ALIGN TECHNOLOGY INC
Form 10-K
February 24, 2011
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SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

x **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2010

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	The NASDAQ Stock Market LLC
(Including associated Preferred Stock Purchase Rights)	(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 x 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 x

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 x 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 x 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. x

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 ¨
Non-accelerated filer ¨	(Do not check if a smaller reporting company)	Smaller reporting company ¨

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ¨ No x

The aggregate market value of the registrant s common stock held by non-affiliates of the registrant was $1,101,023,930 as of June 30, 2010 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 18, 2011, 76,878,090 shares of the registrant s common stock were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant s definitive Proxy Statement relating to its 2011 Annual Stockholders Meeting to be filed pursuant to Regulation 14A within 120 days after the registrant s fiscal year end of December 31, 2010 are incorporated by reference into Part III of this Annual Report on Form 10-K.

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ALIGN TECHNOLOGY, INC.

FORM 10-K

For the Year Ended December 31, 2010

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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, 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 continued growth of our international markets, including the expected commercial launch of Invisalign in China in the second half of 2011, the anticipated number of new doctors trained and reactivated 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 7 Management s Discussion and Analysis of Financial Condition and Results of Operations , and in particular, the risks discussed below in Part I, Item 1A Risk Factors . We undertake no obligation to revise or update these forward-looking statements. Given these risks and uncertainties, readers are cautioned not to place undue reliance on such forward-looking statements.

PART I

ITEM 1. BUSINESS

Our Company

Align Technology, Inc. (We , Our , or Align) designs, manufactures and markets the Invisalign system, a proprietary method for treating malocclusion, or the misalignment of teeth. Invisalign corrects malocclusion using a series of clear, nearly invisible, removable appliances that gently move teeth to a desired final position. Because it does not rely on the use of metal or ceramic brackets and wires, Invisalign significantly reduces the aesthetic and other limitations associated with metal arch wires and brackets, commonly referred to as braces. We received the United States Food and Drug Administration (FDA) clearance to market Invisalign in 1998. The Invisalign system is regulated by the FDA as a Class II medical device.

We distribute the vast majority of our products directly to our customers: the orthodontist and the general practitioner dentist, or GP. In order to provide the Invisalign treatment solution 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 parts of the Asia Pacific, Latin American, and smaller country markets in Europe, the Middle East and Africa regions.

We were incorporated in Delaware in April 1997. Our headquarters are currently located at 2560 Orchard Parkway, San Jose, California 95131, and our telephone number is 408-470-1000. Our international headquarters are located in Amsterdam, Netherlands. Our digital planning and software facility is located in San Jose, Costa Rica and our aligner manufacturing facility is located in Juarez, Mexico.

Industry Background

Malocclusion

Malocclusion, or the misalignment of teeth, is one of the most prevalent clinical dental conditions, affecting approximately 50 to 75% of the population of major developed countries or nearly a billion individuals. 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 our served

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market. While most individuals seek orthodontic treatment to improve their appearance, malocclusion may also be responsible for dental problems such as tooth decay, tooth loss, gum disease, jaw joint pain and headaches. Because of the compromised aesthetics, discomfort and other drawbacks associated with traditional orthodontic treatments, only a relatively small proportion of people with malocclusion seek treatment.

Traditional Orthodontic Treatment

In the U.S., dental professionals treat malocclusion primarily with metal arch wires and brackets, commonly referred to as braces. Occasionally, dental professionals attempt to improve treatment aesthetics by using ceramic, tooth-colored brackets or bond brackets on the inside, or lingual surfaces, of the patient s teeth. Dental professionals also augment braces with elastics, metal bands, headgear and other ancillary devices.

The average treatment takes approximately 12 to 24 months to complete and requires several hours of direct dental professional involvement, or chair time. To initiate treatment, a dental professional will diagnose a patient s condition and create an appropriate treatment plan. In a subsequent visit, the dental professional will bond brackets to the patient s teeth with a bonding agent and attach an arch wire to the brackets. Thereafter, by tightening or otherwise adjusting the braces approximately every six weeks, the dental professional is able to exert sufficient force on the patient s teeth to achieve desired tooth movement. In a final visit, 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.

Fees for traditional orthodontic treatment in the U.S. typically range between $3,500 to $8,000 with a median fee of approximately $5,000; generally only a portion of the fee is reimbursed by insurance. Fees are based on the difficulty of the particular case and on the dental professional s estimate of chair time, and are generally negotiated in advance. A treatment that exceeds the dental professional s estimate of chair time generally results in decreased fees per hour of chair time, and reduced profitability for the dental professional.

Limitations of Traditional Orthodontic Treatment

Although braces are generally effective in correcting a wide range of malocclusions, they are subject to many limitations and disadvantages. Traditional orthodontic treatment is associated with:

Unattractive appearance. Braces call attention to the patient s condition and treatment. In addition, braces trap food, which can further compromise appearance. Braces can also result in permanent discoloration of teeth. As a result of these and other limitations, relatively few adults with malocclusion elect traditional orthodontic treatment and braces can compromise the self esteem of young adults and teenagers.

Oral discomfort. Braces are sharp and bulky and can abrade and irritate the interior surfaces of the mouth. The tightening or adjustment of braces results in root and gum soreness and discomfort, especially in the few days immediately following an orthodontic visit.

Poor oral hygiene. Braces can make it difficult to brush and floss leaving teeth vulnerable to developing decay, plaque, periodontal disease and stains that must be taken care of after braces are removed. Additionally, the bonding of brackets to teeth can cause permanent markings on the teeth.

Inability to project treatment. Historically, dental professionals have not had a means to model the movement of teeth over a course of treatment. Accordingly, dental professionals must rely on intuition and judgment to plan and project treatment. As a result, they cannot be precise about the direction or distance of expected tooth movement between patient visits. This lack of predictability may result in unwanted tooth movements and can limit the dental professional s ability to estimate the duration of treatment. Because most orthodontic treatment is performed on a fixed price basis, extended treatment duration reduces profitability for the dental professional.

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Physical demands on dental professional. The manipulation of wires and brackets requires sustained manual dexterity and visual acuity, and may place other physical burdens on the dental professional.

Root resorption. The sustained high levels of force associated with traditional treatment can result in root resorption, which is a shortening of tooth roots. This shortening can have substantial adverse periodontal consequences for the patient.

Emergencies. At times, brackets and wires need to be repaired or replaced on an emergency basis. Such emergencies cause significant inconvenience to both the patient and the dental professional.

Due to the poor aesthetics, discomfort and other limitations of braces, relatively few adults with malocclusion elect traditional orthodontic treatment. Additionally, teenagers that seek orthodontic treatment have traditionally only had the option of braces for treatment. Accordingly, we believe there is a large unmet need for an alternative orthodontic treatment that addresses these patient concerns.

The Invisalign Solution

Invisalign is a proprietary system for treating malocclusion based on a series of doctor-prescribed, custom manufactured, clear plastic removable orthodontic appliances (aligners). The Invisalign system offers a range of treatment options, specialized services, and proprietary software for treatment visualization. Comprised of several phases, the principal steps of the Invisalign system are the creation of customized digital treatment plans using proprietary software known as ClinCheck software, which occurs in our facility in San Jose, Costa Rica, and the manufacturing of customized Invisalign aligners, which occurs in our facility in Juarez, Mexico.

Orthodontic diagnosis and transmission of treatment data to us. In an initial patient visit, the dental professional determines whether Invisalign is an appropriate treatment. The dental professional then prepares a treatment data package which consists of 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 impression is a critical component of the Invisalign system as it depicts the three-dimensional geometry of the patient s teeth and hence forms the basis for our computer models and subsequent molds and aligners. An impression requires the patient to bite into a viscous material. This material hardens, capturing the shape of the patient s teeth. The prescription is also a critical component of the Invisalign system, describing the desired positions and movement of the patient s teeth. The dental professional sends the treatment data to our facility in Juarez, Mexico.

Preparation of three-dimensional 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. We then transmit this initial computer model together with the dental professional s prescription and supplemental materials electronically to our facility in San Jose, Costa Rica.

Preparation of computer-simulated treatment and viewing of treatment using ClinCheck software. In Costa Rica, we transform this initial digital model into a proposed custom, three-dimensional treatment plan that simulates appropriate tooth movement in a series of two-week increments. This simulated treatment plan, called a ClinCheck treatment plan, is based on an internally developed and proprietary computer modeling program that allows dental professionals to diagnose and plan treatments for their patients. This ClinCheck treatment plan is then reviewed for adherence to prescribed clinical treatment and quality standards. Upon completion of the review, the patient s ClinCheck treatment plan is then made available to the prescribing dental professional via the Invisalign Doctor Site (formally known as the Virtual Invisalign Practice or VIP), our proprietary customer interfacing software portal, which is available on our websites located at *www.invisalign.com* and *www.aligntechinstitute.com*. The dental professional then reviews the ClinCheck treatment plan and can either accept the proposed treatment or request modifications and adjustments until satisfied with the treatment

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plan. The ClinCheck animation allows the dental professional to view this three-dimensional simulation with a high degree of magnification and from any angle. Accordingly, the ClinCheck treatment plan 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 and, thus participates in the customized design of the aligners. At this point, the dental professional may also invite the patient to view the treatment plan, allowing the patient to see the projected course of treatment. The dental professional s final approval of the proposed ClinCheck treatment plan engages us to manufacture the corresponding molds and aligners in Juarez, Mexico.

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. These molds are then used to fabricate the patient s aligners.

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 customized to perform the treatment prescribed by dental professionals for an individual patient by using a ClinCheck treatment plan. Each aligner covers a patient s teeth and is nearly invisible when worn. Aligners are commonly worn in pairs, over the upper and lower dental arches. 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 the teeth movement with each aligner stage. This process is repeated until the final aligners are used and treatment is complete. When treating with Invisalign Full, Invisalign Express and Invisalign Teen, aligners are manufactured and then delivered to the dental professionals in a single shipment. For Invisalign Assist, when the progress tracking feature is selected, aligners are shipped to the dental professional after every nine stages. In certain cases, dental professionals may use Invisalign in conjunction with tooth-colored attachments bonded to the patient s teeth. These attachments are used to increase the force applied to a tooth or teeth in circumstances where the aligners alone may have difficulty in effecting the desired movement. We provide an aligner-like template to the dental professionals to aid the placement of bonding attachments to the patient s teeth where needed. Also, in cases where interproximal reduction, or IPR, is required or requested by the dental professional, we provide an IPR treatment form, quantifying the amount of space to be created through enamel reduction, location, and timing of IPR.

Retention. Upon completion of the treatment, the patient may be prescribed our single clear retainer product or our Vivera retainer product. Vivera retainers are shipped every three months over the one year period.

Our Products

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

Percentage of Revenues by Product	Fiscal Year 2010	Fiscal Year 2009	Fiscal Year 2008
Invisalign Full	68%	75%	84%
Invisalign Express/Lite	9	9	8
Invisalign Teen	14	8	2
Invisalign Assist	4	3	
Non-case	5	5	6
Total	100%	100%	100%

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Invisalign G3. In October of 2010, we launched Invisalign G3, the most significant collection of new features and innovation in our company s history touching virtually every system and product. Significant improvements and enhancements were made to all our customer-facing systems. For instance, the Invisalign Doctor Site now consolidates all of a patient s Invisalign records and treatment tasks together in one location for easy access and the ClinCheck software now includes drag and drop features, additional clinical tools and a more intuitive interface. In addition, with the exception of our Vivera retainers, we introduced new and expanded features across our product line. Engineered to deliver even better clinical results, the new Invisalign G3 aligner and software features make it easier to use Invisalign with patients who have Class II and Class III malocclusion. The new features include:

- Precision Cuts which are custom mesial and distal hooks 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
- New SmartForce features engineered to achieve more predictable tooth movements using custom optimized attachments and Power Ridges.

Invisalign G3 is currently available in North America and will be launched internationally in the second quarter of 2011.

Invisalign Full. Invisalign Full is intended to be used as a complete treatment for a broad range of malocclusions. Each treatment plan is unique to the individual patient and will consist of as many aligners as indicated by ClinCheck treatment plan in order 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 Express and Invisalign Lite. Invisalign Express and Invisalign Lite are lower-cost solutions for less complex orthodontic cases that meet certain predetermined clinical criteria and includes non-comprehensive treatment relapse cases, for minor crowding and spacing, or as a pre-cursor to restorative or cosmetic treatments such as veneers. Invisalign Express uses up to 10 sets of aligners and is sold in the U.S. and Canada. Invisalign Lite uses up to 14 sets of aligners and is sold to our International regions. For Invisalign Express/Lite, aligners are manufactured and then delivered to the dental professionals in a single shipment.

Invisalign Teen. Invisalign Teen is designed to meet the specific needs of the non-adult comprehensive or teen treatment market. Invisalign Teen includes features such as compliance indicators to help gauge patient wear and compliance and specially engineered aligner features to address the natural eruption of key teeth common in teen patients. Predominantly marketed to orthodontists who treat the vast majority of malocclusion in teen patients, these features are intended to meet the treatment needs of those younger patients. As part of Invisalign Teen, we include up to six free individual replacement aligners during active treatment to cover potential aligner loss. For Invisalign Teen, aligners (other than the replacement aligners) are manufactured and then delivered to the dental professionals in a single shipment.

Invisalign Assist. Invisalign Assist is designed specifically for GPs who want more support in selecting, monitoring and finishing Invisalign cases. Intended to help newly-trained and lower volume GPs accelerate the adoption and frequency of use of Invisalign into their practice, Invisalign Assist is intended to make it easier for GPs to select appropriate cases for their experience level or treatment approach, submit cases more efficiently and manage appointments with suggested tasks. In addition, progress tracking features allow GPs 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.

Retention. In addition to our traditional single retainer product, we offer Vivera retainers, where we deliver a new replacement retainer to orthodontic patients every three months for one year. Vivera retainers are produced using the same proprietary technology and material as the Invisalign aligners, and offer an effective, aesthetic retention solution for both Invisalign and non-Invisalign patients.

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Training, Ancillary and Other. The remaining net revenues are generated by training fees and sales of ancillary products, such as cleaning material and adjusting tools used by dental professionals during the course of treatment.

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

Benefits of Invisalign

We believe that Invisalign provides benefits to dental professionals and patients that have the potential to establish Invisalign as the preferred alternative to traditional braces.

Benefits to the dental professional

Ability to visualize the treatment plan and treatment options. The ClinCheck software enables dental professionals to preview and modify the intended outcome of treatment in an interactive three-dimensional computer model. The ClinCheck treatment plan allows dental professionals to analyze multiple treatment alternatives before selecting the course of action they feel is most appropriate for the patient.

Expanded patient base. We believe that Invisalign has the potential to transform the practice of orthodontics. Currently, 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 our served market. As of December 31, 2010, our share of the 2.6 million patients in our served market is approximately 6.6%. Our market research indicates that the vast majority of adults with malocclusion who desire treatment do not elect traditional treatment because of its many limitations. We believe that since Invisalign addresses the primary limitations of braces, adults, who are particularly sensitive to aesthetic limitations of traditional treatment, will be more likely to seek treatment. We therefore believe that Invisalign will allow dental professionals to attract patients who would not otherwise seek orthodontic treatment. In addition, as the primary care provider, GPs have access to a greater number of patients than orthodontists and possess a unique opportunity to introduce Invisalign and expand their practice and patient base.

Practice productivity. We believe that as dental professionals move to a higher volume of Invisalign patients, they will be able to better leverage their existing resources, including staff time and office space resulting in an increase in daily patient appointments and practice productivity.

Benefits to the Patient

Excellent aesthetics. Aligners are nearly invisible when worn, significantly reducing the aesthetic concerns associated with traditional braces.

Comfort. By replacing the six-week adjustment cycle of traditional braces with two-week stages, aligners move teeth more gently. Also, aligners are thin, smooth and low in profile. As a result, aligners are more comfortable and less irritating than traditional braces.

Improved oral hygiene. Patients can remove aligners for tasks that are difficult with traditional braces, such as eating, brushing and flossing. We believe this feature has the potential to reduce enamel decalcification, tooth decay, and periodontal damage during treatment, which may result from traditional fixed braces.

Potentially reduced root resorption. Aligners control force by distributing it broadly over the exposed surfaces of the teeth. We believe that controlling force has the potential to reduce the incidence of root resorption, which is the breakdown or destruction of root structure that can occur during orthodontic treatment.

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Reduced incidence of emergencies. Typically, a lost or broken aligner is simply replaced with the next aligner in the treatment series, minimizing inconvenience to both the patient and the dental professional.

We believe that these benefits will prove attractive to people who currently do not seek treatment because of the limitations of traditional braces or as an alternative, more aesthetic treatment option for teenagers.

Limitations of Invisalign

In some instances, the Invisalign system may have certain limitations relative to traditional treatment. Aligners cost more to produce than traditional braces, and we charge dental professionals more than they generally pay for the supplies used in traditional treatment. Depending on the individual pricing policies of each dental professional and the treatment selected, the cost of Invisalign treatment to the patient may be greater than for traditional braces. Dental professionals must also incorporate our manufacturing cycle times into their overall treatment plan. Once a dental professional submits a case to us, there are a variety of factors that may impact when the corresponding aligners are delivered, one of which includes the timing of when the dental professional accepts the case. Aligners may not be appropriate for all cases, such as severe malocclusion, which may require aligners to be used in combination with traditional braces for optimal results. In addition, because aligners are removable, treatment using Invisalign depends on patients wearing their aligners as recommended. Some patients may experience a temporary period of adjustment to wearing aligners that may mildly affect speech. In some instances, patients have experienced scratched or irritated gums, cheeks and lips and in some rare instances, allergic reactions have been reported. We believe that these limitations are generally outweighed by the many benefits of Invisalign to both patients and dental professionals.

Our Target Market and Patient Base

Our market research indicates that the majority of adults with malocclusion who desire treatment forgo treatment rather than elect traditional treatment due to its many limitations. We believe that since Invisalign addresses the primary limitations of braces, adults, who are particularly sensitive to aesthetic limitations of traditional treatment, will be more likely to seek treatment and therefore represent our most immediate market expansion opportunity. With the launch of Invisalign Teen in July 2008, we now offer a product designed to meet the needs of the non-adult comprehensive, or younger teen, treatment market. Invisalign Teen makes our treatment more applicable to an orthodontist s patient base, which we believe will provide us the opportunity to increase our penetration into and our share of the teen treatment market. In addition, many parents also elect traditional treatment for their children due to limited awareness of Invisalign applicability for teenager use. Our goals are to extend our leadership in clear aligner therapy with adults, increase awareness and consumer demand with moms and teens, and to continue expansion of the clear aligner category overall. By communicating the benefits of Invisalign to both dental professionals and consumers adults, parents and teens we intend to increase the number of patients who seek treatment using Invisalign.

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 our served market. Twenty-five percent of these patients, or approximately 614 thousand have mature dentition (adults and older teens), with fully-erupted second molars and substantially completed jaw growth. Seventy-five percent, or approximately 2.0 million, have erupting dentition (non-adult comprehensive, or younger teens), with partially-erupted second molars, cuspid and second bicuspid teeth. As of December 31, 2010, our share of the 2.6 million patients in our served market is approximately 6.6%.

Published market data for GPs providing treatment for malocclusion is limited, however, as the primary care provider, GPs have access to a greater number of patients than orthodontists and possess a unique opportunity to introduce Invisalign and expand their practice and patient base. We believe GPs represent a significant market expansion opportunity.

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As of December 31, 2010, approximately 1.4 million patients cumulatively worldwide have started treatment using Invisalign. The Invisalign system is sold in North America, Europe, Asia Pacific, Latin America and Japan. International sales accounted for approximately 25%, 24%, and 21% of our net revenues in 2010, 2009, and 2008, respectively. A geographic breakdown of our net revenues is summarized in *Note 17 Segments and Geographical Information in the Notes to our Consolidated Financial Statements*. We operate as one reportable segment the design, development, manufacturing and marketing of Invisalign. Additionally, no single customer accounted for 10% or more of our total net revenues in 2010, 2009, and 2008.

Business Strategy

Our goal is to establish Invisalign as the standard method for treating malocclusion ultimately driving increased product adoption by dental professionals by focusing on the following key strategic initiatives:

1. Continue to accelerate product and clinical innovation, including new products with significant evolution in features and functionality, in order to extend clinical applicability and enhance effectiveness, treat more patients and achieve better outcomes;

2. Enhance the customer experience for our doctors and for their staff through evolution in customer facing systems and programs making it easier and more efficient to adopt Invisalign into their practice and increase utilization;

3. Increase the effectiveness of consumer demand creation and extend Invisalign brand awareness; and

4. Continue to drive International growth, principally in Europe, while opening up additional new markets around the world, such as China.

Product innovation and clinical effectiveness. We believe that product performance and innovation is a cornerstone to our future long-term goal to drive and sustain Invisalign adoption. Our primary channels GPs and orthodontists each have distinct and separate needs. Specifically, orthodontists want a more robust set of tools for greater predictability, wider applicability across their patient base and more flexibility in the use of the Invisalign system. On the other hand, typical GPs want greater ease of use, more efficient and simplified diagnostic tools, guidance through the case set-up process, minimal treatment intervention and self-help tools designed to simplify treatment of cases of mild to moderate malocclusion. The Invisalign system offers a variety of treatment options and products to address both channel needs. For example, Invisalign Teen is predominately marketed to the orthodontist whose patient base largely consists of teen-aged patients. Invisalign Teen has grown from 3% of our total case volume when it was introduced in 2008 to 11% of our total case volume in 2010. We expect that orthodontists will continue to adopt Invisalign Teen steadily, after they experience multiple successful treatment outcomes. Invisalign Assist launched in 2008, is intended to help newly-trained and lower volume Invisalign GPs accelerate the adoption and frequency of use of Invisalign into their practice. Most recently in October of 2010, we launched Invisalign G3, the most significant collection of new features and innovation in our company history touching virtually every system and product. Significant improvements and enhancements were made to both our customer-facing systems (Invisalign Doctor Site and ClinCheck software) and product features across our entire product line except for retainers.

On January 10, 2011, we announced an agreement to jointly develop software applications that will run on Cadent iTero and iOC scanners for use in Invisalign treatment. Cadent Inc. (Cadent) is a manufacturer of 3D digital scanning solutions for orthodontics and dentistry. The agreement embodies our commitment to innovation and our desire to improve the overall customer experience for Invisalign providers. The new applications will optimize case assessment and planning for Invisalign treatment, and bring valuable digital tools chair-side for Invisalign providers who use Cadent scanners. A series of applications will be developed over the next couple of years, and we expect the first application to be available by the end of 2011. Before we can bring these new applications to market, we need to ensure interoperability with Cadent scanners for use in Invisalign treatment. We have established very robust standards for scan quality and accuracy to ensure a specific scanning technology can successfully replace PVS impressions for Invisalign treatment. We are now in final beta tests to validate the Cadent systems, and expect to announce interoperability with Cadent scanners in the second quarter of 2011.

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We believe continuing to introduce new products and product features will keep us at the forefront of the market and increase adoption and frequency of use (what we call utilization or same practice sales) of Invisalign, however, we expect that adoption of these new products will increase gradually over a number of years. During 2011, we plan to continue our efforts to demonstrate clinical efficacy and work towards a long term goal of becoming the orthodontic treatment of choice.

Enhancing the customer experience and increasing adoption. We are committed to enhancing the customer experience through the evolution of our customer facing systems and programs making it easier and more efficient for our customers to adopt Invisalign into their practice and increase utilization. Specifically, we provide robust clinical education resources and training programs, clinical and field sales customer support, assistance with practice development, and incentive programs to encourage our customers integrate Invisalign into their practice.

Clinical Education and Training. Ensuring that trained doctors are confident in using the Invisalign system is a key driver toward our ultimate goal of increasing product adoption. We continuously update our training programs to address the needs of our customers. For instance, we developed Ask-the-Expert webinars, a series of interactive web/phone conferences led by experienced Invisalign providers to educate our customers about new products or features or to discuss relevant clinical topics. In addition, we focus on Invisalign Assist as part of our initial training program, Clear Essentials I, since we believe Invisalign Assist is the right product for newly trained GPs. We anticipate that by using Invisalign Assist, newly trained GPs will exit this initial training program with increased confidence in prescribing Invisalign treatment. Our new doctor training in North America is evolving to identify and focus on practices that are interested in gaining the skills and experience necessary to be successful with Invisalign. We have also incorporated the Invisalign technique into the curriculum of 41 university programs. By educating dental students and orthodontic residents on the benefits of the Invisalign technique, we believe they will be more likely to use this technology in their future practices and offer Invisalign as a treatment option. Other resources that we offer our doctors include the Aligntech Institute (www.aligntechinstitute.com), which is an interactive website that provides clinical education and practice development training. These clinical education and practice development training opportunities include instructor-led training classes, seminars and workshops, conference calls, web-based videos, case studies, blogs and other clinical resources. Many of these courses and resources are eligible for continuing education (CE) credits. Additionally, our Invisalign Doctor Site provides our trained doctors and their staff access to thousands of Invisalign cases and best practices as well as up-to-date support information, programs and marketing materials for continuous support and information access.

Customer Support and Practice Development. Once a doctor is trained, we provide additional services to help our customers increase their confidence in using the Invisalign system through clinical support and continuing education, as well as improving their practice management skills. At our Costa Rica facility, we have over 700 treatment technicians and customer support staff available to help our customers with their cases and treatment plans. Our sales representatives provide additional support and practice development tools such as staff training, ClinCheck software tips and tools, practice marketing guides and marketing materials, as well as any assistance with the Invisalign system process.

Customer Incentive Programs. We offer our customers varying product promotional discounts and incentive programs as a means to improve the customer experience and increase utilization. Our largest North American program, the Advantage Rebate Program, allows eligible orthodontist and GPs to earn volume rebates and marketing benefits for exceeding quarterly case shipment thresholds and participating in continuing education. Additional tiered benefits range from practice development materials, marketing consulting, and access to dedicated clinical technicians. For 2011, we added an additional Super Elite tier to include benefits such as free Invisalign Summit attendance and an Invisalign brand URL license. We believe that by incenting our doctors to enter the Advantage Rebate

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Program and increase their tier status, doctors can gain increased confidence in treating with Invisalign. The program also gives doctors access to marketing materials and programs to better integrate Invisalign into their practice and help develop a stronger partnership with us and increase overall adoption. From time to time, we also offer various product promotions as a means to encourage trial usage of products, including pricing discounts to newly trained doctors and following the introduction of new products. The largest program for International, the Case Pack program, rewards twelve month purchase commitments made by Invisalign practitioners with case discounts commensurate with commitment tier and preferred placement in Doctor Locator on the Invisalign website.

Increasing the effectiveness of our consumer demand creation and extending Invisalign brand awareness. Marketing to the consumer and creating demand is one of our key strategic objectives to driving long-term growth. Our market research indicates that the majority of adults with malocclusion who desire treatment forgo treatment rather than elect traditional treatment due to its many limitations, such as compromised aesthetics and oral discomfort. In addition, many parents also elect traditional treatment for their children due to limited awareness of Invisalign applicability for teenager use. Our goals are to extend our leadership in clear aligner therapy with adults, increase awareness and consumer demand with moms and teens, and to continue expansion of the clear aligner category overall. By communicating the benefits of Invisalign to both dental professionals and consumers adults, parents and teens we intend to increase the number of patients who seek treatment using Invisalign. We continue to be successful with programs that more effectively and efficiently generate demand or pull for Invisalign. In 2010, we became more efficient in our approach. We continued building awareness and demand through an integrated consumer marketing platform of traditional media, event marketing and digital and social media. In addition, we continued to evolve our marketing program aimed at the teenage segment to increase awareness and educate prospective teen patients and their parents. Specifically, we expanded our public relations and event marketing programs this past year for Invisalign Teen to include participation and sponsorship of major summer events such as the Teen Choice Awards and Journeyz Backyard BBQ Tour, a nationwide action sports tour. We leveraged online and mobile widgets, social media and blogs directly targeted to teens and launched a commercial prompting parents and teens to learn more about Invisalign. Additionally, we evolved the Invisalign brand strategy while refreshing the Invisalign look and feel with a more modern logo and new brand positioning, updated consumer website, and base marketing materials focused on treatment outcome and practice growth. We will continue to build on these programs and efforts in 2011.

Growth of international markets. We will continue to focus our efforts towards increasing adoption of Invisalign by dental professionals in our key international markets. Similar to the North America market, our objective internationally is to increase the number of doctors that are motivated to become an Invisalign provider and committed to making Invisalign a key part of their practices. In 2010, our international sales increased from approximately 24% of net revenues to approximately 25% of net revenues. Through December 2010, we trained over 17,400 doctors internationally, predominantly orthodontists in Europe which is our primary international market. Product line expansion is key to providing doctors with treatment options that address a wider range of potential patient needs with greater treatment flexibility. Invisalign Teen will continue to gain adoption as specific Europe teen marketing campaigns are being introduced in 2011. In addition, we are preparing to launch Invisalign G3 in the second quarter of 2011. Invisalign G3 is engineered to deliver even better clinical results, with new aligner and software features that make it easier to use Invisalign with patient with Class II and Class III malocclusion. Due to the higher number of complex cases in international markets, the planned international launch of the Invisalign G3 features designed to address those complex treatment issues is a significant near term focus. We will carry on our efforts to increase brand awareness and consumer demand in Europe by continuing our consumer advertising campaign while beginning to focus on the teenage segment.

In October, we announced that we had received regulatory approval from the Chinese State Food and Drug Administration (SFDA) to market and sell the Invisalign system as a Class II medical device for the treatment of malocclusion. We received our License of Medical Device Operation Enterprise (Enterprise License) from the

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Shanghai Food and Drug Administration, which allows us to distribute Invisalign in China. We expect to begin commercial availability of Invisalign in the second half of 2011. While we do not expect meaningful revenue from China for several years, our focused strategy to launch Invisalign in key major cities of China provides us a large growth opportunity long term.

Additionally, although the vast majority of our international revenues are from direct sales, approximately 10% of our international sales are through distributors covering less strategic international markets, specifically Asia Pacific, Latin America, and smaller country markets in Europe, the Middle East and Africa. With these efforts, we expect our international revenues to continue to increase in absolute dollars and as a percentage of total net revenues in the foreseeable future.

Manufacturing

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.

Manufacturing administration is located in San Jose, California; however, our digital planning and manufacturing facilities are located outside of the U.S. in San Jose, Costa Rica and Juarez, Mexico. As of December 31, 2010, our digital planning, manufacturing and operations staff in the U.S., Costa Rica and Mexico consisted of 1,374 people. At our facility in Costa Rica, technicians use a sophisticated, internally developed computer-modeling program to prepare digital treatment plans. Upon acceptance of the ClinCheck treatment plan by the dental professional, these plans are then transmitted electronically to Juarez, Mexico. The ClinCheck treatment plan and supporting digital files are used to manufacture SLA (stereolithography) aligner molds. Our order acquisition operations, the manufacturing of aligner molds and aligners, as well as the packaging and shipment of aligners, are conducted in our facility in Juarez, Mexico. 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.*

We rely on two vendors who are each the sole source of the polymer and resin used in our manufacturing process. In the event that either of these vendors becomes unable for any reason to supply us with their respective products, we would experience a manufacturing disruption while we qualify and obtain an alternate source.

Throughput Management

Because we manufacture each case on a build-to-order basis, we must conservatively build manufacturing capacity for anticipated demand. To increase throughput, we must improve the efficiency and increase the scale of our manufacturing processes.

In order to increase the efficiency of our manufacturing processes, we focus our efforts on software development and the improvement of rate-limiting processes, or bottlenecks. We continue to 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. We are also continuing the development of automated systems for the fabrication and packaging of aligners manufactured in Juarez, Mexico. In order to meet the demands from expected volumes and continued international expansion, we expect that we will continue to invest in capital equipment and intend to add a new aligner fabrication facility outside of North America by the end of 2011.

Quality Assurance

Align s quality system is required to be in compliance with the Quality System regulations enforced by the Food and Drug Administration (FDA), and similar regulations enforced by other worldwide regulatory

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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. Between June 29 and August 9, 2010, the FDA conducted a routine Quality Systems inspection of our San Jose, California facility. The FDA inspection resulted in the issuance of a Form 483 Notice that contained four observations related to how Align reports and manages patient complaints. We submitted a written response to the Form 483 Notice on August 26 and an additional written response on November 8 that provided a full and complete update of the corrective actions we had taken to our complaint and Medical Device Reporting procedures to address the observations. On November 18, 2010, we received a Warning Letter from the FDA, which requested additional documentation relating to our written implemented corrective actions. On November 22, we submitted a written response to the Warning Letter that included copies of documentation requested by the FDA. We are continuing to work closely with the FDA to resolve and close-out the matter. Failure to fully address the FDA s concerns could result in further regulatory sanctions, including additional Warning Letters, adverse publicity, refusal to clear or approve applications for new or modified products, injunctions, fines, civil penalties or criminal prosecution. Any FDA enforcement action could have a material adverse effect on us.

Since we custom manufacture our aligners on a build-to-order basis, we do not offer refunds on our products. Because each ClinCheck treatment plan and each aligner is unique, we inspect the product at various points during the manufacturing process, to ensure that the product meets our customers expectations. Aligners are subject to the Invisalign product warranty, which covers defects in materials and workmanship. Our materials and workmanship warranty is in force until the Invisalign case is completed. In the event aligners fall within the scope of the Invisalign product warranty, we will replace the aligners at our expense. Our warranty is contingent upon proper use of the aligners for the purposes for which they are intended. If a patient chooses not to wear the aligners, and as a result, requests additional Invisalign treatment, the dental professional pays the additional expense of the replacement aligners. Warranty treatment requires that the dental professional submit new impressions of the patient s dentition to us. We use the impressions to create a new ClinCheck treatment plan for the dental professional to approve, from which a successive series of aligners will be produced that will allow the patient to finish treatment.

The Invisalign product warranty does not provide any assurances regarding the outcome of treatment using Invisalign. Actual treatment results may deviate significantly from the approved ClinCheck treatment plan. Deviations not covered under warranty have typically been the result of unpredictable biological factors, such as variations in bone density or tooth topography and abnormal jaw growth.

Sales and Marketing

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, and to consumers through online and traditional advertising, digital and social networking, and event marketing. Based on our experience with marketing and commercial sales, we believe that making consumers aware of Invisalign as a treatment alternative generates significant demand for Invisalign.

Professional Marketing

We provide training, marketing and clinical support to orthodontists and GPs throughout North America and internationally. As of December 31, 2010, there are approximately 43,000 active Invisalign providers worldwide.

As of December 31, 2010 our North American sales organization consisted of 171 people, of which, 134 were quota carrying sales representatives and 37 were regional sales managers and administration.

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Internationally, we had 54 people engaged in sales and sales support as of December 31, 2010. We continually evaluate cost effective ways to support our customers in smaller markets. For instance, we use distributors for the sale of our products in part of the Asia Pacific, Latin American regions, and smaller country markets in Europe, the Middle East and Africa. We will consider selling through a distributor in other smaller markets as well as consider expanding directly into additional countries on a case-by-case basis.

Invisalign relies on the same orthodontic principles that apply to traditional treatment. Our sales teams conduct training primarily in a workshop format. The key topics covered in training include Invisalign applicability, instructions on filling out the Invisalign treatment form and submitting required records, clinical tips and techniques, guidance on pricing and instructions on interacting with our ClinCheck software and the many other features of the Invisalign Doctor Site.

After doctors complete their training, sales representatives may follow up with the dental professional to ensure that their staff is prepared to handle Invisalign cases. These practice development activities may include assisting the dental professional in taking dental impressions, treatment planning processes and familiarizing them with our dental online portals and tools. Sales representatives may also provide practice-building assistance, including helping the dental professional to market Invisalign to prospective patients through direct mail or other forms of media. Many dental professionals have commenced promotional activity in their local region with our assistance.

Consumer Marketing

Our experience indicates that prospective patients seek information from these primary sources:

- an orthodontist;
- a GP;
- our websites, which can be accessed at either *www.invisalign.com*, *www.invisalignteen.com*, *www.aligntech.com*, *or www.aligntechinstitute.com;*
- traditional and digital advertising, social media, print and public relations and;
- word of mouth from current and former Invisalign patients.

Research and Development

Our research and development effort is focused on extending the range of clinical effectiveness and applicability of Invisalign, enhancing the software used in the virtual clinical design, manufacturing process and enhancing our Invisalign treatment options, including the development of distinct product platforms that meet the specific needs of GPs and orthodontists such as Invisalign Assist and Invisalign Teen. Our research and development expenses were $26.0 million for 2010, $22.3 million for 2009, and $26.2 million for 2008.

In an effort to demonstrate Invisalign s broad treatment capabilities, various clinical case studies and articles have been published that highlight the applicability of Invisalign to malocclusion cases, including those of severe complexity. We are also undertaking post-marketing studies and making additional technological improvements to the product and manufacturing process. As mentioned in our Business Strategy, we are making investments in the development of new products and enhancements of existing products to meet the needs of our customers and increase adoption and utilization of Invisalign such as the agreement to jointly develop software applications with Cadent.

Intellectual Property

We believe our intellectual property position represents a substantial business advantage. As of December 31, 2010, we had 152 issued U.S. patents, 136 pending U.S. patent applications, and 75 foreign issued patents, as well as 128 pending foreign patent applications. See *Item 3 Legal Proceedings for a discussion on Reexamination Proceedings pending with the United States Patent and Trademark Office.*

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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 where Invisalign is distributed 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

Seasonal fluctuations in the number of doctors in their offices and available to take appointments have affected, and are likely to continue to affect, our business. Specifically, our customers often take vacation or are on holiday during the summer months and therefore tend to start fewer cases, particularly in Europe. In addition, 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 teens started in treatment before the start of the school year. As a result, adult appointments, including adult Invisalign patient starts, are often pushed further into late summer or early fall. With the availability of Invisalign Teen combined with our marketing efforts aimed at teens and parents, we have been actively competing for a share of teen patient starts. We believe that the increasing percentage of teenaged patients using Invisalign helped moderate the downward trend we would otherwise see for our North American orthodontic customers during the summer months. These seasonal trends have caused and will likely continue to cause, fluctuations in our quarterly results, including fluctuations in sequential revenue growth rates.

Backlog

Due to the nature of our business, 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 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 sales. Our quarterly revenues can be impacted by the timing of the ClinCheck treatment plan acceptances and our ability to ship those cases in the same quarter.

Competition

We compete for the attention of dental professionals with manufacturers of traditional orthodontic appliances (or wires and brackets), which include 3M s Unitek, Danaher Corporation s Sybron Dental Specialties, and Dentsply International, Inc. We also compete directly with established companies that manufacture and distribute products that are similar in use to Invisalign, including the products manufactured and distributed by Ormco Orthodontics, a division of Sybron Dental Specialties (a division of Danaher Corporation) and Dentsply GAC International (a division of Dentsply International, Inc.). In the future, we may face further competition from early stage and more mature companies who enter our target markets to manufacture and distribute products that are similar in use to Invisalign. Information regarding risks associated with increased competition may be found in *Item 1A* of this Annual Report on Form 10-K under the heading Risk Factors.

We believe that in addition to price, the principal competitive factors in the market for orthodontic appliances include the following:

aesthetic appeal of the treatment method;

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effectiveness of treatment;

customer support;

software features;

customer online interface;

unique engineering;

comfort associated with the treatment method;

oral hygiene;

ease of use; and

dental professionals chair time.

We believe that Invisalign compares favorably with our competitors products with respect to each of these factors.

Government Regulation

FDA s Quality System Regulation for Medical Devices. The Invisalign system is classified as a Class II medical device. In 1998, we received pre-market clearance from the FDA pursuant to the 510(k) pre-market notification procedure, allowing us to market the product in the U.S. The Invisalign system was originally cleared for use by the FDA in patients with permanent teeth and contraindicated the device for patients presenting with mixed dentition, severe overbite, severe overjet, tooth malocclusion requiring surgical correction, adolescent patients with a skeletally narrow jaw, and adult patients with dental prosthetics/implants. In 2008, the FDA cleared new labeling for the Invisalign system, by removing the permanent dentition limitation from the indications for use. In addition, certain conditions previously listed as contraindications are now listed as precautions. We are subject to routine inspections by the FDA and state agencies to determine compliance with Quality System requirements. We are registered with the State of California as a medical device manufacturer.

If the FDA determines that we failed to 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 criminal prosecution.

Health Canada s Medical Device Regulations. In Canada, we are required to comply with Health Canada s Medical Device Regulations. Our products are registered with Health Canada. We believe we are in compliance with their regulations and have been granted clearance to market our products in Canada.

European Union s MDD Requirements & ISO 13485:2003. In Europe, Invisalign is regulated as a custom device and as such, we follow the requirements of the Medical Device Directives. We are ISO 13485:2003 certified, which facilitates commercialization of Invisalign outside the United States and especially in Europe.

China s FDA Regulations and Enterprise License. In October 2010, we received regulatory approval from the Chinese State Food and Drug Administration (SFDA) to market and sell the Invisalign system as a Class II medical device for the treatment of malocclusion. We also received its License of Medical Device Operation Enterprise (Enterprise License) from the Shanghai Food and Drug Administration, which allows us to distribute Invisalign in China.

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 certain health

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information. Confidentiality and security of patient records and the circumstances under which these records may be released by healthcare professionals 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 protect the unauthorized release or disclosure of patient information. Although compliance is the responsibility of the hospital, physician or other healthcare provider, we understand the importance to our customers and their patients of maintaining the confidentiality of patient information. Accordingly, we have designed our product and service offerings to be consistent with the requirements of the Privacy and Security standards under HIPAA and applicable corresponding state laws and regulations. Maintaining systems that are consistent 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 as permitted by our FDA 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, and federal law will require us to track and disclose these payments starting in 2013.

Employees

As of December 31, 2010, we had 2,097 employees, including 1,374 in manufacturing and operations, 372 in sales and marketing, 150 in research and development and 201 in general and administrative functions. We had 435 employees in North America, 797 employees in Costa Rica, 208 employees in Europe, 645 employees in Mexico, and 12 employees in Japan.

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

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located at the SEC s Public Reference Room at 100 F Street, NE, Washington, D.C. 20549. Information on the operation of the Public Reference Room can be obtained by calling the SEC at 1-800-SEC-0330. The SEC maintains an internet site that contains reports, proxy and information statements and other information regarding our filings at *www.sec.gov*.

Executive Officers of the Registrant

The following table sets forth certain information regarding our executive officers as of February 24, 2011:

Name	Age	Position
Thomas M. Prescott	55	President and Chief Executive Officer
Kenneth B. Arola	55	Vice President, Finance and Chief Financial Officer
Dana C. Cambra	53	Vice President, Research & Development and Information Technology
Dan S. Ellis	59	Vice President, North American Sales
Roger E. George	45	Vice President, Legal and Corporate Affairs General Counsel
Len M. Hedge	53	Senior Vice President, Business Operations
Sheila Tan	47	Vice President, Marketing and Chief Marketing Officer
Richard Twomey	46	Vice President, International
Emory M. Wright	41	Vice President, Operations

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.

Dana C. Cambra our Vice President, Research & Development and Information Technology has been with Align since June 2008. Prior to joining us, Mr. Cambra served as Senior Vice President, Research and Development for Pharsight Corporation, a provider of simulation and modeling software for pharmaceutical and biotechnology companies from March 2007 to June 2008. Prior to his role at Pharsight, Mr. Cambra was Vice President, Engineering at Stentor Inc., a medical image and information management software provider from October 2002 to February 2006. Earlier roles included executive engineering and operations positions at Visto Corporation and iScribe, Inc. Mr. Cambra also spent several years in positions of increasing responsibility at Acuson Corporation, now a Siemens Company.

Dan S. Ellis has served as our Vice President, North American Sales since June 2005. Prior to joining us, Mr. Ellis was Vice President, Sales for privately-held BARRx Medical, a medical device company, from September 2004 to June 2005. From June 1999 to May 2004, Mr. Ellis was at Fusion Medical Technologies, a division of Baxter Healthcare, most recently as Vice President, BioSurgery US. From January 1998 to June 1999, Mr. Ellis served as Vice President, Sales & Marketing for Cardiac Pathways, Inc. Earlier in his career, Mr. Ellis held national sales positions of increasing scope and responsibility at Fusion Medical Technologies and Eli Lilly MDD/Guidant Corporation.

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

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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.

Len M. Hedge has served as our Senior Vice President, Business Operations since December 2007. He joined us as our Director of Manufacturing in January 1999 and was our Vice President, of Operations from March 2002 to December 2007. Prior to joining us, Mr. Hedge served as Vice President of Operations for Plynetics Express Corporation, a rapid-prototyping and stereolithography services supplier, from December 1996 to December 1998. From October 1991 to December 1996, Mr. Hedge worked at Beckman Instruments Corporation as Manager for Prototype Manufacturing and Process Development.

Sheila Tan was appointed Vice President, Marketing and Chief Marketing Officer in March 2009. Ms. Tan joined us in September 2008 as Vice President of Product Innovation and Marketing Strategy. Prior to joining us, Ms. Tan was Vice President, Marketing for Moka5, Inc., a provider of virtual desktop technology, from August 2007 to July 2008. She served as Vice President Marketing of Presto Services Inc., a digital-delivery service that enables families and friends to stay in touch via email, without the need for a computer or Internet connection, from June 2006 to August 2007. Prior to that, Ms. Tan was Senior Director of Marketing, QuickBooks at Intuit from 2000 to 2005. From 1995 to 2000, Ms. Tan held marketing positions of increasing scope and responsibility at The Procter & Gamble Company and its subsidiaries.

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.

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ITEM 1A. RISK FACTORS

We depend on the sale of the Invisalign system for the vast majority of our revenues, and any decline in sales of Invisalign for any reason, including as a result of changes to the proficiency program, a continued weakness in general economic conditions, or a decline in average selling prices would adversely affect revenues, gross margin and net profits.

We expect that revenues from the sale of the Invisalign system will continue to account for the vast majority of our total 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. Factors that could cause the adoption of Invisalign to occur at a lower rate than we expect, as well as the risk related to declining average selling prices are described more fully below.

Consumers may not adopt Invisalign 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 United States 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 or a reduction in the demand for Invisalign generally either of which would have a material adverse effect on our sales and operating results. In addition, Invisalign represents a significant change from traditional orthodontic treatment, 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 as both an alternative to braces and as a clinical method for treatment of malocclusion, but a number of dental professionals believe that Invisalign is appropriate for only a limited percentage of their patients. Increased market acceptance will depend in part upon the recommendations of dental professionals, as well as other factors including effectiveness, safety, ease of use, reliability, aesthetics, greater comfort and hygiene compared to traditional orthodontic products and price for Invisalign compared to competing products.

Orthodontists and GPs may not adopt Invisalign in sufficient numbers or as rapidly as we anticipate for a number of reasons, including, changes to the Proficiency Program or as a result of increased competition.

Our success depends upon increasing acceptance and frequency of use of the Invisalign system by dental professionals (what we refer to as utilization). In April 2010, we eliminated the case start requirements and in October 2010 we eliminated the annual CE requirements, effectively terminating the Proficiency Program. We may experience variability in customer activity over the next several quarters as doctors adjust to the changes to the Proficiency Program requirements. In addition, increased competition from direct competitors could cause us to lose market share and reduce dental professionals efforts and commitment to expand their Invisalign practice. If adoption does not increase as we anticipate for any reason, our revenues may fail to grow as expected and our operating results may be harmed.

The frequency of use 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 Invisalign 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.

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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, expand our discount programs in the future, if participation in these programs increases, if our product mix shifts to lower priced products or newer products that have a higher percentage of deferred revenue, or if sales by our international distributors, particularly in the Asia-Pacific region, grows at a faster pace than our direct sales, our average selling price would be adversely affected and our revenues, gross margin and net profits (losses) may be reduced. Furthermore, although the U.S. dollar is our reporting currency, a portion of our revenues and profits are generated in foreign currencies. Revenues and profits 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 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 intend to open a new manufacturing facility outside of North America by the end of 2011. Our ability to plan, construct and equip additional manufacturing facilities is subject to significant risk and uncertainty, including risks inherent in the establishment of a new manufacturing facility, such as:

Hiring and retaining employees;

Delays and cost overruns as a result of a number of factors, any of which may be out of our control, such as:

Labor shortages and disputes;

Delays in government approvals;

Delays in the customization, delivery and installation of equipment; and

Production start-up problems;

Implementing, integrating and improving operational and financial systems, procedures and controls, including our computer systems; and

Managing expanding operations in multiple locations and multiple time zones.

If the opening of this facility is significantly delayed or demand for our product in 2011 exceeds our current expectations, we may not be able to fulfill orders timely, which may negatively impact our financial results and overall business. Conversely, if demand for our products decreases, the fixed costs associated with excess manufacturing capacity may harm our financial results.

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

If we are to sustain or increase profitability in future periods, we will need to continue to increase our revenues, while controlling our expenses. Because our business is evolving, it is difficult to predict our future

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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. 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 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;

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;

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;

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;

aggressive price competition from competitors;

costs and expenditures in connection with litigation;

disruptions to our business due to the impact of an epidemic that 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 revenues, production and other operating costs; and

investments in research and development to develop new products and enhancements to Invisalign.

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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 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 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. We launched Invisalign Teen in July 2008 and Invisalign Assist in October 2008. In October 2010, we introduced Invisalign G3, a collection of new features and innovations that touch every product and virtually every system at Align. 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. 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 include functionality and features that address customer requirements, compatibility of our computer operating systems and hardware configurations with customers, the availability of third-party reimbursement of procedures using our new products, the existence of competing products and general economic conditions affecting purchasing patterns. 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. 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 revenues to decline.

A disruption in the operations of our primary freight carrier or higher shipping costs could cause a decline in our revenues or a reduction in our earnings.

We are dependent on commercial freight carriers, primarily UPS, to deliver our products. If the operations of these carriers are disrupted for any reason, we may be unable to 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 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 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

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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. 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;
- 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 Mexico 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 technicians to use our sophisticated computer modeling program that produces the digital treatment plan that forms the basis of ClinCheck 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 timely create ClinCheck treatment plans within the timeframe our customers expect. Any delay in ClinCheck processing time could delay the ultimate delivery of finished aligners to our customers. Such a delay could cause us to lose existing customers or fail to attract new customers. This could cause a decline in our revenues and net profits and could adversely affect our results of operations.

Our headquarters, digital dental modeling processes, and other manufacturing processes are all 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

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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.

We experience competition from manufacturers of traditional braces and expect aggressive competition from these and other companies that may introduce new technologies in the future.

Currently, our Invisalign product competes directly against products manufactured and distributed by Ormco Orthodontics, a division of Sybron Dental Specialties (a Danaher Corporation subsidiary), and traditional braces manufactured by 3M s Unitek and Dentsply International. These manufacturers 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. 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, any of which could have a material adverse effect on our revenues, volume growth, net profit (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, we will need to continually upgrade and enhance our information systems. 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, 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, including those upgrades and enhancements associated with the launch in the fall of 2010 of Invisalign G3 that touched every product and virtually each of our systems, 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. Furthermore, we continuously upgrade our customer facing software applications, specifically the

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ClinCheck software and the Invisalign Doctor Site. 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.

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, 2010, we had 152 issued U.S. patents, 136 pending U.S. patent applications, and 75 issued foreign patents, and 128 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 an Annual 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

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disclosure of any material weaknesses in our internal control over financial reporting identified by management. While we currently believe our internal control over financial reporting is 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. If we are unable to assert that our internal control over financial reporting is effective in any future period (or if our auditors are unable to express an opinion on the effectiveness of our internal controls or conclude that our internal controls are ineffective), we could lose investor confidence in the accuracy and completeness of our financial reports, which could have an adverse effect on our stock price.

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

We are highly dependent on the key employees in our clinical engineering, technology development, sales 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.

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. We maintain single supply relationships for many of these machines and materials technologies. In particular, our scanning and stereolithography equipment are provided by a single supplier. We are also committed to purchasing all of our resin and polymer, the primary raw materials used in our manufacturing process, from a single source. 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

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manufacturers to produce the needed equipment and materials in sufficient quantities to support our growth. 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 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 depends upon our direct sales force within our North American and international markets. As of December 31, 2010, our North American sales organization consisted of 171 people, of which 134 were quota carrying sales representatives and 37 were regional sales managers and administration. Internationally, we had 54 people engaged in sales and sales support as of December 31, 2010. 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 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 revenues may be harmed.

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

Our products are 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. For

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instance, on November 18, 2010, we received a Warning Letter from the FDA, which requested additional documentation relating to our written implemented corrective actions to our Complaint and Medical Device Reporting procedures. We responded to the Warning Letter on November 22, 2010, and we are working closely with the FDA to address their concerns and close the matter. Should we fail to promptly and fully address the issues listed in the Warning Letter may result in further regulatory sanctions, including additional Warning Letters, adverse publicity, refusal to clear or approve applications for new or modified products, injunctions, fines, civil penalties or criminal prosecution. 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 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.

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. This tax applies to all medical devices, including our products. These taxes, will result in a significant increase in the tax burden on our industry, 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.

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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.

We currently sell our products in Europe, Asia Pacific, Latin America and Japan and may expand into other countries from time to time. We do not know whether orthodontists, GPs and consumers outside our North American market will adopt Invisalign in sufficient numbers or as rapidly as we anticipate. In addition, sales of our products outside the U.S. 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 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;

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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. A securities class action suit was filed against us on behalf of all persons or entities who purchased our common stock between January 30, 2007 and October 24, 2007. While we believe the lawsuit is without merit and intend to vigorously defend ourselves, we could incur substantial legal fees, and our management s attention and resources may be diverted from operating our business in order to respond to the litigation.

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 accounting principles generally accepted in the United States of America. These principles are subject to interpretation by the SEC and various bodies formed to interpret and create appropriate accounting policies. A change in these policies can have a significant effect on our reported results and may even retroactively affect previously reported transactions. Our accounting policies that recently have been or may be affected by changes in the accounting rules are as follows:

revenue recognition;

accounting for share-based payments;

leases; and

accounting for income taxes.

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

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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, changing interpretations of existing tax laws or regulations, the future levels of tax benefits of stock option deductions relating to incentive stock options and employee stock purchase plans and changes in overall levels of pretax earnings. In June 2009, the Costa Rica Ministry of Foreign Trade, an agency of the Government of Costa Rica, granted a twelve year extension of 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 2010. As a result of these incentives, income taxes were reduced by $12.7 million in 2010. 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.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

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ITEM 2. PROPERTIES

We occupy approximately four facilities with a total office and manufacturing area of over 276,000 square feet of leased properties. At December 31, 2010, these facilities were occupied as follows:

Location	Property / Approximate Size	Use	Expiration of lease
San Jose, California	Buildings/129,000 sq. feet	Leased office for headquarters, research & development, administrative personnel	September 2017
San Jose, Costa Rica	Building/63,000 sq. feet	Leased office for administrative personnel, manufacturing personnel, and customer care	September 2013
Juarez, Mexico	Building/68,000 sq. feet	Leased manufacturing and office for manufacturing and administrative personnel	July 2013
Amsterdam, Netherlands	Building/16,000 sq. feet	Leased office for European headquarters and administrative personnel	June 2012

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. In order to meet the demands from expected volumes and continued international expansion, we intend to add a new aligner fabrication facility outside of North America by the end of 2011.

ITEM 3. LEGAL PROCEEDINGS

Weber

On May 18, 2007, Debra A.Weber filed a consumer class action lawsuit against us, OrthoClear, Inc. and OrthoClear Holdings, Inc. (d/b/a OrthoClear, Inc.) in Syracuse, New York, U.S. District Court. The complaint alleges two causes of action against the OrthoClear defendants and one cause of action against us for breach of contract. The cause of action against us titled Breach of Third Party Benefit Contract references our agreement to make Invisalign treatment available to OrthoClear patients, alleging that we failed to provide the promised treatment to Plaintiff or any of the class members. On June 2, 2010, the Court granted our motion for summary judgment and dismissed us from the action.

On June 29, 2010, Weber requested that the Court enter final judgment as to Align pursuant to Federal Rule of Civil Procedure 54(b) in order to certify Align s dismissal for immediate appeal. We filed an opposition to Weber s request on July 19, 2010, on the grounds that Weber failed to show that exceptional circumstances warranted the entry of a final judgment where fewer than all claims or parties had been dismissed. On August 20, 2010, the Court denied Weber s motion. On October 29, 2010, the Court dismissed the action against OrthoClear and OrthoClear Holdings Inc. with prejudice at the request of the remaining parties pursuant to a settlement. The Stipulation and Order of Dismissal with Prejudice entered by the Court provides that the settlement and dismissal does not affect any rights Weber may have to appeal dismissal of the action as against us.

Leiszler

On May 10, 2010, Christopher J. Leiszler filed a complaint against us in the United States District Court for the Northern District of California. The complaint alleges that we implemented unfair and fraudulent

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requirements for the prescription of Invisalign through the Invisalign Proficiency Requirements. In January 2010 Dr. Leiszler s Invisalign provider status was suspended for failing to meet the Proficiency Requirements. Dr. Leiszler sued on behalf of himself and all others similarly situated. The complaint seeks a refund of the price paid to us for Invisalign training. On October 19, 2010, we entered into a memorandum of understanding to resolve this litigation, and on November 30, 2010, we executed a formal Stipulation of Settlement which must be approved by the Court. On December 23, 2010, the Court granted preliminary approval of the proposed settlement. The Court has scheduled a hearing in April 2011 to determine whether to grant final approval of the proposed settlement. Under terms of the proposed settlement, class members can be reinstated to prescribe Invisalign treatment under certain circumstances (the Reinstatement Benefit). Certain class members will have the option to elect a cash remedy instead of the Reinstatement Benefit. Pursuant to the proposed settlement, in January 2011, we deposited approximately $8.0 million into an escrow account to pay eligible class members who elect the cash remedy, as well as legal fees and other costs. We recorded a total litigation settlement charge of $4.5 million during 2010 for our estimated liability related to this settlement. We will continue to assess and evaluate the matter with our legal counsel and update the estimated settlement charge as appropriate as new information becomes available.

Securities Litigation

In August 2009, Plaintiff Charles Wozniak filed a lawsuit against us and our Chief Executive Officer and President, Thomas M. Prescott (Mr. Prescott), in District Court for the Northern District of California on behalf of a claimed class consisting of all persons or entities who purchased our common stock of between January 30, 2007 and October 24, 2007. The complaint alleges that Align and Mr. Prescott violated Section 10(b) of the Securities Exchange Act of 1934 and that Mr. Prescott violated Section 20(a) of the Securities Exchange Act of 1934. Specifically, the complaint alleges that during the class period we failed to disclose that we had shifted the focus of our sales force to clearing backlog, causing a significant decrease in the number of new case starts. On November 13, 2009, the Court appointed Plumbers and Pipefitters National Pension Fund as lead plaintiff. The lead plaintiff filed an amended complaint on January 29, 2010. The amended complaint alleges that we and Mr. Prescott issued a number of purportedly false and misleading statements throughout the class period concerning the Patients First program, our production capacity, a purported backlog, and the focus of our sales force. On March 26, 2010, we and Mr. Prescott filed a motion to dismiss the amended complaint. The motion was heard by the Court on July 9, 2010 and the Court has not yet released a ruling on the motion. We believe the lawsuit to be without merit and intend to vigorously defend ourselves.

Litigating claims of the types discussed in this Annual Report on Form 10-K, whether or not ultimately determined in our favor or settled by us, is costly and diverts the efforts and attention of our management and technical personnel from normal business operations. Any of these results from litigation could adversely affect our results of operations and stock price. From time to time, we have received, and may again receive, letters from third parties drawing our attention to their patent rights. While we do not believe that we infringe any such rights that have been brought to our attention, there may be other more pertinent proprietary rights of which we are presently unaware.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

There were no matters submitted to a vote of security holders during the fourth quarter of 2010.

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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, 2010:		
Fourth quarter	$ 21.40	$ 16.25
Third quarter	$ 19.95	$ 13.90
Second quarter	$ 20.56	$ 13.18
First quarter	$ 20.00	$ 16.11
Year Ended December 31, 2009:		
Fourth quarter	$ 18.85	$ 14.18
Third quarter	$ 14.91	$ 9.15
Second quarter	$ 12.91	$ 7.62
First quarter	$ 9.67	$ 6.10

On February 18, 2011, the closing price of our common stock on the NASDAQ Global Market was $20.79 per share. As of January 31, 2011 there were approximately 167 holders of record of our common stock. Because the majority of our shares of outstanding common stock is 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. Our credit facility contains certain restrictive loan covenants, including restrictions on our ability to pay dividends. See *Item 7 Management s Discussion and Analysis of Financial Condition and Results of Operations Liquidity and Capital Resources* .

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.

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COMPARISON OF 5 YEAR CUMULATIVE TOTAL RETURN

The following graph compares the cumulative total stockholder return on our common stock with that of the NASDAQ Stock Market US Index, a broad market index published by the National Association of Securities Dealers, Inc., S&P 1500 Composite Health Care Equipment & Supplies Index. The comparison for each of the periods assumes that $100 was invested on January 1, 2005 in our common stock, the stocks in the NASDAQ Stock Market US Index, and the S&P Index, and that all dividends were reinvested.

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

* $100 invested on 12/31/05 in stock or index, including reinvestment of dividends.
Fiscal year ending December 31.

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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, 2010. The selected consolidated financial data is qualified in its entirety and should be read in conjunction with the Consolidated Financial Statements and related Notes thereto set forth on pages 61 to 89 and *Management s Discussion and Analysis of Financial Condition and Results of Operations* beginning on page 40. We have derived the statement of operations data for the years ended December 31, 2010, 2009 and 2008 and the balance sheet data as of December 31, 2010 and 2009 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, 2007 and 2006 and the balance sheet data as of December 31, 2008, 2007 and 2006 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,				
	2010	**2009**	**2008**	**2007**	**2006**
Consolidated Statement of Operations Data:					
Net revenues(1)	$ 387,126	$ 312,333	$ 303,976	$ 284,332	$ 206,354
Gross profit(2)	$ 303,417	$ 233,492	$ 225,126	$ 209,297	$ 141,579
Profit (loss) from operations(3)	102,734	(34,012)	15,514	33,855	(37,536)
Other income (expense), net	(731)	119	1,562	3,095	3,401
Net profit (loss) before provision for (benefit from) income taxes(3)	102,003	(33,893)	17,076	36,950	(34,135)
Provision for (benefit from) income taxes	27,750	(2,624)	(62,911)	1,226	828
Net profit (loss)(3)	$ 74,253	$ (31,269)	$ 79,987	$ 35,724	$ (34,963)
Net profit (loss) per share					
Basic	$ 0.98	$ (0.45)	$ 1.20	$ 0.53	$ (0.55)
Diluted	$ 0.95	$ (0.45)	$ 1.18	$ 0.50	$ (0.55)
Shares used in computing net profit (loss) per share:					
Basic	75,825	69,094	66,812	67,176	63,246
Diluted	78,080	69,094	68,064	71,444	63,246

	December 31,				
	2010	**2009**	**2008**	**2007**	**2006**
Consolidated Balance Sheet Data:					
Working capital(4)	$ 295,637	$ 180,056	$ 117,335	$ 123,058	$ 40,306
Total assets	476,943	355,240	279,341	222,761	151,558
Total long-term liabilities	6,222	961	229	148	219
Stockholders equity	$ 377,747	$ 273,036	$ 218,540	$ 161,154	$ 83,556

(1) 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, 2010 and 2009 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.

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

$14.3 million release of previously deferred revenue for Invisalign Teen replacement aligners in 2010. See *Note 1 Summary of Significant Accounting Policies in the Notes to our Consolidated Financial Statements*.

$0.8 million and $6.2 million of amortization of prepaid royalties related to the litigation settlement with Ormco in 2010 and 2009, respectively. See *Note 6 Litigation Settlements in the Notes to our Consolidated Financial Statements.*

$4.5 million related to the class action litigation settlement with Leiszler in 2010. See *Note 6 Litigation Settlements in the Notes to our Consolidated Financial Statements.*

$8.7 million 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. See *Note 6 Litigation Settlements in the Notes to our Consolidated Financial Statements.*

Litigation settlement charge of $69.7 million related to Ormco in 2009. See *Note 6 Litigation Settlements in the Notes to our Consolidated Financial Statements.*

Restructuring charges of $1.3 million and $6.2 million in 2009 and 2008, respectively. See *Note 18 Restructurings in the Notes to our Consolidated Financial Statements.*

$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. See *Note 13, Income Taxes , in the Notes to our Consolidated Financial Statements*.

$1.8 million credit and $14.3 million charge for the Patients First Program and settlement cost in 2007 and 2006, respectively.

(4) Working capital is calculated as the difference between total current assets and total current liabilities.

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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

We design, manufacture and market the Invisalign system, a proprietary method for treating malocclusion, or the misalignment of teeth. Invisalign corrects malocclusion using a series of clear, nearly invisible, removable appliances that gently move teeth to a desired final position. Because it does not rely on the use of metal or ceramic brackets and wires, Invisalign significantly reduces the aesthetic and other limitations associated with metal arch wires and brackets, commonly referred to as braces. We received the United States Food and Drug Administration (FDA) clearance to market Invisalign in 1998. The Invisalign system is regulated by the FDA as a Class II medical device.

We distribute the vast majority of our products directly to our customers: the orthodontist and the general practitioner dentist, or GP. Orthodontists and GPs must complete an initial Invisalign training course in order to begin providing the Invisalign treatment solution to their patients. 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 parts of the Asia Pacific, Latin American and EMEA (Europe, Middle East and Africa) regions.

Each Invisalign treatment plan is unique to the individual patient. Our Invisalign Full treatment consists of as many aligners as indicated by our proprietary ClinCheck software in order to achieve the doctors treatment goals. Our Invisalign Express/Lite are lower cost solutions for less complex orthodontic cases, such as adult relapse cases, for minor crowding and spacing, or as a pre-cursor to restorative or cosmetic treatments such as veneers. Invisalign Express uses up to 10 sets of aligners and is sold in the United States and Canada. Invisalign Lite uses up to 14 sets of aligners and is sold to our international customers. Invisalign Teen is designed to meet the specific needs of the non-adult comprehensive or teenaged treatment market particularly younger teenagers aged 11 to 15 years. Invisalign Assist is intended to help newly-trained and lower volume Invisalign GPs accelerate the adoption and frequency of use of Invisalign into their practice. Upon completion of an Invisalign or non-Invisalign treatment, the patient may be prescribed our traditional retainer product, or our Vivera retainers, a clear aligner set designed for ongoing retention. Our goal is to establish Invisalign as the standard method for treating malocclusion ultimately driving increased product adoption by dental professionals by focusing on the four key objectives: driving product and clinical innovation, enhancing the customer experience, increasing the effectiveness of consumer demand creation and extending Invisalign brand awareness and continuing to drive international growth. Each of these four key objectives is described more fully in *Item I Business Business Strategy* of our 2010 Annual Report on Form 10-K. As we execute on our business strategy, we will continue to deliver significant evolutions in product features and functionality, as well as customer facing systems.

In addition to the successful execution of our business strategy, a number of other factors may affect our results in 2011 and beyond, the most important of which are set forth below.

Joint Development with Cadent. On January 10, 2011, we announced an agreement to jointly develop software applications that will run on Cadent iTero and iOC scanners for use in Invisalign treatment. Cadent is a manufacturer of 3D digital scanning solutions for orthodontics and dentistry. The new applications will optimize case assessment and planning for Invisalign treatment, and bring valuable digital tools chair-side for Invisalign providers who use Cadent scanners. A series of applications will be developed over the next couple of years and we expect the first application to be available by the end of 2011. Before we can bring these new applications to market, we need to ensure interoperability with Cadent scanners for use in Invisalign treatment. We have established very robust

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standards for scan quality and accuracy to ensure a specific scanning technology can successfully replace PVS impressions for Invisalign treatment. We are now in final beta tests to validate the Cadent systems, and expect to announce interoperability with Cadent scanners in the second quarter of 2011.

Accelerate product and clinical innovation. In October 2010, we launched Invisalign G3, the most significant collection of new features and innovation in our company history touching virtually every system and product. Significant improvements and enhancements were made in to all our customer-facing systems. For instance, the Invisalign Doctor Site now consolidates all of a patient s Invisalign records and treatment tasks together in one location for easy access and the ClinCheck software now includes drag and drop features, additional clinical tools and a more intuitive interface. In addition, with the exception of our Vivera retainers, we introduced new and expanded features across our product line. Engineered to deliver even better clinical results, the Invisalign G3 new aligner and software features make it easier to use Invisalign with more complex and challenging cases, including Precision Cuts designed for use on patients with Class II and Class III malocclusion, new SmartForce features designed for increased predictability of certain tooth movements, and simpler, more intuitive software to streamline treatment planning and review.

Elimination of the Proficiency Program. In June 2009, we introduced the Invisalign Product Proficiency Requirements (Proficiency Program) which mandated that every Invisalign provider in North America submit a minimum number of case starts and complete a minimum number of continuing education (CE) credits. In April 2010, we eliminated the case start requirements and in October 2010 we eliminated the annual CE requirements, effectively terminating the Proficiency Program. With the elimination of the minimum case requirements, we may experience variability in customer activity over the next several quarters as doctors, especially lower volume doctors, adjust to the elimination of the Proficiency Program requirements.

Investments to Increase Manufacturing Capacity. We expect capital expenditures to increase in 2011 compared to 2010 as we invest in our manufacturing facility in Juarez, Mexico to add incremental capacity. In addition, in order to meet the increased demands from expected volumes and continued international expansion, we expect to open an additional aligner fabrication site outside of North America by the end of 2011. Our ability to plan, construct and equip this additional manufacturing facility is subject to significant risk and uncertainty, including delays and cost overruns. If the opening of this facility is significantly delayed for any reason, or if demand for our product in 2011 exceeds our current expectations, we may not be able to fulfill orders timely, which may negatively impact our financial results and overall business.

Number of new doctors trained. In 2010, we trained approximately 3,140 new doctors in North America, which included approximately 900 doctors who had their account suspended as a result of the Proficiency Requirements at the end of 2009. In addition, pursuant to the terms of the proposed settlement agreement related to the Leiszler class action described above in *Item 3 Legal Proceedings* in this Annual Report on Form 10-K, approximately 22,000 class members (approximately 14,000 of whom have either never submitted a case or submitted just 1 case prior to June 2008) could be reinstated to prescribe Invisalign treatment following completion of a free 3-hour on-line course. While we would like doctors to adopt Invisalign into their practice, we do not know how many doctors will ultimately seek to be reinstated to prescribe Invisalign, and of those doctors who do seek to be reinstated whether they will change their previous level of utilization. As a result, we currently expect that the number of new and reactivated doctors trained in North America will be higher in 2011 compared to 2010. As a result of the planned international release of Invisalign G3 second quarter, we expect to train fewer international doctors in 2011 compared to 2010 since we will scale back on training until the roll out is complete.

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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 ten quarters are as follows:

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

Utilization rates in the fourth quarter of 2010 for the North American Ortho and GP channels decreased slightly compared to the third quarter of 2010. Summer is typically the busiest season for orthodontists with practices that have a high percentage of adolescent and teenage patients, as the percentage of teenaged patients using Invisalign increases, we expect that fourth quarter utilization rates, especially in our North America orthodontist channel will be adversely impacted. North American GP utilization decreased from the prior quarter, which may have reflected a slowdown in patient traffic in our customer s offices during the first half of the quarter. On a year over year basis, total worldwide utilization increased, reflecting increased use across all customer channels.

Seasonal fluctuations. Seasonal fluctuations in the number of doctors in their offices and available to take appointments have affected, and are likely to continue to affect our business. Specifically, our customers often take vacation during the summer months and therefore tend to start fewer cases, especially North American GPs and European doctors.

In 2010, sequential case growth from second quarter to the third quarter in the North American Ortho channel was essentially flat. With the availability of Invisalign Teen, we can actively compete for a share of teen patient starts. Summer is typically the busiest season for orthodontists with practices that have a high percentage of adolescent and teenage patients. Many parents want to get their teens started in treatment before the start of the school year. We believe that Invisalign Teen and the increasing percentage of teenaged patients using Invisalign helped moderate the historical downward trend we have typically seen for our North American orthodontic customers during the summer months. In the third quarter of 2010, we saw a decline in the number of cases submitted as well as a decline in the number of submitters in our North American GP channel which is consistent with our historical trend during this quarter.

Foreign exchange rates. Although the U.S. dollar is our reporting currency, a portion of our revenues and profits are generated in foreign currencies. Revenues and profits generated by subsidiaries

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operating outside of the United States 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 exchanges rates against the U.S. dollar will continue to affect the reported amount of revenues and profits in our consolidated financial statements.

Growth of international markets. In October 2010, we announced regulatory approval to market and sell Invisalign in China and expect to begin commercial launch in the second half of 2011. While we do not expect meaningful revenue from China for several years, our focused strategy to launch Invisalign in key major cities of China provides us a large growth opportunity long term.

Operating Expenses. In the first quarter of 2011, we expect operating expenses to increase reflecting additional spending in sales and marketing with increased focused on the teenage segment, commercialization activities for Invisalign G3, continued investment in our international expansion in both Europe and China, and development costs related to the Cadent Joint Development Agreement.

Results of Operations

Comparison of Years Ended December 31, 2010, 2009 and 2008:

Net revenues and case volume by channel and product:

Invisalign product revenues by channel and other non-case revenues, which represents training, retainer and ancillary products, for the years ended December 31, 2010, 2009 and 2008 are as follows (in millions):

	Years Ended December 31,						
Net revenues	**2010**	**Net Change**	**% Change**	**2009**	**Net Change**	**% Change**	**2008**
North America:							
Ortho	$ 117.4	$ 27.0	29.9%	$ 90.4	$ 2.1	2.4%	$ 88.3
GP	145.1	12.3	9.3%	132.8	(2.7)	(2.0%)	135.5
Total North American Invisalign	262.5	39.3	17.6%	223.2	(0.6)	(0.3%)	223.8
International Invisalign	90.1	18.1	25.1%	72.0	10.0	16.1%	62.0
Total Invisalign revenues	352.6	57.4	19.4%	295.2	9.4	3.3%	285.8
Teen deferred revenue release	14.3	14.3	N/A			N/A	
Other non-case revenues	20.2	3.1	18.1%	17.1	(1.1)	(6.0%)	18.2
Total net revenues	$ 387.1	$ 74.8	24.0%	$ 312.3	$ 8.3	2.7%	$ 304.0

Case volume data which represents Invisalign case shipments by channel, for the years ended December 31, 2010, 2009, and 2008 are as follows (in thousands):

	Years Ended December 31,						
Invisalign case volume	**2010**	**Net Change**	**% Change**	**2009**	**Net Change**	**% Change**	**2008**
North America:							
Ortho	90.3	17.3	23.7%	73.0	2.4	3.4%	70.6
GP	109.1	9.0	9.0%	100.1	(3.4)	(3.3%)	103.5
Total North American Invisalign	199.4	26.3	15.2%	173.1	(1.0)	(0.6%)	174.1

International Invisalign	61.5	14.0	29.5%	47.5	9.6	25.3%	37.9
Total Invisalign case volume	260.9	40.3	18.3%	220.6	8.6	4.1%	212.0

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Invisalign revenues by product and other non-case revenues, which represents training, retainer and ancillary products, for the years ended December 31, 2010, 2009 and 2008 are as follows (in millions):

	Years Ended December 31,						
Net revenues	2010	Net Change	% Change	2009	Net Change	% Change	2008
Invisalign Full	$ 264.8	$ 30.0	12.8%	$ 234.8	$ (20.7)	(8.1%)	$ 255.5
Invisalign Express	34.6	5.6	19.3%	29.0	5.5	23.4%	23.5
Invisalign Teen(1)	52.8	26.9	103.9%	25.9	19.7	317.7%	6.2
Invisalign Assist	14.7	9.2	167.3%	5.5	4.9	816.7%	0.6
Other non-case revenues	20.2	3.1	18.1%	17.1	(1.1)	(6.0%)	18.2
Total net revenues	$ 387.1	$ 74.8	24.0%	$ 312.3	$ 8.3	2.7%	$ 304.0

(1) Net revenues for the year ended December 31, 2010 includes a $14.3 million release of previously deferred revenue for Invisalign Teen replacement aligners. Excluding the $14.3 million for the Invisalign Teen replacement aligners, the percentage change from 2009 to 2010 was approximately 48.6%.

Case volume data which represents Invisalign case shipments by product, for the years ended December 31, 2010, 2009, and 2008 are as follows (in thousands):

	Years Ended December 31,						
Invisalign case volume	2010	Net Change	% Change	2009	Net Change	% Change	2008
Invisalign Full	179.7	24.4	15.7%	155.3	(17.1)	(9.9%)	172.4
Invisalign Express	37.4	4.4	13.3%	33.0	1.0	3.1%	32.0
Invisalign Teen	28.7	2.8	10.8%	25.9	19.1	280.9%	6.8
Invisalign Assist	15.1	8.7	135.9%	6.4	5.6	700.0%	0.8
Total Invisalign case volume	260.9	40.3	18.3%	220.6	8.6	4.1%	212.0

Fiscal Year 2010 compared to Fiscal Year 2009

Total net revenues increased in 2010 as compared to 2009 primarily as a result of worldwide volume growth across all customer channels. The release of revenue previously deferred for Invisalign Teen replacement aligners in the second quarter of 2010 contributed an additional $14.3 million to total net revenues for 2010.

In 2010, North America revenue increased 17.6% compared to 2009 due to overall case volume growth of 15.2% as well as an increase in our average selling price. Higher case volume was driven primarily by the North American orthodontic channel reflecting increased penetration into the teenage orthodontic market, especially with the Invisalign Teen product. Additionally, the increase also reflects a significant reduction in our revenue deferral rate for Teen replacement aligners and lower discounts and rebates.

Our International Invisalign revenue increased 25.1% in 2010 compared to 2009 mainly due to 29.5% growth in case volumes across all products partially offset by a mix shift towards our lower priced products, as well as unfavorable foreign exchange rates.

Invisalign Teen includes up to six replacement aligners which may be ordered at any time throughout treatment. Through the second quarter of 2010, revenue for these replacement aligners was deferred based on 100 percent of the fair value of the aligners until the replacement aligners were used or the case completed. Since the launch of Invisalign Teen over two years ago, we evaluated the usage experience of the replacement aligners and determined that there is sufficient historical experience to establish an estimated usage rate. As a result, in June 2010, we reduced deferred revenue for Invisalign Teen replacement aligners by $14.3 million to reflect the lower estimated usage for in-process cases.

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Other non-case revenues, consisting of training fees and sales of ancillary products, were higher in 2010 compared to 2009 primarily due to increased sales of our Vivera and retainer products.

Fiscal Year 2009 compared to Fiscal Year 2008

Total net revenues increased in 2009 compared to 2008 primarily as a result of revenue growth in our International and North American orthodontic channels and partially offset by a slight decline in North American GP revenues.

Overall, 2009 North American Invisalign revenues were comparable to 2008 and reflect a full year impact of product mix shifting from Invisalign Full towards Invisalign Teen and Invisalign Assist, both of which have higher amounts of deferred revenue than Invisalign Full. Additionally, 2009 North American revenues also include the full year impact of North American price increases that were effective in the beginning of the year. The North American orthodontic channel experienced an increase in revenue and case volume primarily driven by the full year availability of Invisalign Teen. North American GP revenues declined in 2009 compared to 2008 as a result of the product mix shift towards Invisalign Assist combined with an overall slightly lower case volume.

Our International Invisalign revenues grew in 2009 compared to 2008 as a result of increased Invisalign Full case volumes and was supplemented by a partial year impact of Invisalign Teen, which was launched in March 2009. This increase was offset by unfavorable exchange rates.

Other revenues, consisting of training fees and sales of ancillary products, were lower in 2009 compared to 2008 primarily due to a decreased number of doctors trained year over year.

Cost of revenues and gross margin (in millions):

	Years Ended December 31,				
	2010	Change	2009	Change	2008
Cost of revenues	$ 83.7	$ 4.9	$ 78.8	$ (0.1)	$ 78.9
% of net revenues	21.6%		25.2%		25.9%
Gross profit	$ 303.4	$ 69.9	$ 233.5	$ 8.4	$ 225.1
Gross margin %	78.4%		74.8%		74.1%

Cost of revenues 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, training costs and stock-based compensation expense. Through April 2009, cost of revenues also included the cost of our third party shelter service provider in Juarez, Mexico.

Gross margin improved in 2010 compared to 2009 primarily due to the increase in case volume which resulted in higher cost absorption and reduced cost per case. Additionally, the gross margin for 2010 was favorably impacted by the release of teen deferred revenue of $14.3 million during 2010.

Gross margin improved slightly in 2009 compared to 2008 primarily due to an increase in case volume over our relatively fixed cost structure, continued improvement in operating efficiencies, and the cost savings from the commencement of direct fabrication of our aligners. These efficiencies were partially offset by $6.2 million of royalty costs resulting from the Ormco litigation settlement.

Sales and marketing (in millions):

	Years Ended December 31,				
	2010	Change	2009	Change	2008
Sales and marketing	$ 114.0	$ 1.5	$ 112.5	$ (2.6)	$ 115.1
% of net revenues	29.5%		36.0%		37.9%

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Sales and marketing expense includes sales force compensation (including travel-related costs), marketing personnel-related costs, media and advertising, clinical education, product marketing and stock-based compensation expense.

Sales and marketing expense increased in 2010 compared to 2009 primarily due to increases in media, advertising, travel and entertainment costs of $2.5 million and higher facility information technology costs of approximately $1.8 million primarily associated with the preparation and transition into our new building. These costs were partially offset by approximately $1.6 million of clinical education costs that were included in gross margin during the first three quarters in 2010 as a result of the Proficiency Program as well as lower sales commission expenses of approximately $1.3 million.

Sales and marketing expense decreased during 2009 compared to 2008 due to a $4.8 million reduction in commission-related costs as a result of the restructuring plans implemented in 2008 as well as lower marketing, media and clinical education expenses of $1.5 million associated with our 2008 product launches. These costs were partially offset by higher sales commission expenses of $4.3 million.

General and administrative (in millions):

	Years Ended December 31,				
	2010	Change	2009	Change	2008
General and administrative	$ 64.8	$ 3.1	$ 61.7	$ (0.5)	$ 62.2
% of net revenues	16.7%		19.8%		20.5%

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

General and administrative expense for 2010 increased compared to 2009 primarily due to higher payroll-related and credit card processing costs of approximately $1.8 million as well as higher legal, accounting and consulting fees of approximately $1.0 million.

General and administrative expense decreased slightly during 2009 compared to 2008 primarily due to lower outside services relating to legal fees of $2.5 million. These costs were partially offset by higher payroll-related costs.

Research and development (in millions):

	Years Ended December 31,				
	2010	Change	2009	Change	2008
Research and development	$ 26.0	$ 3.7	$ 22.3	$ (3.9)	$ 26.2
% of net revenues	6.7%		7.1%		8.6%

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, conducting clinical and post-marketing trials and stock-based compensation expense.

Research and development expense increased in 2010 compared to 2009 primarily due to higher payroll-related costs of approximately $2.2 million as a result of an increased headcount in 2010 and higher facility and information technology costs of approximately $0.9 million primarily associated with the transition to our new building.

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Research and development expense decrease in 2009 compared to 2008 primarily due to lower payroll-related expenses of approximately $2.4 million as well as lower outside consulting expenses of approximately $1.0 million.

Restructurings (in millions):

	Years Ended December 31,				
	2010	Change	2009	Change	2008
Restructurings	$	$ (1.3)	$ 1.3	$ (4.9)	$ 6.2
% of net revenues			0.4%		2.1%

During 2008, we announced restructuring plans in July and October to increase efficiencies across the organization and with the expectation of lowering the overall cost structure by approximately $3.5 million per quarter. In July 2008, we implemented a restructuring plan to reduce our full time headcount by 67 employees including a phased-consolidation of order acquisition operations from our then corporate headquarters in Santa Clara, California to Juarez, Mexico, which was completed by the end of 2008. The October restructuring plan included a total reduction of 111 full time headcount in Santa Clara, California by July 2009 when we moved our customer care, accounts receivable, credit and collections, and customer event registration organizations in Santa Clara, California to our existing facilities in Costa Rica.

We incurred approximately $1.3 million during 2009 of cost related to severance and termination benefits, where in 2008, we incurred approximately $6.2 million in restructuring expenses that included $0.7 million related to the acceleration of stock option vesting and $5.5 million related to severance and termination benefits. There was no restructuring activity during 2010.

Litigation settlement (in millions):

	Years Ended December 31,				
	2010	Change	2009	Change	2008
Litigation settlement	$ 4.5	$ (65.2)	$ 69.7	$ 69.7	$
% of net revenues	1.2%		22.3%		0.0%

Ormco

In August 16, 2009, we entered into a litigation settlement with Ormco valued at $76.7 million which was comprised of a cash payment of $13.2 million and a stock issuance of approximately 7.6 million shares of common stock. We recognized the litigation settlement of $69.7 million in our operating expenses. The remaining $7.0 million was recorded to prepaid expenses, of which $6.2 million was amortized to cost of sales based on case shipments during 2009 and $0.8 million during the first quarter of 2010.

Leiszler

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. See *Note 6 Litigation Settlements in the Notes to our Consolidated Financial Statements* for additional information about the settlement accounting.

Insurance settlement (in millions):

	Years Ended December 31,				
	2010	Change	2009	Change	2008
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.

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

	Years Ended December 31,				
	2010	Change	2009	Change	2008
Interest income	$ 0.6	$	$ 0.6	$ (2.5)	$ 3.1
Interest (expense)		0.1	(0.1)	(0.1)	
Other income (expense), net	(1.3)	(0.9)	(0.4)	1.1	(1.5)
Total interest and other income (expense), net	$ (0.7)	$ (0.8)	$ 0.1	$ (1.5)	$ 1.6

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

Interest income and interest expense in 2010 was consistent with 2009. Other expense, net, increased in 2010 compared to 2009 by $0.9 million reflecting increases in foreign exchange losses during 2010.

Interest income in 2009 decreased by $2.5 million compared to 2008 primarily due to lower returns on our investments. Interest rates for investments throughout the marketplace were lower due to the low Federal Funds Rate during 2009. Other expense, net, decreased in 2009 compared to 2008 reflecting increases in foreign exchange gains during 2009.

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

	Years Ended December 31,				
	2010	Change	2009	Change	2008
Provision for (benefit from) income taxes	$ 27.8	$ 30.4	$ (2.6)	$ 60.4	$ (63.0)

We recorded an income tax provision of $27.8 million for 2010 and income tax benefits of $2.6 million and $63.0 million for 2009 and 2008, respectively. These represented effective tax rates of 27.2%, 7.7%, and (368.4%) in 2010, 2009 and 2008, respectively. Our income tax provision is based upon our operating results for each taxable jurisdiction in which we operate and the amount of statutory tax that we incur in each jurisdiction.

We exercised significant judgment in regards to estimates of future market growth, forecasted earnings and projected taxable income, in determining the provision for income taxes, and for purposes of assessing our ability to utilize any future benefit from deferred tax assets. At December 31, 2008, based on an evaluation of the available positive and negative evidence, we determined that most of our deferred tax assets would be realized with the exception of certain capital loss and foreign net operating loss carryforwards. In making that determination, we considered the historical and projected pretax operating profit, excluding stock-based compensation, as well as the cyclical nature of our business and the uncertainty as to the impact of new product launches. Specifically, at December 31, 2008, we considered the following positive evidence:

- cumulative seven quarters of pretax operating profitability plus permanent items
- the then-projected pretax book income for 2009 and beyond suggesting that deferred tax assets will be utilized

We also considered the following negative evidence:

history of operating losses in 2006 and prior to 2003

cyclical nature of the business and price volatility

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We believed that the positive evidence is of sufficient quality and quantity to overcome the negative evidence and as a result, we released our tax valuation allowance of $64.6 million in the fourth quarter of 2008. The remaining valuation allowance of approximately $6.1 million is related to capital loss and foreign net operating loss carryforwards as of December 31, 2010 because we cannot forecast sufficient future capital gains or 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.

The California 2009-2010 budget legislation included the ability to elect to apply a single sales factor apportionment for years beginning after January 1, 2011. As a result of our anticipated election of the single sales factor, we are required to re-measure our deferred taxes taking into account the expected California tax rate under the elective single sales factor. We have determined that by electing a single sales factor apportionment, our deferred tax assets decreased by approximately $1.2 million (net of federal benefit). Of the $1.2 million tax impact, $0.6 million was recorded as a discrete item in 2009 and the remaining $0.6 million was recorded as a discrete item in 2010.

At December 31, 2010, we had federal net operating loss carryforwards of approximately $134.5 million, which, if not used, will begin to expire in 2020. 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 $67.6 million, which, if not used, will begin to expire in 2013. At December 31, 2010, we had research credit carryforwards of approximately $4.5 million for federal purposes and $3.8 million for California state tax purposes. If not utilized, the federal credit carryforwards will begin to expire in 2017. The California state credit can be carried forward indefinitely.

Financial Accounting Standard Board (FASB) Accounting Standard Codification (ASC) 718 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 $9.3 million as of December 31, 2010 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 have not provided additional U.S. income taxes on undistributed earnings from non-U.S. operations as of December 31, 2010 because such earnings are intended to be reinvested indefinitely outside of the United States.

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, 2010, 2009 and 2008, we had the following cash and cash equivalents, and short-term and long-term investments (in thousands):

	Years Ended December 31,		
	2010	2009	2008
Cash and cash equivalents	$ 294,664	$ 166,487	$ 87,100
Short-term investments	8,615	19,978	23,066
Long-term investments	9,089		
Total	$ 312,368	$ 186,465	$ 110,166

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Cash flows (in thousands):

	Years Ended December 31,		
	2010	2009	2008
Net cash flow provided by (used in):			
Operating activities	$ 129,529	$ 74,165	$ 39,746
Investing activities	(15,920)	(1,556)	(1,055)
Financing activities	14,707	6,837	(40,355)
Effects of exchange rate changes on cash and cash equivalents	(139)	(59)	(355)
Net increase (decrease) in cash and cash equivalents	$ 128,177	$ 79,387	$ (2,019)

Operating Activities

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:

Changes in non-cash activities

Deferred taxes increased by $17.3 million primarily due to the utilization of our deferred tax assets. See *Note 13 Income Taxes in the Notes to our Consolidated Financial Statements* for additional information

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, increasing our cash inflow 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 increase of $0.9 million, increasing our cash inflow from operations.

For the year ended December 31, 2009, cash flows from operations of $74.2 million resulted primarily from the following reasons listed below offset by our net loss of $31.3 million:

Changes in non-cash activities

Litigation settlement cost and amortization of prepaid royalties increased by $62.7 million due to our settlement with Ormco. See *Note 6 Litigation Settlements in the Notes to our Consolidated Financial Statements* for additional information.

Other non-cash activities including deferred taxes, depreciation and amortization, stock-based compensation, provision for doubtful accounts, excess tax provision for our share-based payments, and loss on the retirement/disposal of our fixed assets resulted in a net increase of $26.9 million.

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Changes in working capital

Deferred revenues increased by $15.5 million reflecting increases in revenues specifically related to our Teen product that carried a higher deferred revenue component, increasing our cash inflow from operations.

Other working capital comprising of accounts receivable, inventory, prepaid expenses and other assets, accounts payable, and accrued liabilities resulted in a net increase of $0.4 million, increasing our cash inflow from operations.

For the year ended December 31, 2008, cash flows from operations of $39.7 million resulted primarily from our net income of approximately $80.0 million and the following reasons:

Changes in non-cash activities

A decrease in deferred taxes as a result of our tax valuation allowance release on most of our deferred tax assets of $64.6 million. See *Note 13 Income Taxes in the Notes to our Consolidated Financial Statements* for additional information.

Other non-cash activities including, depreciation and amortization, stock-based compensation, provision for doubtful accounts, the acceleration of stock-based compensation, loss on impairment of fixed assets, excess tax provision for our share-based payments, and benefit on the retirement/disposal of our fixed assets resulted in a net increase of $32.7 million.

Changes in working capital

Working capital comprising of accounts receivable, inventory, prepaid expenses and other assets, accounts payable, accrued liabilities, and deferred revenue resulted in a net decrease of $8.3 million, reducing our cash inflow from operations.

Investing Activities

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.

Net cash used in investing activities was $1.6 million for the year ended December 31, 2009, primarily consisted of approximately $7.2 million used for the purchase of property and equipment which were partially offset by $6.0 million of net maturities from marketable securities.

Net cash used in investing activities was $1.1 million for the year ended December 31, 2008, primarily consisted of $14.3 million for the purchase of property and equipment which were partially offset by $12.9 million of net maturities of marketable securities.

Financing Activities

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 provision 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 cash provided by financing activities was $6.8 million for the year ended December 31, 2009, which resulted primarily from $8.1 million in proceeds from the issuance of our common stock. These proceeds were partially offset from the tax benefit excess of shared-based payments and taxes paid on vesting restricted stock units of $1.1 million.

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Net cash used in financing activities was $40.4 million for the year ended December 31, 2008 and resulted primarily from our $50.1 million stock repurchase including commissions which were partially offset by $10.5 million in proceeds from the issuance of our common stock, principally from exercises of employee stock options and purchases under the employee stock purchase plan.

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 exercise. 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 2010, 2009, and 2008, we paid $1.1 million, $0.5 million, and $0.5 million of taxes related to RSUs that vested during the period for executive officers, respectively.

Stock Repurchase

On April 29, 2008, we announced that our Board of Directors had approved a stock repurchase program of up to $50 million. During the year ended December 31, 2008, we repurchased 4.7 million shares of common stock at an average price of $10.76 per share for an aggregate purchase price of $50.1 million including commissions. As of December 31, 2008, we had completed repurchases under the stock repurchase authorization. There were no stock repurchases in 2010 or 2009.

Line of Credit

On December 14, 2010, we renegotiated and amended our existing credit facility with Comerica Bank. Under this revolving line of credit, we have $30.0 million of available borrowings with a maturity date of December 31, 2012. The interest rate on borrowings will range from Libor plus 1.5% to 2.0% depending upon the amount of cash we maintain at Comerica Bank. This credit facility requires a quick ratio covenant and also requires us to maintain a minimum unrestricted cash balance of $10.0 million. Additionally, in the event our unrestricted cash deposited is less than $55.0 million, the unused facility fee will increase from 0.050% per quarter to 0.125% per quarter. As of December 31, 2010, we had no outstanding borrowings under this credit facility and are in compliance with the financial covenants.

Contractual Obligations/Off Balance Sheet Arrangements

The impact that our contractual obligations as of December 31, 2010 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	$ 22,836	$ 5,596	$ 7,897	$ 5,024	$ 4,319
Funding of litigation settlement escrow account	$ 7,976	$ 7,976	$	$	$

On January 26, 2010, we entered into an agreement to lease new corporate headquarters of approximately 129,024 square feet in San Jose, California. The lease agreement commenced on June 28, 2010 and will continue for an initial term of seven years and two months. The agreement for our previous corporate headquarters in Santa Clara, California, expired on June 30, 2010.

As part of the proposed terms related to the Leiszler class action settlement, in January 2011 we deposited approximately $8.0 million for certain class members who elect the cash remedy into an escrow account.

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Our contractual obligations table above excludes approximately $11.0 million of non-current uncertain tax benefits which are included in other long-term obligations on our balance sheet as of December 31, 2010. 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 expect capital expenditures to increase in 2011 compared to 2010 as we invest in our manufacturing facility in Juarez, Mexico to add incremental capacity. In addition, in order to meet the increased demands from expected volumes and continued international expansion, we expect to open an additional aligner fabrication site outside of North America by the end of 2011.

We had no off-balance sheet arrangements as defined in Regulation S-K Item 303(a) (4) as of December 31, 2010.

We believe that our current cash and cash equivalents combined with our existing borrowing capacity will be sufficient to fund our operations for at least the next 12 months. If we are unable to generate adequate operating cash flows, 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.

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 our 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 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 when persuasive evidence of an arrangement exists, delivery has occurred, the sales price is fixed or determinable, and collection is probable. Product is considered delivered to the customer once it has been shipped and title and risk of loss have been transferred. Revenues are recognized from product sales, net of discounts and rebates. Service revenues related to the training of dental professionals and staff on the Invisalign treatment processes are recorded when the services are completed.

We enter into arrangements that involve multiple future deliverables. Included in the price of Invisalign Full, Invisalign Teen and Invisalign Assist, we offer 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. We use vendor specific objective evidence of fair value to allocate revenue to the case refinement deliverable and recognize the residual revenue upon shipment. We defer the fair value of case refinement upon shipment based on a breakage factor, which is determined by sufficient historical experience of case refinement usage. Actual usage rates could differ from the historical breakage factor requiring future adjustments to revenue.

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Invisalign Teen is delivered in a single shipment except for six replacement aligners that are included in the price of the product and may be ordered at any time throughout treatment. We use vendor specific objective evidence of fair value to allocate revenue to the replacement aligners and recognize the residual revenue upon initial shipment. Through the second quarter of 2010, we deferred 100 percent of the fair value for the six replacement aligners. This deferred revenue was subsequently recognized as the replacement aligners were shipped or when the case was completed. Management evaluated the actual usage of replacement aligners since the launch of Invisalign Teen over two years ago and believes that there is sufficient historical evidence to establish an estimated usage rate. As a result, in June 2010, we reduced deferred revenue for Invisalign Teen replacement aligners by $14.3 million to reflect the estimated usage for in-process cases and starting in July 2010, we began deferring the fair value of the replacement aligners based on the estimated usage rate. We believe that this estimated usage is reasonable and appropriate because of the relative stability of the Invisalign Teen replacement utilization since it was first offered. Although we are not expecting any material changes, we will continue to analyze the usage of replacement aligners and may adjust the estimated usage rate as necessary.

The Vivera retainer includes four shipments per year, and revenue is deferred upon the first shipment and recognized as each shipment occurs. For Invisalign Assist, when the progress tracking feature is selected, aligners are shipped to the dental professional after every nine stages. For these cases, revenue is deferred upon the first staged shipment and will be recognized upon shipment of the final staged shipment.

We estimate and record a provision for amounts of estimated losses on sales, if any, in the period such sales occur. 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.

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, net of an estimated forfeiture rate. We estimate the fair value of stock options using a Black-Scholes valuation model, which requires the input of highly subjective assumptions, including the option s expected term and stock price volatility. In addition, judgment is also required in estimating the number of stock-based awards that are expected to be forfeited. Forfeitures are estimated based on historical experience at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. The assumptions used in calculating the fair value of share-based payment awards represent management s best estimates, but these estimates involve inherent uncertainties and the application of management s judgment. As a result, if factors change and we use different assumptions, our stock-based compensation expense could be materially different in the future. See *Note 10 Stockholders Equity in the Notes to our Consolidated Financial Statements* for additional information.

Long-lived assets, including finite lived purchased intangible assets

Long-lived assets, including intangible assets other than goodwill are amortized over their useful lives, unless these lives are determined to be indefinite. Intangible assets are carried at cost less accumulated amortization. We perform an impairment test whenever events or changes in circumstances indicate that the carrying value of such assets may not be recoverable. Examples of such events or circumstances include significant underperformance relative to historical or projected future operating results, significant changes in the manner of use of the acquired assets or the strategy for its business, significant negative industry or economic trends, or a significant decline in our stock price for a sustained period. Impairments are recognized based on the difference between the fair value of the asset and its carrying value, and fair value is generally measured based on discounted cash flow analyses. In 2008, management decided to no longer invest in an internally developed software tool for business process management resulting in an asset impairment charge of $1.7 million which was recorded in general and administrative expense in the fourth quarter of 2008. There were no asset impairments during 2010 or 2009.

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Deferred Tax Valuation Allowance

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. In the fourth quarter of 2008, with the exception of certain capital loss and foreign net operating loss carryforwards, we determined that it was more likely than not the deferred tax assets would be realized. Accordingly, we released the tax valuation allowance on most of the deferred tax assets and recorded an income tax benefit of $64.6 million for the year ended December 31, 2008.

As of December 31, 2010, with the exception of certain capital loss and foreign net operating loss carryforwards, we believed that the amount of deferred tax assets recorded on our balance sheet would ultimately be realized. However, 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.

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.

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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, 2010, we had approximately $17.7 million invested in available-for-sale marketable securities. An immediate 10% increase 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, 2010 and therefore, we are not subject to risks from immediate interest rate decreases.

Currency Rate Risk

We operate in North America, Europe, Asia-Pacific, Costa Rica and Japan. 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 decline of 10% in foreign currency exchange rates relative to the U.S. dollar on our results of operations and financial position could be material.

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ITEM 8. CONSOLIDATED FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Quarterly Results of Operations

	Three Months Ended							
	2010				2009			
	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)	$ 92,893	$ 95,947	$ 108,196	$ 90,090	$ 86,616	$ 79,269	$ 76,316	$ 70,132
Gross profit(2)	71,756	74,933	87,018	69,710	63,806	59,001	57,978	52,707
Profit (loss) from operations(3)	14,770	21,923	45,344	20,697	14,645	(60,194)	6,253	5,284
Net profit (loss)(3)	$ 9,905	$ 16,815	$ 32,603	$ 14,930	$ 11,492	$ (49,942)	$ 4,545	$ 2,636
Net profit per share:								
Basic	$ 0.13	$ 0.22	$ 0.43	$ 0.20	$ 0.15	$ (0.72)	$ 0.07	$ 0.04
Diluted	$ 0.13	$ 0.22	$ 0.42	$ 0.19	$ 0.15	$ (0.72)	$ 0.07	$ 0.04
Shares used in computing net profit per share:								
Basic	76,333	76,081	75,703	75,166	74,482	69,528	66,285	65,983
Diluted	78,724	78,109	77,607	77,597	76,831	69,528	67,373	66,447

(1) Net revenues for June 2010 included a $14.3 million release of previously deferred revenue for Invisalign Teen replacement aligners.

(2) Gross profit for March 2010, December 2009, and September 2009 included amortization of prepaid royalties of $0.8 million, $4.3 million, and $1.9 million, respectively, related to the litigation settlement with Ormco. In addition, June 2010 gross profit also included the $14.3 million release of previously deferred revenue for Invisalign Teen replacement aligners.

(3) Profit (loss) from operations and net profit (loss) included:

$14.3 million release of previously deferred revenue for Invisalign Teen replacement aligners for June 2010. See *Note 1 Summary of Significant Accounting Policies in the Notes to our Consolidated Financial Statements.*

$0.8 million, $4.3 million, and $1.9 million of amortization of prepaid royalties related to the litigation settlement with Ormco for March 2010, December 2009 and September 2009, respectively. See *Note 6 Litigation Settlements in the Notes to our Consolidated Financial Statements.*

$1.2 million and $3.3 million related to the class action litigation settlement with Leiszler for December 2010 and September 2010, respectively. See *Note 6 Litigation Settlements in the Notes to our Consolidated Financial Statements.*

Litigation settlement charge of $69.7 million related to Ormco in September 2009. See *Note 6 Litigation Settlements in the Notes to our Consolidated Financial Statements.*

Restructuring charges of $0.4 million and $0.9 million in June 2009 and March 2009, respectively. See *Note 18 Restructurings in the Notes to our Consolidated Financial Statements*

$8.7 million 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 June 2010. See *Note 6 Litigation Settlements in the Notes to our Consolidated Financial Statements.*

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INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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REPORT OF MANAGEMENT ON INTERNAL CONTROL OVER FINANCIAL REPORTING

Management of Align is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934. Our internal control over financial reporting is designed 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, 2010. 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, 2010, our internal control over financial reporting was effective 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.

Our internal control over financial reporting as of December 31, 2010 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report which is included herein, which expresses an unqualified opinion on the effectiveness of our internal control over financial reporting as of December 31, 2010.

/s/ Thomas M. Prescott
Thomas M. Prescott
President and Chief Executive Officer

February 24, 2011

/s/ Kenneth B. Arola
Kenneth B. Arola
Vice President, Finance and Chief Financial Officer

February 24, 2011

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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, 2010 and 2009, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2010 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, 2010, 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

February 24, 2011

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ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per share data)

	Years Ended December 31,		
	2010	2009	2008
Net revenues:			
Invisalign (1)	$ 366,955	$ 295,215	$ 285,798
Non-case	20,171	17,118	18,178
Total net revenues	387,126	312,333	303,976
Cost of revenues:			
Invisalign	74,418	71,530	69,536
Non-case	9,291	7,311	9,314
Total cost of revenues	83,709	78,841	78,850
Gross profit	303,417	233,492	225,126
Operating expenses:			
Sales and marketing	114,013	112,542	115,062
General and administrative	64,790	61,718	62,154
Research and development	25,997	22,252	26,165
Litigation settlement costs	4,549	69,673	
Insurance settlement	(8,666)		
Restructurings		1,319	6,231
Total operating expenses	200,683	267,504	209,612
Profit (loss) from operations	102,734	(34,012)	15,514
Interest income	555	579	3,052
Interest expense	(19)	(85)	(24)
Other expense	(1,267)	(375)	(1,466)
Net profit (loss) before provision for income taxes	102,003	(33,893)	17,076
Provision for (benefit from) income taxes	27,750	(2,624)	(62,911)
Net profit (loss)	$ 74,253	$ (31,269)	$ 79,987
Net profit (loss) per share:			
Basic	$ 0.98	$ (0.45)	$ 1.20
Diluted	$ 0.95	$ (0.45)	$ 1.18
Shares used in computing net profit (loss) per share:			
Basic	75,825	69,094	66,812
Diluted	78,080	69,094	68,064

(1) Net revenues for the year ended December 31, 2010 includes a $14.3 million release of previously deferred revenue for Invisalign Teen replacement aligners.

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

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ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

(in thousands, except per share data)

	December 31, 2010	December 31, 2009
ASSETS		
Current assets:		
Cash and cash equivalents	$ 294,664	$ 166,487
Marketable securities, short-term	8,615	19,978
Accounts receivable, net of allowance for doubtful accounts of $735 and $1,033, respectively	65,430	54,537
Inventories	2,544	2,046
Prepaid expenses and other current assets	17,358	18,251
Total current assets	388,611	261,299
Marketable securities, long-term	9,089	
Property and equipment, net	30,684	24,971
Goodwill	478	478
Intangible assets, net	2,188	4,988
Deferred tax asset	42,439	61,535
Other assets	3,454	1,969
Total assets	$ 476,943	$ 355,240
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 7,768	$ 6,122
Accrued liabilities	51,358	42,822
Deferred revenues	33,848	32,299
Total current liabilities	92,974	81,243
Other long-term liabilities	6,222	961
Total liabilities	99,196	82,204
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; 76,390 and 74,568 issued and outstanding, respectively)	8	7
Additional paid-in capital	555,851	525,073
Accumulated other comprehensive income, net	134	455
Accumulated deficit	(178,246)	(252,499)
Total stockholders equity	377,747	273,036
Total liabilities and stockholders equity	$ 476,943	$ 355,240

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

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ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY

For the years ended December 31, 2010, 2009 and 2008

(in thousands)

	Common Stock		Additional Paid in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total
	Shares	Amount				
Balances at December 31, 2007	68,642	$ 7	$ 450,140	$ 657	$ (289,650)	$ 161,154
Net profit					79,987	79,987
Net change in unrealized gain from available-for sale securities				33		33
Net change in cumulative translation adjustment				(421)		(421)
Comprehensive net income						79,599