit from our share-based arrangements. These proceeds were partially offset by approximately $7.8 million common stock repurchases and $2.0 million of taxes paid for our employees' vesting of restricted stock units.

Net cash provided by financing activities was $14.7 million for the year ended December 31, 2010 primarily resulting from approximately $11.8 million in proceeds from the issuance of our common stock and approximately $4.0 million from excess tax benefit from our share-based arrangements. These proceeds were partially offset by approximately $1.0 million of taxes paid for our employees' vesting of restricted stock units.

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 restricted stock units ("RSUs") which, unlike stock options, do not generate cash from exercises. As a result, we will likely generate less cash from the proceeds of the sale of our common stock in future periods. In addition, because RSUs are taxable to the individuals when they vest, the number of shares we issue to each of our executive officers will be net of applicable

withholding taxes which will be paid by us on their behalf. During 2012, 2011, and 2010, we paid $2.1 million, $1.9 million, and $1.1 million of taxes related to RSUs that vested during the period for executive officers, respectively.

Stock Repurchase

On October 27, 2011, we announced that our Board of Directors approved a stock repurchase program pursuant to which we may repurchase up to $150.0 million of common stock. Purchases under the stock repurchase program may be made from time to time in the open market. During 2012, we repurchased approximately 1.7 million shares of common stock at an average price of $27.28 per share for an aggregate purchase price of approximately $47.2 million including commissions. The common stock repurchases reduced additional paid-in capital by approximately $15.4 million and increased accumulated deficit by $31.8 million. All repurchased shares were retired. As of December 31, 2012, there remains $95.1 million under our existing stock repurchase authorization.

Contractual Obligations/Off Balance Sheet Arrangements

The impact that our contractual obligations as of December 31, 2012 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	1-2 Years	3-5 Years	More than 5 Years
Operating lease obligations	$25,718	$7,289	$11,424	$7,005	$—

Our contractual obligations table above excludes approximately $20.6 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, 2012. 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, 2012.

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 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 a particular period. As of December 31, 2012, 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.

Revenue Recognition

We recognize 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, services and extended warranties. 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 ("RSP") 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 and on estimated selling price ("ESP") if neither VSOE or TPE exist.

- VSOE – In most instances, products are sold separately in stand-alone arrangements. Services are also sold separately through renewals of contracts with varying periods. We determine VSOE based on its 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.
- ESP – The 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 does not exist for all elements, we determine ESP for the arrangement element based on sales, cost and margin analysis, as well as other inputs based on its pricing practices. Adjustments for other market and Company-specific factors are made as deemed necessary in determining ESP.

We estimate and record a provision for amounts of estimated losses on sales, if any, in the period such sales occur. We have not recorded any estimated losses for the periods presented. Provisions for discounts and rebates to customers are provided for in the same period that the related product sales are recorded based upon historical discounts and rebates.

Clear Aligner

We enter into arrangements ("treatment plans") that involve multiple future product deliverables. For example, included in the price of Invisalign Full, Invisalign Teen and Invisalign Assist, we offer optional case refinement, which is a finishing tool used to adjust a patient's teeth to the desired final position. Case refinement may be elected by the dental professional at any time during treatment however it is generally ordered in the last stages of orthodontic treatment. Invisalign Teen also includes up to six optional replacement aligners in the price of the product and may be ordered at any time throughout treatment.

We use VSOE adjusted by estimated usage rates for case refinements and replacement aligners to determine the relative selling price. In the absence of VSOE, we determine our best estimate of selling price, as if it is sold on a stand-alone basis, and take into consideration our pricing and discounting strategies, market conditions, as well as historical price. We regularly review our estimates of selling price and maintain internal controls over the establishment and update of these estimates.

We determined that our treatment plans, except Invisalign Assist with progress tracking, are comprised of three possible deliverables that represent separate units of accounting: single-batched aligners, case refinement and replacement aligners. We allocate revenue for each treatment plan based on each unit's relative selling price 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”). Beginning January 1, 2011, we were 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. Prior to January 1, 2011, revenue was deferred upon the first batch shipment and was recognized upon the final batch shipment. The Vivera retainer includes four shipments per year, and revenue is recognized ratably as each shipment occurs. In the first quarter of 2013, we will begin to consolidate Vivera Retainer product shipments down to one shipment per year, compared to the current process of four shipments per year.

Prior to January 1, 2011, we used VSOE as fair value to allocate revenue to the case refinement and replacement aligner deliverables. We deferred the fair value of case refinement and replacement aligner deliverables based on estimated usage rates and recognized the residual revenue upon initial batch shipment. The deferred revenue was subsequently recognized as the refinement and replacement aligners were shipped.

Scanners and CAD/CAM Services

We recognize revenues from the sales of iTero and iOC 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 iCast, OrthoCAD iQ, and 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. Revenue, net of related discounts and allowances, is recognized when products or equipment have been shipped, installed and on-site training completed, 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, no significant obligations remain, and allowances for discounts, returns, and customer incentives can be reliably estimated. Discounts are deducted from revenue at the time of sale or when the discount is offered, whichever is later and free cases or training is included as a deliverable in the multiple-element arrangement assessment. Returns of products, excluding warranty related returns, are infrequent and insignificant.

Services: 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.

Extended Warranties: 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.

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 pricing and discounting strategies. We will continue to review our estimates as we continue to integrate Cadent into our business.

Revenues for unlimited scanning service agreements and extended warranty are recognized ratably over the service periods. If a customer selects a pay per use basis for scanning service fees, the revenue is recognized as the service is provided.

For direct sales and sales to certain distributors, intra-oral scanner revenue is recognized once the intra-oral scanner has been installed and on-site training is completed. For other 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.

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 estimate the fair value of stock options using a Black-Scholes valuation and Monte Carlo simulation model, which requires the input of highly subjective assumptions, including the option’s expected term and stock price volatility. 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 the Cadent acquisition. These assets are amortized using the straight-line method over their estimated useful lives of one to fifteen years, 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 or whenever an event occurs or circumstances changes that 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 are based on relative synergies generated as a result of an acquisition. The impairment test for goodwill is a two-step process. Step one 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 in our consolidated financial statements). If the carrying amount of the reporting unit is in excess of its fair value, step two requires the comparison of the implied fair value of the reporting unit’s goodwill against the carrying amount of the reporting unit’s goodwill. Any excess of the carrying value of the reporting unit’s goodwill over the implied fair value of the reporting unit’s goodwill is recorded as an impairment loss.

Interim Testing

We test our goodwill balances for impairment annually on November 30th or more frequently if indicators are present or circumstances change that suggest an impairment may exist. During the third quarter of 2012, we determined that the goodwill for our SCCS reporting unit should be tested for impairment between annual impairment tests since an event occurred or circumstances changed that would more likely than not reduce the fair value of our SCCS reporting unit below its carrying amount. These indicators included the termination of an exclusive distribution arrangement with Straumann for iTero intra-oral scanners in Europe, as well as the termination of their non-exclusive distribution arrangement for iTero intra-oral scanners in North America, together with market conditions and business trends within the SCCS reporting unit. While we continue to expect revenue growth in our SCCS business, our expectations for future growth and profitability rates projected for the SCCS reporting unit are lower than our previous estimates primarily driven by overall lower than expected financial results.

As a result, we performed step one analysis for our SCCS reporting unit, which consists of a comparison of the fair value of the SCCS reporting unit against its carrying amount, including the goodwill allocated to it. In deriving the fair value of the SCCS reporting unit, we utilized a combination of both the income and market approach, which are classified as level 3 within the fair value hierarchy. The income approach provides an estimate of fair value based on discounted expected future cash flows. The market approach provides an estimate of fair value using various prices or market multiples applied to the reporting unit's operating results and then applies an appropriate control premium in order to reconcile to our market capitalization. As a result of our step one analysis, we concluded that the fair value of the SCCS reporting unit was less than its carrying value, therefore, we proceeded to perform step two of the goodwill impairment analysis.

Step two of the goodwill impairment analysis measures the impairment charge by allocating the reporting unit's fair value to all of the assets and liabilities of the reporting unit in a hypothetical analysis that calculates the implied fair value of goodwill in the same manner as if the reporting unit was being acquired in a business combination. This allocation process was performed only for the purposes of measuring the goodwill impairment, and not to adjust the carrying values of the recognized tangible assets and liabilities. 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. Based on our analysis, the implied fair value of goodwill was substantially lower than the carrying value of the goodwill for the SCCS reporting unit. We recorded a preliminary goodwill impairment charge during the third quarter of 2012 of $24.7 million and an additional $11.9 million during the fourth quarter of 2012, representing a change in estimate upon finalizing our 2013 annual budget process, for a total impairment charge of $36.6 million. None of the goodwill

impairment charge was deductible for tax purposes.

Annual Impairment Test

In addition to our interim goodwill testing for our SCCS reporting unit, we also performed our annual goodwill impairment test for both our reporting units, Clear Aligner and SCCS, on November 30th, in accordance with our accounting policy. In step one, we compare the carrying value of our reporting units to the estimated fair value as determined by both the income and market approaches. For our Clear Aligner reporting unit, we determined that the estimated fair value significantly exceeded its carrying value and therefore was not at risk for impairment.

For our SCCS reporting unit, we concluded that the carrying value of this reporting unit exceeded its estimated fair value, therefore, we proceeded to step two of the goodwill impairment analysis. As a result, we performed step two of the goodwill impairment analysis to quantify the amount of impairment, if any, based on our analysis as of November 30, 2012. In this step, the estimated fair value of the entire SCCS reporting unit was allocated to all of the assets and liabilities in a hypothetical analysis that calculated the implied fair value of goodwill in the same manner as if the reporting unit was being acquired in a business combination. The allocation process was performed only for purposes of measuring the goodwill impairment, and not to adjust the carrying values of recognized tangible assets or liabilities. Accordingly, we did not record any impairment charge under our step two analysis as the implied fair value of the allocated goodwill exceeded the carrying value as of November 30, 2012 by approximately 10%. A change in any one of the key assumptions as described below would result in an additional impairment:

- A 1.9 percentage point decrease to the discount rate used to determine the fair value of our Customer relationship intangible asset.

- A 12 percentage point increase in the costs to support new customers which is factored in the fair value of our Customer relationship intangible asset.

- A one percentage point decrease in the terminal growth rate assumption in the discounted cash flow model used in the income approach.

In conjunction with our goodwill impairment test, we tested for recoverability of the SCCS asset group including the carrying value of the intangible assets and concluded the asset group including the intangible assets was not impaired as determined by the undiscounted cash flows of the asset group under the long-lived asset impairment guidance. As such, no writedown of the intangible assets were recorded as of November 30th or during 2012.

Although no impairment existed for the intangible assets, because the carrying value of intangible assets included in step one of the goodwill impairment test are significantly higher than the hypothetical fair value of the reporting unit's intangible assets used in step two of the goodwill impairment test, the SCCS reporting unit will continue to fail step one of the goodwill impairment test. We have determined that, for the foreseeable reporting periods, the SCCS reporting unit will continue to fail step one of the goodwill impairment test but may pass step two.
In fiscal years 2011 and 2010 we performed the annual goodwill impairment testing during the fourth quarter for our reporting unit(s) and found no impairment as the fair value of our reporting unit(s) was significantly in excess of the carrying value.

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 a long-lived asset 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. There were no asset impairments during 2012, 2011 or 2010.
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 uncertain tax issues 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, 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. 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 recover our deferred tax assets. Should there be a change in our ability to recover 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 recover 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 not more likely than not that we will recover 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 recoverable. The available positive evidence at December 31, 2012 included historical operating profits and a projection of future income sufficient to realize most of our remaining deferred tax assets. As of December 31, 2012, 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.

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. Such unrecognized deferred tax benefits totaled $23.0 million as of December 31, 2012 and will be accounted for as a credit to additional paid-in capital, if and when 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.

U.S. income taxes and foreign withholding taxes associated with the repatriation of earnings of foreign subsidiaries were not provided for on a cumulative total of $109.2 million of undistributed earnings for certain foreign subsidiaries as of the end of the year ended December 31, 2012. We intend to reinvest these earnings indefinitely in our foreign subsidiaries. If these earnings were distributed to the United States 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.

Recent Accounting Pronouncements

See Note 1 “Summary of Significant Accounting Policies” in the Notes to our 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, 2012, we had approximately $49.7 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, 2012 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 sell our products in the local currency for the respective countries. This provides some natural hedging because most of the subsidiaries' operating expenses are denominated in their local currencies as discussed further below. Regardless of this natural hedging, our results of operations may be adversely impacted by the exchange rate fluctuation. 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, we are not currently engaged in any financial hedging transactions. 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							
	2012				2011			
	31-Dec	30-Sep	30-Jun	31-Mar	31-Dec	30-Sep	30-Jun	31-Mar
	(in thousands, except per share data)							
	(unaudited)							
Net revenues(1)	$142,840	*$136,496	$145,626	$135,079	$128,905	$125,894	$120,086	$104,856
Gross profit(2)	106,478	100,350	108,800	100,760	95,550	92,370	91,137	82,226
Income from operations(3)	17,071	4,503	36,012	28,006	26,430	26,312	16,595	21,023
Net income (loss)(3)	9,559	(353)	28,492	20,984	20,449	19,264	11,162	15,841
Net income per share:								
Basic	$0.12	$(0.00)	$0.35	$0.26	$0.26	$0.25	$0.14	$0.21
Diluted	$0.12	$(0.00)	$0.34	$0.26	$0.25	$0.24	$0.14	$0.20
Shares used in computing net income per share:								
Basic	81,043	81,437	80,384	79,235	78,737	78,455	77,888	76,844
Diluted	82,981	81,437	82,954	81,856	80,849	80,266	80,321	79,361

* In the fourth quarter of 2012, we identified an error that the actual case refinement usage rate was lower than our estimate and, as a result, we recorded a net revenue release of $4.9 million previously deferred for case refinement of which $5.2 million was a correction of an error of which $4.5 million relates to the first three quarters for the fiscal year 2012 and $0.7 million relates to the fiscal year 2011. The adjustment was not material to any quarter within 2012. The net amount of $4.9 million is not material to the results of operations for twelve months ended December 31, 2012.

(1) Net revenues for the quarters ended June 2011, September 2011 and December 2011 include revenues from our scanners and CAD/CAM services business of approximately $6.4 million, $11.6 million, and $10.0 million, respectively, as a result of our acquisition of Cadent on April 29, 2011. Net revenues for the quarter ended June 2010 included a $14.3 million release of previously deferred revenue for Invisalign Teen replacement aligners.

(2) Gross profit for the quarter ended March 2012 included acquisition and integration related costs of $0.1 million, amortization of intangible assets of $0.3 million, and exit costs of $0.3 million. Gross profit for the quarter ended June 2012 included acquisition and integration related costs of $0.1 million, amortization of intangible assets of $0.2 million, and exit costs of $0.1 million. Gross profit for the quarter ended September 2012 included acquisition and integration related costs of $0.1 million, amortization of intangible assets of $0.2 million, and exit costs of $0.1 million. Gross profit for the quarter ended December 2012 amortization of intangible assets of $0.2 million. Gross profit for the quarter ended June 2011 included acquisition and integration related costs of $0.1 million and amortization of intangible assets of $0.2 million. Gross profit

for the quarter ended September 2011 included acquisition and integration related costs of $0.2 million, amortization of intangible assets of $0.3 million and exit costs of $0.2 million. Gross profit for the quarter ended December 2011 included acquisition and integration related costs of $0.1 million, amortization of intangible assets of $0.3 million, and exit costs of $0.6 million.

(3) Income (loss) from operations and net income (loss) included:

- $14.3 million release of previously deferred revenue for Invisalign Teen replacement aligners for quarter ended June 2010.
- Acquisition and integration related costs of $0.7 million for the quarter ended March 2012, $0.3 million for the quarter ended June 2012, and $0.2 million for the quarter ended September 2012.

- Acquisition and integration related costs of $1.5 million for the quarter ended March 2011, $5.9 million for the quarter ended June 2011, $1.5 million for the quarter ended September 2011 and $1.1 million for the quarter ended December 2011.
- Amortization of intangible assets of $1.1 million for the quarter ended March 2012, $1.1 million for the quarter ended June 2012, $1.0 million for the quarter ended September 2012 and $1.0 million for the quarter ended December 2011
- Amortization of intangible assets of $0.8 million for the quarter ended June 2011, $1.1 million for the quarter ended September 2011 and $1.3 million for the quarter ended December 2011.
- Exit costs of $0.5 million for the quarter ended March 2012, $0.2 million for the quarter ended June 2012, and $0.1 million for the quarter ended September 2012.
- Exit costs of $0.2 million for the quarter ended September 2011 and $0.8 million for the quarter ended December 2011.
- Impairment of goodwill of $24.7 million for the quarter ended September 2012 and $11.9 million for the quarter ended December 2012.

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 and 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, 2012. In making this assessment, management used the criteria set forth in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

Based on its assessment and those criteria, management has concluded that, as of December 31, 2012, our internal control over financial reporting was effective based on criteria in Internal Control - Integrated Framework issued by the COSO.

The effectiveness of our internal control over financial reporting as of December 31, 2012 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report which is included herein.

/S/ THOMAS M. PRESCOTT
Thomas M. Prescott
President and Chief Executive Officer
March 1, 2013

/S/ KENNETH B. AROLA
Kenneth B. Arola
Vice President, Finance and Chief Financial Officer
March 1, 2013

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

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, 2012 and December 31, 2011, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2012 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, 2012, based on criteria established in Internal Control—Integrated Framework 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.

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

March 1, 2013

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

	Years Ended December 31,		
	2012	2011	2010
Net revenues	$560,041	$479,741	$387,126
Cost of revenues	143,653	118,458	83,709
Gross profit	416,388	361,283	303,417
Operating expenses:			
Sales and marketing	152,041	142,174	114,013
General and administrative	95,840	89,152	64,790
Research and development	42,869	37,154	25,997
Impairment of goodwill	36,591	—	—
Litigation settlement costs	—	—	4,549
Insurance settlement	—	—	(8,666)
Amortization of acquired intangible assets	3,455	2,443	—
Total operating expenses	330,796	270,923	200,683
Income from operations	85,592	90,360	102,734
Interest income	757	552	555
Other expense, net	(2,053)	(971)	(1,286)
Net income before provision for income taxes	84,296	89,941	102,003
Provision for income taxes	25,605	23,225	27,750
Net income	$58,691	$66,716	$74,253
Net income per share:			
Basic	$0.73	$0.86	$0.98
Diluted	$0.71	$0.83	$0.95
Shares used in computing net income per share:			
Basic	80,529	77,988	75,825
Diluted	83,040	80,294	78,080

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

ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS COMPREHENSIVE INCOME
(in thousands)

	Years Ended December 31,		
	2012	2011	2010
Net income	$58,691	$66,716	$74,253
Net change in cumulative translation adjustment	129	10	(19)
Change in unrealized gains (losses) on available-for sale securities, net of tax	28	(98)	(302)
Other comprehensive income (losses)	157	(88)	(321)
Comprehensive income	$58,848	$66,628	$73,932

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, 2012	2011
ASSETS		
Current assets:		
Cash and cash equivalents	$306,386	$240,675
Restricted cash	1,575	4,026
Marketable securities, short-term	28,485	7,395
Accounts receivable, net of allowance for doubtful accounts and returns of $2,484 and $780, respectively	98,992	91,537
Inventories	15,122	9,402
Prepaid expenses and other current assets	35,233	31,781
Total current assets	485,793	384,816
Marketable securities, long-term	21,252	—
Property, plant and equipment, net	79,191	53,965
Goodwill	99,236	135,383
Intangible assets, net	45,777	50,022
Deferred tax assets	21,609	22,337
Other assets	3,454	2,741
Total assets	$756,312	$649,264
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$19,549	$19,265
Accrued liabilities	74,247	76,600
Deferred revenues	61,975	52,252
Total current liabilities	155,771	148,117
Other long-term liabilities	19,224	10,366
Total liabilities	174,995	158,483
Commitments and contingencies (Notes 7 and 9)		
Stockholders' equity:		
Preferred stock, $0.0001 par value (5,000 shares authorized; none issued)	—	—
Common stock, $0.0001 par value (200,000 shares authorized; 80,611 and 78,776 issued and outstanding in 2012 and 2011, respectively)	8	8
Additional paid-in capital	670,732	607,240
Accumulated other comprehensive income, net	203	46
Accumulated deficit	(89,626)	(116,513