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SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2009

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)**

881 Martin Avenue
Santa Clara, California 95050
(Address of principal executive offices)
(408) 470-1000
(Registrant's telephone number, including area code)

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

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

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

None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ 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 ☒

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 ☒ 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 ☐ 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. ☒

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 ☒		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 ☒

The aggregate market value of the registrant's common stock held by non-affiliates of the registrant was $601,598,887 as of June 30, 2009 based on the closing sale price of the registrant's common stock on the NASDAQ Global Market on such date. Shares held by persons who may be deemed affiliates have been excluded. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

On February 19, 2010, 75,277,984 shares of the registrant's common stock were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement relating to its 2010 Annual Stockholders' Meeting to be filed pursuant to Regulation 14A within 120 days after the registrant's fiscal year end of December 31, 2009 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, 2009
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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 Proficiency Requirements and its impact on our case volume and revenues, the anticipated impact our new products and product enhancements will have on doctor utilization and our market share, our expectations regarding product mix and product adoption, our expectations regarding the existence and impact of seasonality, our expectations regarding the continued growth of our international markets, our expectations regarding the impact of increased consumer marketing programs in Europe, the anticipated level of our operating expenses, 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. 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. In addition, for North America dental professionals, every Invisalign provider must start 10 Invisalign cases and complete at least 10 Invisalign-specific continuing education (CE) credits each calendar year. See discussion of Invisalign Proficiency Requirements in *Item 1 – Business – Business Strategy – Becoming a Leading Invisalign provider*. 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 and Latin American regions. Additionally, we recently announced the addition of an international distributor for the smaller country markets in Europe, the Middle East and Africa.

We were incorporated in Delaware in April 1997. Our headquarters are currently located at 881 Martin Avenue, Santa Clara, California 95050, and our telephone number is 408-470-1000. In January 2010, we entered into a lease agreement for office space located at 2560 Orchard Parkway, San Jose, California for our new corporate headquarters. We expect to commence conducting business at this location on or about June 28, 2010. 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 4 million people annually elect treatment by orthodontists worldwide, of which approximately 2.2 million have mild to moderate malocclusion and are applicable to Invisalign—our served 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 typically range between U.S. $3,500 to $7,000 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.

- *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 system that addresses these patient concerns.

The Invisalign Solution

Invisalign is a proprietary system for treating malocclusion. The Invisalign system is comprised of several phases, the principal steps of which are the creation of customized digital treatment plans using proprietary software known as ClinCheck, 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 a polyvinyl-siloxane, or PVS impression of the relevant dental arches, x-rays of the patient's dentition, photographs of the patient, a bite impression depicting the relationship between the patient's upper and lower dental arches and an Invisalign treatment planning form, or prescription. 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. 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 ClinCheck, is an internally developed and proprietary computer modeling program that allows dental professionals to diagnose and plan treatments for their patients. This ClinCheck simulation is then reviewed for adherence to prescribed clinical treatment and quality standards. Upon completion of the review, the patient's ClinCheck is then made available to the prescribing dental professional via Virtual Invisalign Practice (VIP), our proprietary customer interfacing software portal, which is available on our websites located at *www.invisalign.com* and *www.aligntech.com*. The dental professional then reviews the ClinCheck and can either

accept the proposed treatment or request modifications and adjustments until satisfied with the treatment plan. ClinCheck allows the dental professional to view this three-dimensional simulation with a high degree of magnification and from any angle. Accordingly, ClinCheck 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 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 simulation, 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 simulation. Aligners are customized to perform the treatment prescribed for an individual patient by dental professionals using ClinCheck. 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 simulation. 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, aligners are manufactured in batches based on a progress tracking feature integrated into 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 2009	Fiscal Year 2008	Fiscal Year 2007
Invisalign Full	75%	84%	86%
Invisalign Express	9	8	8
Invisalign Teen	8	2	—
Invisalign Assist	3	—	—
Other	5	6	6
Total	100%	100%	100%

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 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. Invisalign Express is a lower-cost solution for less complex orthodontic cases. Invisalign Express is a dual arch orthodontic treatment for cases that meet certain predetermined clinical criteria and consist of up to ten sets of aligners. Invisalign Express is intended to help a broader range of patients elect orthodontic treatment by providing a lower-cost option for adult relapse cases, for minor crowding and spacing, or as a pre-cursor to restorative or cosmetic treatments such as veneers. For Invisalign Express, 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.

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 and VIP (Virtual Invisalign Practice) 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*. ClinCheck enables dental professionals to preview and modify the intended outcome of treatment in an interactive three-dimensional computer model. ClinCheck 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 4 million people annually elect treatment by orthodontists worldwide, of which approximately 2.2 million have mild to moderate malocclusion and are applicable to Invisalign—our served market. As of December 31, 2009, our share of the 2.2 million patients in our served market is approximately 6%. Our market research indicates that the vast majority of people 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 overall treatment time.* Aligners control force by distributing it broadly over the exposed surfaces of the teeth. In addition, the ClinCheck simulation from which aligners are produced is designed to reduce unintended and unnecessary tooth movements. Together, these factors may reduce overall treatment time relative to traditional braces.
- *Potentially reduced root resorption.* We believe that controlling force and shortening treatment time 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.
- *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 people 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.

Approximately 4 million people annually elect treatment by orthodontists worldwide of which approximately 2.2 million have mild to moderate malocclusion and are applicable to Invisalign—our served market. Twenty-three percent of these patients, or approximately 510,000, have mature dentition (adults and older teens), with fully-erupted second molars and substantially completed jaw growth. Seventy-seven percent, or approximately 1.7 million, have erupting dentition (non-adult comprehensive, or younger teens), with partially-erupted second molars, cuspid and second bicuspid teeth. As of December 31, 2009, our share of the 2.2 million patients in our served market is approximately 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.

As of December 31, 2009, approximately 1,164,695 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 24%, 21% and 17% of our net revenues in 2009, 2008 and 2007, respectively. A geographic breakdown of our net revenues is summarized in *Note 18 "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 2009, 2008, and 2007.

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 technology innovation in order to extend clinical effectiveness and treat more patients and achieve better outcomes;
2. Enhance the customer experience for our doctors and for their staff by making it easier and more efficient to adopt Invisalign into their practice and increase utilization;
3. Drive more efficient consumer demand creation, improve conversion rates and re-fresh the Invisalign brand image and positioning; and
4. Continue to drive European growth while opening up additional new markets around the world.

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 product 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 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. Based on this knowledge we announced two new products in 2008 to address these distinct needs. In July 2008, we released Invisalign Teen which is designed to meet the specific needs of the non-adult comprehensive or younger teen market. Predominantly marketed to the orthodontist, the launch of a teen-specific product makes the Invisalign system more applicable to an orthodontist's patient base, which we believe will increase our penetration into and our share of the teen treatment market over time. Invisalign Teen has grown from 3% of our total case volume when it was introduced in 2008 to 12% of our total case volume in 2009 and we expect that orthodontists will continue to adopt Invisalign Teen slowly, after they experience multiple successful treatment outcomes. In October 2008, we announced the release of Invisalign Assist, which is intended to help newly-trained and lower volume Invisalign GPs accelerate the adoption and frequency of use of Invisalign into their practice. Invisalign Assist features are intended to make it easier for doctors to select appropriate cases for their experience level or treatment approach. In October 2009, additional features were added or enhanced in Invisalign Assist that are intended to expand the capabilities of Invisalign Assist and give doctors the confidence and control necessary to treat a wider range of patients. We also introduced new and enhanced features in all other Invisalign products. The new product line features are designed to overcome barriers to treatment by addressing clinical issues that some orthodontists and GPs have traditionally perceived as challenging in Invisalign treatment, such as extrusion and rotation of teeth, root movements and interproximal reduction (IPR). 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.

We continue to make significant progress with new products and features for Invisalign, yet total Invisalign case starts are still small relative to our total served market. During 2010, 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 by focusing on specific customer "touch points", or areas where we interact directly with our customers. Specifically, we provide robust clinical education resources and training programs, improving customer support, providing field sales support and helping doctors with practice development on how to better 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 a pre-training course intended to familiarize doctors with the Invisalign system prior to attending the full training course. In addition, we recently updated our initial training program, Clear Essentials I, by focusing on Invisalign Assist, instead of Invisalign Full, 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. In the past, many doctors completed this training course as a means of learning more about Invisalign or leveraging the marketing benefits of Invisalign, but then only sporadically submitted cases. Building on our experience with the Proficiency Requirements, we expect that in the future doctors are more likely to attend our Clear Essentials I training course when they are actually ready to begin using Invisalign in their practices right away. As a result, over time, we believe we are likely to have a more focused,

engaged and committed customer base that maintains a baseline of up-to-date Invisalign product knowledge.

We have also incorporated the Invisalign technique into the curriculum of 38 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 program (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, and other clinical resources. Many of these courses and resources are eligible for continuing education (CE) credits. Additionally, our VIP portal (Virtual Invisalign Practice) 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.
- *Becoming a Leading Invisalign provider.* Our goal is to help ensure that every practice that works with Invisalign can achieve great clinical and commercial outcomes and that every patient in Invisalign treatment gets the smile they want.

On June 2, 2009, we announced the implementation of the Invisalign Product Proficiency Requirements (or the Proficiency Requirements) in North America to help ensure that Invisalign-trained doctors have the experience and confidence necessary to achieve high quality treatment outcomes for Invisalign patients. Under the Proficiency Requirements, every Invisalign provider in North America must have 10 Invisalign case starts (measured by ClinCheck acceptance) and complete at least 10 Invisalign-specific continuing education (CE) credits each calendar year. Doctors who met the proficiency requirements of 10 case starts and 10 Invisalign CE hours by the end of 2009 will benefit from a new addition to Align's consumer marketing programs, one that encourages prospective patients to seek out "Invisalign Preferred Providers." Starting in January 2010, this new Invisalign Preferred designation will be highlighted on the Invisalign web site and in television ads as a way to recognize doctors' commitment to continued proficiency with Invisalign. The Invisalign Preferred designation will then be awarded on an annual basis to doctors who meet the proficiency requirements for a given year.

In October 2009, we updated the Proficiency Requirements in order to further support our customers through this significant change and provided a one-time, additional six month qualification period for doctors who were unable to meet the proficiency requirements for 2009, but demonstrated a desire to continue using Invisalign. The additional six month qualification period stipulated that doctors who had at least one case start and at least one Invisalign CE hour at the end of 2009 will be allowed to maintain their active Invisalign provider status through June 30, 2010, provided that they meet half of the annual proficiency requirements (at least 5 case starts and 5 Invisalign CE hours) between January 1 and June 30, 2010. Doctors will still be responsible for meeting the total annual requirements of at least 10 case starts and 10 Invisalign CE hours by the end of 2010 to qualify as providers for the following year.

Doctors with zero case starts or zero Invisalign CE hours at the end of 2009 were not eligible for the additional qualification period. They will be able to continue treating in-progress cases but will not be

able to submit new Invisalign cases or use Invisalign branding or marketing resources. Doctors can reactivate their provider status by retaking Invisalign Clear Essentials I training and meeting the proficiency requirements during the new calendar year.

As of January 2010, approximately 6,400 doctors met the Invisalign Proficiency Requirements and another 15,800 doctors met the criteria for the additional six-month qualification period in 2009. We limited the account status of approximately 13,400 doctors who did not meet either Proficiency Requirements or the additional qualification period requirements but can continue treating and finishing in progress patients. In addition, we deactivated approximately 9,600 Invisalign-trained doctors who had never submitted a single Invisalign case. See *Item 1A – Risk Factors of this Annual Report on Form 10-K for risks related to the Proficiency Requirements.*

Increasing the effectiveness of our consumer demand creation and re-freshing the Invisalign brand. 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 people with malocclusion who desire treatment forgo treatment rather than elect traditional treatment due to its many limitations, such as compromised aesthetics and oral discomfort. By communicating the benefits of Invisalign to both dental professionals and consumers, we intend to increase the number of patients who seek treatment using Invisalign. Historically, our marketing programs have been directed to an adult audience, however, with the introduction of Invisalign Teen, this past year we directed our communication efforts directly to teens and their parents. We continue to be successful with programs that more effectively and efficiently generate demand or "pull" for Invisalign. In 2009, we became more efficient in our approach and grew overall lead generation and awareness on lower total spending. We also shifted our marketing mix from conventional media towards more digital marketing and social networking activity. We introduced a new public relations program for Invisalign Teen, launched a teen specific website and leveraged online and mobile widgets, social media and blogs directly targeted to teens. We believe that consumer demand creation is a key component to our long-term growth. As a result, we will continue to invest in efforts to increase consumer awareness of Invisalign through a variety of media outlets. We will continue to drive consumer demand among the adult population primarily though our conventional media programs, and increasingly leverage digital and event marketing and social networking activity to directly target teens and their parents. Additionally, we are evolving the Invisalign brand strategy while refreshing the Invisalign look and feel. We are introducing a new and more modern logo and new brand positioning focused on treatment outcome and practice growth. As part of this effort, in January 2010, we completely updated our consumer website, *www.invisalign.com*, *www.aligntechinstitute.com*, *and* *www.invisalign.com/teen* and base marketing materials. Preferred Providers will be the first customers to be able to utilize the new Invisalign branding for use in their own marketing.

Growth of international markets. We will continue to focus our efforts towards increasing adoption of Invisalign by dental professionals in our key international markets, Europe and Japan. 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. Through December 31, 2009, we have trained over 15,700 doctors, predominantly orthodontists in core Europe, our primary international market. Product line expansion is key to providing doctors a solution that addresses a wider range of potential patient needs with greater treatment flexibility. In March 2009, we announced the availability of Invisalign Teen for Invisalign-trained doctors worldwide, except for Japan. As a result, we expect the addressable market for our product to expand and ultimately increase adoption. In addition, we will carry on our efforts to increase brand awareness and consumer demand in Europe by continuing our consumer advertising campaign. Additionally, although the vast majority of our international revenues are from direct sales, approximately 9% of our international sales are through distributors covering smaller international markets, specifically Asia Pacific and Latin America. We will consider selling through distributors in other smaller or less strategic markets as well as consider expanding directly into additional countries on a case-by-case basis. For example, we recently announced the addition of an international distributor for 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. In 2009, our international sales increased from 21% of net revenues to 24% of net revenues.

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 Santa Clara, 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, 2009, our digital planning, manufacturing and operations staff in the U.S., Costa Rica and Mexico consisted of 1,271 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 set-up treatment plan by the dental professional, these plans are then transmitted electronically to Juarez, Mexico. ClinCheck 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. In April 2009 we terminated our shelter services arrangements with International Manufacturing Solutions Operaciones, S.R.L., or IMS and became a direct manufacturer of our clear aligners at the 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 scale our manufacturing capacity, we expect that we will continue to invest in capital equipment.

Quality Assurance

Align's quality system is in compliance with Food & Drug Administration's Medical Device regulations, 21CFR Part 820, and Health Canada's Medical Device Regulations. We are certified to EN ISO 13485:2003, internationally recognized standards for Medical Device manufacturing. We have a formal, documented quality system by which quality objectives are defined, understood and achieved. Systems, processes and procedures are implemented to ensure high levels of product and service quality. We monitor the effectiveness of the quality system based on internal data and direct customer feedback and strive to continually improve our systems and processes, taking corrective action, as needed.

Since we custom manufacture aligners on a build-to-order basis, we do not offer refunds on our products. Because each ClinCheck 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, mail campaigns, trade shows, trade journals and print media, and to consumers through advertising, digital media, event marketing and social networking activities. Based on our experience with advertising and commercial sales, we believe that making consumers aware of Invisalign as a new 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, 2009, we had trained 59,890 dental professionals worldwide to use Invisalign. Of those trained dental professionals, approximately 74% are dental professionals in our North American market. Within our North American market, we have trained 8,935 orthodontists and 35,215 GPs cumulatively through the end of 2009. As part of the Proficiency Requirements, in January 2010, we deactivated approximately 9,600 Invisalign-trained doctors who had never submitted an Invisalign case. In addition, we limited the account status of approximately 13,400 doctors who did not meet either the Proficiency Requirements or the additional qualification period requirements but can continue treating and finishing in progress patients. See discussion of Invisalign Product Proficiency Requirements in *Item 1—Business—Business Strategy—"Becoming A Leading Invisalign Provider"*.

As of December 31, 2009 our North American sales organization consisted of 164 people, of which 150 were direct sales representatives and 14 were sales administration and management. Internationally, we had 45 people engaged in sales and sales support as of December 31, 2009. 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 and Latin American regions. We have also recently announced the addition of an international distributor in the 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 and orthodontic 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, clinical tips and techniques, guidance on pricing and instructions on interacting with our ClinCheck software and the many other features of our website.

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;
- consumer marketing and advertising;
- our websites, which can be accessed at either *www.invisalign.com*, *www.invisalignteen.com*, *www.aligntech.com*, *or www.aligntechinstitute.com;*
- direct-to-consumer mail and digital advertising;
- public relations efforts; and
- other 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 manufacturing process and enhancing our Invisalign system product lines, including the development of distinct product platforms for the GPs and orthodontists such as Invisalign Assist and Invisalign Teen. Our research and development expenses were $22.3 million for 2009, $26.2 million for 2008, and $25.7 million for 2007.

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.

Intellectual Property

We believe our intellectual property position represents a substantial business advantage. As of December 31, 2009, we had 131 issued U.S. patents, 160 pending U.S. patent applications, and numerous foreign issued patents, as well as 122 pending foreign patent applications. See *Item 3 "Legal Proceedings" for a discussion on Reexamination Proceedings pending with the United States Patent and Trademark Office.*

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. 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. However, with the availability of Invisalign Teen, 2009 was the first summer we were able to actively compete for a share of teen patient starts. We believe that Invisalign Teen may have helped and may in the future help moderate the historical downward trend we have typically seen 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 treatment plan, or ClinCheck, 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 ClinCheck. Our backlog consists of ClinCheck- approved cases, which are generally shipped within a short period of time. As a result, we believe that backlog is not a good indicator of future sales, and our quarterly revenues depend largely on the timing of ClinCheck approvals and the impact on cases shipped in that 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). 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;
- effectiveness of treatment;
- customer support;
- 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 will now be listed as precautions. We believe our Invisalign system is in compliance in all material respects with applicable quality system regulations, record keeping and reporting requirements in the production and distribution of the Invisalign system. 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.

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 information. Confidentiality of patient records and the circumstances under which these records may be released are subject to substantial regulations under the HIPAA Standards for Privacy of Individually Identifiable Health Information, referred to as the Privacy Standard, and other state laws and regulations. The Privacy Standard governs both the disclosure and the use of confidential patient medical 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 U.S. Food and Drug Administration 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 statute 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.

Employees

As of December 31, 2009, we had 1,895 employees, including 1,271 in manufacturing and operations, 281 in sales and marketing, 132 in research and development and 211 in general and administrative functions. We had 411 employees in North America, 766 employees in Costa Rica, 177 employees in Europe, 531 employees in Mexico, and 10 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 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 26, 2010:

Name	Age	Position
Thomas M. Prescott	54	President and Chief Executive Officer
Kenneth B. Arola	54	Vice President, Finance and Chief Financial Officer
Dana Cambra	52	Vice President, Research & Development and Information Technology
Dan S. Ellis	58	Vice President, North American Sales
Roger E. George	44	Vice President, Legal and Corporate Affairs General Counsel and Corporate Secretary
Len M. Hedge	52	Senior Vice President, Business Operations
Gil Laks	44	Vice President, International
SheilaTan	46	Vice President, Marketing and Chief Marketing Officer
Emory Wright	40	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. Mr. Prescott serves as a director of InterPULSE, Inc., a privately held company.

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 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 Vice President, 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.

Gil Laks has served as our Vice President, International since September 2005, and served as our Vice President, Europe since June 2001. Prior to joining us, Mr. Laks was Vice President, Business Development for the diagnostic imaging division of Singapore Technologies, from November 1999 to May 2001. He also served as Director of International for ISIX, Ltd., an educational computing services firm, from October 1996 to October 1999. In January 2010, we announced the addition of an international distributor for smaller country markets in Europe, the Middle East and Africa (EMEA). As part of the distribution agreement for EMEA, Mr. Laks will leave Align and take on a new role as owner of the new distributor in the second quarter of 2010.

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.

Emory M. Wright has served as our Vice President, Operations since December 2007. He has been with us since March 2000, predominantly in manufacturing and operations roles. Previously, Mr. Wright served as Vice President, Manufacturing and most recently was General Manager of New Product Development. Prior to joining us, Mr. Wright was Senior Manufacturing Manager at Metrika, Inc. a medical device manufacturer, from May 1999 to March 2000. From July 1994 to May 1999, Mr. Wright served as Manager of Manufacturing and Process Development for Metra Biosystems Inc.

ITEM 1A. RISK FACTORS

We depend on the sale of the Invisalign system for the vast majority of our revenues, and any decline in sales of Invisalign for any reason, including as a result of the introduction of the Proficiency Requirements or 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 the introduction of the Proficiency Requirements or continued weakness in general economic conditions.

Our success depends upon increasing acceptance and frequency of use of the Invisalign system by dental professionals (what we refer to as utilization). We have a large number of low volume doctors that make up a large portion of our customer base. We want every Invisalign provider to be one we can comfortably direct a prospective patient to with an expectation of knowledgeable treatment and a great outcome. On June 2, 2009, we announced the implementation of the Invisalign Proficiency Requirements (or the Proficiency Requirements) in North America to help ensure that Invisalign-trained doctors have the experience and confidence necessary to achieve high quality treatment outcomes for Invisalign patients. Under the Proficiency Requirements, every Invisalign provider in North America must have 10 Invisalign case starts (measured by ClinCheck acceptance) and complete at least 10 Invisalign-specific continuing education (CE) credits each calendar year. In October 2009, we updated the Proficiency Requirements in order to further support our customers through this significant change and provided a one-time, additional six month qualification period stipulating that for those doctors who had at least one case start and at least one Invisalign CE hour at the end of 2009 will be allowed to maintain their active Invisalign provider status through June 30, 2010, provided that they meet half of the annual proficiency requirements (at least 5 case starts and 5 Invisalign CE hours) between January 1 and June 30, 2010. Doctors will still be responsible for meeting the total annual requirements of at least 10 case starts and 10 Invisalign CE

hours by the end of 2010 to qualify as providers for the following year. Doctors with zero case starts or zero Invisalign CE hours at the end of 2009 were not eligible for the additional qualification period. They will be able to continue treating in-progress cases but will not be able to submit new Invisalign cases or use Invisalign branding or marketing resources. Doctors can reactivate their provider status by retaking Invisalign training and meeting the proficiency requirements.

As of January 2010, approximately 6,400 doctors met the Invisalign Proficiency Requirements and another 15,800 doctors met the criteria for the additional six-month qualification period in 2009. We limited the account status of approximately 13,400 doctors who did not meet either Proficiency Requirements or the additional qualification period requirements. These doctors can continue treating and finishing in progress patients. In addition, we deactivated approximately 9,600 Invisalign-trained doctors who had never submitted a single Invisalign case. Although we want every doctor to achieve and maintain the Proficiency Requirements with Invisalign, we expect that a number of our lower volume doctors may choose not to meet these requirements. As a result, the Proficiency Requirements may result in greater variability among customer activity, particularly in the second half of 2010 after the additional six-month qualification period expires on June 30, 2010. If the number of our customers who fail to maintain and/or increase utilization to meet the Proficiency Requirements is greater than we anticipate, our case volumes will decrease and our revenues will be harmed. In addition, if GPs and Orthos do not attend our training courses in sufficient numbers for any reason, including the introduction of the Proficiency Requirements, or continued weakness in general economic conditions, our revenue may fail to grow as expected. 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 and utilization does not increase as we anticipate, 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.

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, expand our discount programs in the future, if participation in these programs increases or if our product mix shifts to lower priced products or newer products that have a higher percentage of deferred revenue, 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.

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. While we generated positive operating cash flow in 2008 and in 2009, we cannot be certain that we will be able to achieve positive cash flow from operations, from period to period, in

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

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

Our operating results have fluctuated in the past and we expect our future quarterly and annual operating results to fluctuate as we focus on increasing doctor and consumer demand for our products. These fluctuations could cause our stock price to decline. 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;
- disruptions to our business due to the impact of an epidemic, such as the H1N1 virus, 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;
- 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;
- seasonal fluctuations in the number of doctors in their offices and their availability to take appointments;
- success of 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 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;
- inaccurate forecasting of revenues, production and other operating costs; and
- investments in research and development to develop new products and enhancements to Invisalign.

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 2009, we introduced new and enhanced features in all Invisalign products. There can be no assurance that we will be able to successfully develop, sell and achieve market acceptance of these and other new products and applications and enhanced versions of our existing product. 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, 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 ClinCheck 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 Santa Clara, 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 such as the outbreak of the H1N1 virus in the event travel to and from Mexico is restricted;
- 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 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 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 ClinCheck and VIP. 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 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, 2009, we had 131 issued U.S. patents, 160 pending U.S. patent applications, and 60 issued foreign patents, and 122 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. Any of these results from our litigation could adversely affect our results of operations and stock price.

We are currently a party to various other legal proceedings and claims. 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. See *Part I, Item 3 of this Annual Report on Form 10-K for a summary of our material pending legal proceedings.*

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 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 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, 2009, our North American sales organization consisted of 164 people, of which 150 were direct sales representatives and 14 were sales administration. Internationally,

we had 45 people engaged in sales and sales support as of December 31, 2009. 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. Our failure to take satisfactory corrective action in response to an adverse inspection or the failure to comply with applicable manufacturing regulations could result in enforcement action, and we may be required to find alternative manufacturers, which could be a long and costly process.

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, there have been and continue to be proposals by the Obama administration, members of Congress, state governments, regulators and third-party payors to control these costs and, more generally, to reform the U.S. healthcare system. In December 2010, the United States Senate advanced legislation that included a market-share based excise tax of approximately $2 billion annually on medical device manufacturers beginning in 2011. This legislation compares to a bill previously passed by the House of Representatives that includes a 2.5 percent sales-based excise tax on medical device manufacturers beginning in 2013. At this point in the legislative process, the differences between each version have not yet been reconciled. We cannot predict whether legislation will be enacted, the final form any legislation might take or the effects of such legislation. These taxes, if implemented, would 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.

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;
- 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. Recently, 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; 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. With the current unstable credit environment, we might incur significant realized, unrealized or impairment losses associated with these investments.

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

Our board of directors has the authority to issue up to 5,000,000 shares of preferred stock and to determine the rights, preferences, privileges and restrictions of such shares without any further vote or action by our shareholders. To date, our board of directors has designated 200,000 shares as Series A participating preferred stock in connection with our shareholder rights' plan. The issuance of preferred stock under certain circumstances could have the effect of delaying or preventing an acquisition of the company 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 2009. Because Costa Rica incurred a net loss in 2009, no tax benefit was realized from these incentives in 2009. 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.

ITEM 2. PROPERTIES

We occupy approximately four facilities with a total office and manufacturing area of over 274,000 square feet of leased properties. At December 31, 2009, these facilities were occupied as follows:

Location	Property / Approximate Size	Use	Expiration of lease
Santa Clara, CA	Buildings/127,000 sq. feet	Leased office for headquarters, reasearch & development, administrative personnel	June 2010
San Jose, Costa Rica	Building/63,000 sq. feet	Leased office for administrative 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

On January 26, 2010, we entered into an agreement for new corporate headquarters to lease approximately 129,024 square feet in San Jose, California. The lease agreement commences on the earlier of August 1, 2010 or the date we first commence conducting business in the premises, which is expected to be on or about June 28, 2010 and will continue for an initial term of seven years and two months. The lease agreement for our current office headquarters in Santa Clara, California expires on June 30, 2010.

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

ITEM 3. LEGAL PROCEEDINGS

Consumer Class Action

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 July 3, 2007, we filed our answer to the complaint and asserted 17 affirmative defenses. On July 20, 2007, we filed a motion for summary judgment on the Third Cause of Action (the only cause of action alleged against us). On August 24, 2007, Weber filed a motion for class certification. On October 1, 2007, we filed an opposition to the motion of class certification and we are currently awaiting rulings from the Court. OrthoClear has filed a motion to dismiss. The initial case management conference and all discovery has been stayed pending the Court’s decision on the motion for class certification, OrthoClear’s motion to dismiss and our motion for summary judgment. We believe the lawsuit to be without merit and intend to vigorously defend ourselves.

Securities Litigation

In August 2009, Plaintiff Charles Wozniak filed a lawsuit against the Company 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 the common stock of

Align 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. The Court has recently selected a lead plaintiff. 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 2009.

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 listed on the NASDAQ Global Market under the symbol "ALGN." Public trading of our common stock commenced on January 26, 2001. Prior to that date, there was no public market for our common stock. The following table shows, for the periods indicated, the high and low per share closing prices of our common stock, as reported by the NASDAQ Global Market:

	High	Low
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
Year Ended December 31, 2008:		
Fourth quarter	$ 10.48	$ 5.00
Third quarter	$ 13.48	$ 10.01
Second quarter	$ 13.19	$ 9.84
First quarter	$ 16.55	$ 10.34

On February 19, 2010, the closing price of our common stock on the NASDAQ Global Market was $17.94 per share. As of February 19, 2010 there were approximately 172 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

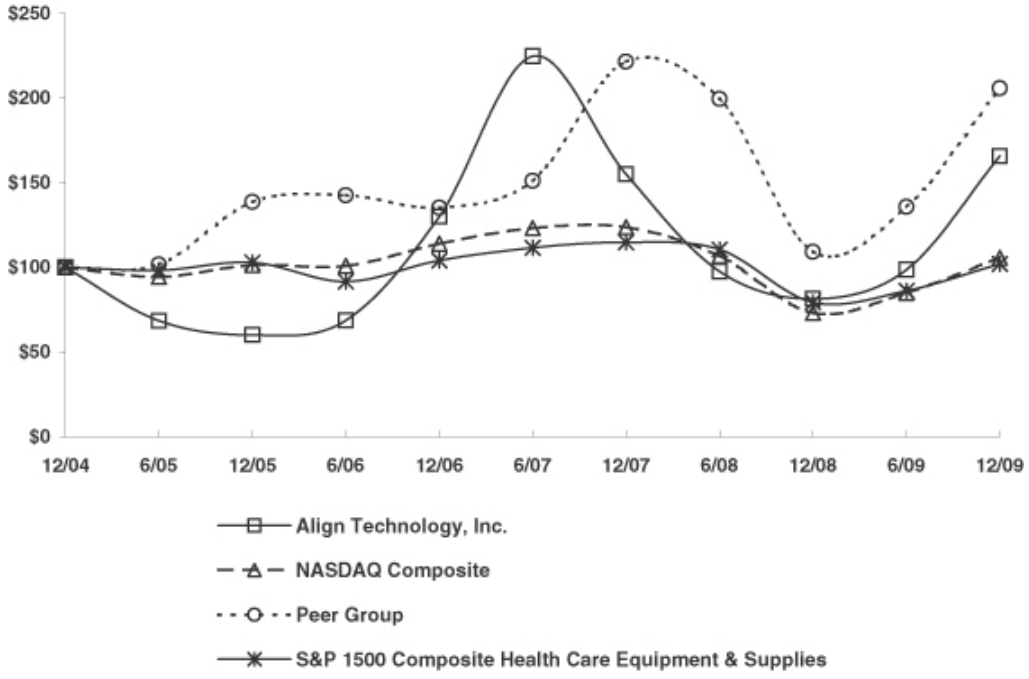
Notwithstanding any statement to the contrary in any of our previous or future filings with the SEC, the following information relating to the price performance of our common stock shall not be deemed "filed" with the SEC or "Soliciting Material" under the Securities Exchange Act of 1934, as amended, 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.

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., a peer group that we used from August 2007 until August 2009 and 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 stocks in the former peer group and the S&P Index, and that all dividends were reinvested.

The former peer group consisted of 13 companies listed below.

American Medical Systems Holdings, Inc.
Ansys Inc.
ArthroCare
Integra Lifesciences Hldgs.
Intuitive Surgical.
Natus Medical Inc.
Nektar Therapeutics.
Nuvasive Inc.
Sirona Dental Systems Inc.
Sonosite.
Vital Images Inc.



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, 2009. 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 65 to 90 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, 2009, 2008 and 2007 and the balance sheet data as of December 31, 2009 and 2008 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, 2006 and 2005 and the balance sheet data as of December 31, 2007, 2006 and 2005 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,				
	2009	2008	2007	2006	2005
Consolidated Statement of Operations Data:					
Net revenues	$312,333	$303,976	$284,332	$206,354	$207,125
Gross profit(4)	$233,492	$225,126	$209,297	$141,579	$143,341
Profit (loss) from operations(1)(2)(4)	(34,012)	15,514	33,855	(37,536)	2,446
Other income (expense), net	119	1,562	3,095	3,401	283
Net profit (loss) before provision for (benefit from) income taxes(1)(2)(4)	(33,893)	17,076	36,950	(34,135)	2,729
Provision for (benefit from) income taxes	(2,624)	(62,911)	1,226	828	1,316
Net profit (loss)(1)(2)(3)(4)	$ (31,269)	$ 79,987	$ 35,724	$ (34,963)	$ 1,413
Net profit (loss) per share					
Basic	$ (0.45)	$ 1.20	$ 0.53	$ (0.55)	$ 0.02
Diluted	$ (0.45)	$ 1.18	$ 0.50	$ (0.55)	$ 0.02
Shares used in computing net profit (loss) per share:					
Basic	69,094	66,812	67,176	63,246	61,644
Diluted	69,094	68,064	71,444	63,246	63,152

	December 31,				
	2009	2008	2007	2006	2005
Consolidated Balance Sheet Data:					
Working capital	$ 180,056	$ 117,335	$ 123,058	$ 40,306	$ 62,978
Total assets	355,240	279,341	222,761	151,558	142,110
Total long-term liabilities	961	229	148	219	64
Stockholders' equity	$ 273,036	$ 218,540	$ 161,154	$ 83,556	$ 93,438

(1) Profit (loss) from operations, net profit (loss) before provision for income taxes and net profit (loss) for the years ended December 31, 2007 and 2006 included a $1.8 million credit and a $14.3 million charge, respectively, for the Patients First Program and settlement costs. See *Note 5 "Patients First Program and settlement costs" in the Notes to Consolidated Financial Statements* for additional information.

(2) Profit from operations and net profit before benefit from income taxes included a $6.2 million restructuring charge for the year ended December 31, 2008. In addition, 2008 net profit included a $6.1 million

restructuring charge net of taxes of $129,000. See *Note 19 "Restructurings" in the Notes to Consolidated Financial Statements* for additional information.

(3) Net profit for the year ended December 31, 2008 included a $64.6 million benefit to income taxes as a result of the release of a tax valuation allowance on most of the deferred tax assets. See *Note 14 "Income Taxes" in the Notes to Consolidated Financial Statements* for additional information.

(4) Gross profit for the year ended December 31, 2009 included the amortization of prepaid royalties of $6.2 million related to the litigation settlement with Ormco. In addition, loss from operations, net loss before benefit from income taxes, and net loss included a litigation settlement charge of $69.7 million. See *Note 7 "Ormco Litigation Settlement" in the Notes to Consolidated Financial Statements* for additional information.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

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

Overview

Align Technology, Inc. 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.

Each Invisalign treatment plan is unique to the individual patient. Our Invisalign Full treatment consists of as many aligners as indicated by ClinCheck in order to achieve the doctors' treatment goals. Our Invisalign Express is a dual arch orthodontic treatment for cases that meet certain predetermined clinical criteria and consist of up to ten sets of aligners. Invisalign Express treatment is intended to assist dental professionals to treat a broader range of patients by providing a lower-cost option for adult relapse cases, for minor crowding and spacing, or as a pre-cursor to restorative or cosmetic treatments such as veneers. Invisalign Teen is designed to meet the specific needs of the non-adult comprehensive or teen treatment market. 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 innovation and clinical effectiveness, enhancing the customer experience, generating consumer demand and expanding into international markets. Each of these four key objectives is described more fully in *Item I—Business—Business Strategy* of this Annual Report on Form 10-K and is incorporated herein by this reference. In addition to whether we successfully execute our business strategy, a number of other factors, the most important of which are set forth below, may affect our results in 2010 and beyond.

- *Proficiency Requirements.* Our success depends upon increasing acceptance and frequency of use of the Invisalign system by dental professionals (what we refer to as utilization). We have a large number of low volume doctors that make up a large portion of our customer base. We want every Invisalign provider to be one we can comfortably direct a prospective patient to with an expectation of knowledgeable treatment and a great outcome. On June 2, 2009, we announced the implementation of the Invisalign Product Proficiency Requirements (or the Proficiency Requirements) in North America to help ensure that Invisalign-trained doctors have the experience and confidence necessary to achieve high quality treatment outcomes for Invisalign patients. Under the Proficiency Requirements, every Invisalign provider in North America must have 10 Invisalign case starts (measured by ClinCheck acceptance) and complete at least 10 Invisalign-specific continuing education (CE) credits each calendar year. Doctors who met the proficiency requirements of 10 case starts and 10 Invisalign CE hours by the end of 2009 will benefit from a new addition to Align's consumer marketing programs, one that encourages prospective patients to seek out "Invisalign Preferred Providers." Starting in January 2010, this new Invisalign Preferred designation will be highlighted on the Invisalign web site and in television ads as a way to recognize doctors' commitment to continued proficiency with Invisalign. The Invisalign Preferred designation will then be awarded on an annual basis to doctors who meet the proficiency requirements for a given year.

In October 2009, we updated the Proficiency Requirements in order to further support our customers through this significant change and provided a one-time, additional six month qualification period for doctors who were unable to meet the proficiency requirements for 2009, but demonstrated a desire to continue using Invisalign. The additional six month qualification period stipulated that for those doctors who had at least one case start and at least one Invisalign CE hour at the end of 2009 will be allowed to maintain their active Invisalign provider status through June 30, 2010, provided that they meet half of the annual proficiency requirements (at least 5 case starts and 5 Invisalign CE hours) between January 1 and June 30, 2010. Doctors will still be responsible for meeting the total annual requirements of at least 10 case starts and 10 Invisalign CE hours by the end of 2010 to qualify as providers for the following year.

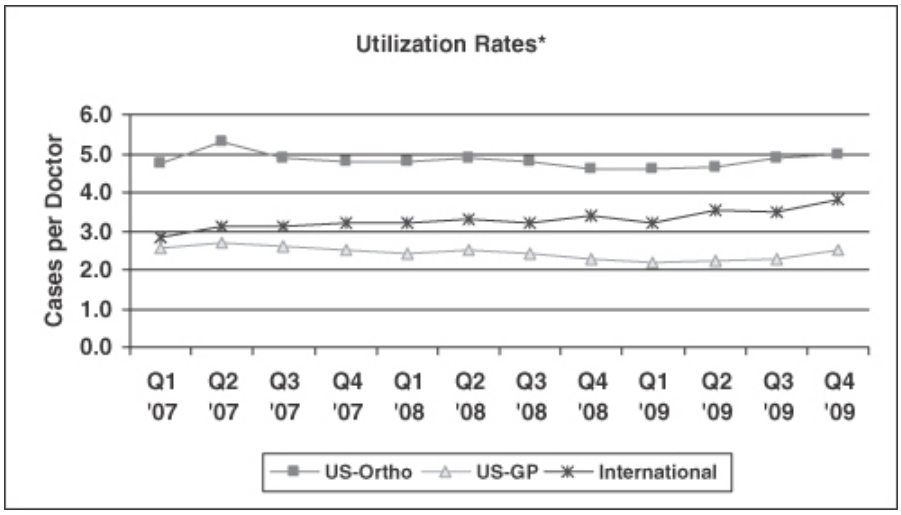
Doctors with zero case starts or zero Invisalign CE hours at the end of 2009 were not eligible for the additional qualification period. They will be able to continue treating in-progress cases but will not be able to submit new Invisalign cases or use Invisalign branding or marketing resources. Doctors can reactivate their provider status by retaking Invisalign training and meeting the proficiency requirements.

As of January 2010, approximately 6,400 doctors met the Invisalign Proficiency Requirements and another 15,800 doctors met the criteria for the additional six-month qualification period in 2009. We limited the account status of approximately 13,400 doctors who did not meet either Proficiency Requirements or the additional qualification period requirements. These doctors can continue treating and finishing in progress patients. In addition, we deactivated approximately 9,600 Invisalign-trained doctors who had never submitted a single Invisalign case.

Although approximately 15,800 doctors met the criteria for the additional six-month qualification period, the Proficiency Requirements may result in greater variability among customer activity, particularly in the second half of 2010 after the additional six-month qualification period expires. There can be no assurance on the number of doctors that ultimately meet the criteria for the additional six-month qualification period. If the number of our customers who fail to maintain and/or increase utilization to meet the additional qualification requirements on June 30, 2010 is greater than expected, our case volumes in the second half of 2010 will decrease and our revenues will be harmed. We want every doctor to achieve and maintain the Proficiency Requirements with Invisalign, we expect, however, that a number of our lower volume doctors may choose not to meet these requirements. In addition, if GPs and Orthos do not attend our training courses in sufficient numbers for any reason, including the introduction of the Proficiency Requirements, or declining general economic conditions, our revenue may fail to grow as expected.

- *Number of new doctors trained.* Prior to 2009, we historically have trained at least 5,000 new dentists per year in North America. With the introduction of the Proficiency Requirements and a renewed focus on attracting the right kind of customer, we trained approximately 2,825 new doctors in North America in 2009. 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. In the past, many doctors completed this training course as a means of learning more about Invisalign or leveraging the marketing benefits of Invisalign, but then only sporadically submitted cases. Building on our experience with the Proficiency Requirements, going forward, we expect that doctors are more likely to attend our training course when they are actually ready to begin using Invisalign in their practices right away. As a result, over time, although we are likely to have a more focused, engaged and committed customer base that maintains a baseline of up-to-date Invisalign product knowledge, we expect that the number of new doctors trained in North America will be relatively comparable to 2009.

- *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 from the years ended December 31, 2009, 2008, and 2007 are as follows:



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

Although utilization rates in the fourth quarter of 2009 for each of our Ortho, GP, and International channels were higher than the same quarter last year, we expect to see fluctuation in our utilization rates as practices adjust to the Proficiency Requirements. As a result of the Proficiency Requirements, we expect that in 2010, we will ship cases to fewer doctors each quarter compared to prior years. This will likely result in greater variability in utilization rates, particularly in the second half of 2010 after the additional qualification period expires. Due to this and other factors, we believe that quarter-to-quarter comparisons of utilization rates may not be as meaningful in 2010.

- *Impact of new products on deferred revenue.* Many of our products launched in 2008 (Vivera retainers, Invisalign Teen, Invisalign Assist) include features of staged delivery or the option to receive replacement aligners during the course of treatment. As a result of these features, these products have a significantly higher amount of deferred revenue as a percentage of their average selling prices compared to Invisalign Full. Vivera retainers are delivered in four shipments over the course of a year, and revenue is initially deferred and then recognized as each shipment occurs. Invisalign Teen which includes up to six replacement aligners, is delivered in a single shipment except for the replacement aligners. Currently, the revenue for the six replacement aligners is 100 percent deferred based on the fair market value and recognized as the replacement aligners are used or when the case is completed. Although Invisalign Teen has been available since July 2008, we do not have sufficient evidence to support a usage rate less than 100 percent for the six replacement aligners at this time, however, we are continually gathering and evaluating our historical experience. If and when we gather sufficient historical experience to support a usage rate for the six replacement aligners less than 100 percent, we would adjust our deferred revenue balance to the estimated usage rate and prospectively apply this rate to future Invisalign Teen shipments. For Invisalign Assist, when the progress tracking feature is selected, aligners are shipped every nine stages. As a result, revenue for these cases is deferred upon the first shipment and will be recognized upon the final shipment. Depending on customers' adoption of these products, our mix of products may continue to gradually shift towards these products, which will result in an increase in deferred revenue on our balance sheet.

- *Impact on consumer spending due to 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. Continued weakness in the United States economy and certain international economies in 2009 and into 2010 has adversely affected consumer spending habits. As a result of the uncertain economic outlook for 2010, our case volumes from quarter to quarter are difficult to predict with certainty, and our revenue may fail to grow as expected.
- *International expansion.* We will continue to focus our efforts towards increasing adoption of Invisalign by dental professionals in our key international markets, Europe and Japan. With the availability of Invisalign Teen in March 2009 for Invisalign-trained doctors worldwide, we expect the addressable market for our product internationally to expand and ultimately increase adoption. In addition, we will continue to focus on increasing brand awareness and consumer demand in Europe by continuing our consumer advertising campaign. Additionally, although the vast majority of our international revenues are from direct sales, approximately 9% of our international sales are through distributors covering smaller international markets, specifically Asia Pacific and Latin America. We recently announced the addition of an international distributor for smaller country markets in Europe, the Middle East and Africa. We will continue to consider selling through distributors in other smaller or less strategic markets as well as consider expanding directly into additional countries on a case-by-case basis. 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. In 2009, our international sales increased from 21% of net revenues to 24% of net revenues.
- *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 in Europe. In addition, 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. As a result, adult appointments, including adult Invisalign patient starts, are often pushed further into late summer or early fall. In 2009, we did not experience the normal seasonality in our business and had sequential case growth in the North American orthodontic from second quarter to the third quarter. With the availability of Invisalign Teen, 2009 was the first summer we were able to actively compete for a share of teen patient starts and believe that Invisalign Teen may have helped moderate the historical downward trend we have typically seen for our North American orthodontic customers during the summer months. However, there can be no assurance that our historical seasonal trends will not continue to cause, fluctuations in our quarterly results, including fluctuations in sequential revenue growth rates.
- *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 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.
- *Ormco Litigation Settlement*. On August 16, 2009, the Company and Ormco entered into a Settlement Agreement, pursuant to which the Company (1) paid Ormco a cash amount equal to approximately $13.2 million, and (2) agreed to issue to Danaher Corporation (“Danaher”), an affiliate of Ormco, 7.6 million fully paid and non-assessable shares of the Company’s Common Stock, 5.6 million and 2.0 million of which were issued to Danaher on August 16, 2009 and September 22, 2009, respectively, pursuant to the Stock Purchase Agreement entered into between the Company and Danaher on August 16, 2009.

Joint Development, Marketing and Sales Agreement. In connection with the settlement reached with Ormco, on August 16, 2009, Align and Ormco entered into the Joint Development, Marketing and Sales Agreement, pursuant to which the parties have agreed to an exclusive collaboration over the next seven years to jointly develop and commercialize a combination orthodontic treatment system involving the use of both Align's clear aligner system and Ormco's brackets and arch wire system, which system will be capable of treating even the most complex orthodontic cases.

See *Note 7 "Ormco Litigation Settlement" for additional information about the settlement accounting.*

- *2010 Operating Expenses.* During 2010, we expect our research and development as well as selling and general administrative expenses to be higher as we continue to invest in our international operations, although we expect there will be quarterly fluctuations based on the timing of media spend, significant trade shows and industry events.
- *Tax Valuation Allowance.* We continually evaluate both the positive and negative evidence in assessing our need for a tax valuation allowance. As a result of our analysis, we released the tax valuation allowance on most of the deferred tax assets with the exception of certain capital loss and foreign net operating loss carryforwards as of December 31, 2008. However, should there be a change in our ability to recover these deferred tax assets, the tax provision would increase in the period in which it is more likely than not that the we cannot recover our deferred tax assets.
- *Effective Tax Rate*. 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.

Results of Operations

Comparison of Years Ended December 31, 2009, 2008 and 2007:

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, 2009, 2008, and 2007 are as follows (in millions):

	Years Ended December 31,						
Net revenues	2009	Net Change	% Change	2008	Net Change	% Change	2007
North America:							
Ortho	$ 90.4	$ 2.1	2.4%	$ 88.3	$ (1.2)	(1.3%)	$ 89.5
GP	132.8	(2.7)	(2.0%)	135.5	3.7	2.8%	131.8
Total North American Invisalign	223.2	(0.6)	(0.3%)	223.8	2.5	1.1%	$221.3
International Invisalign	72.0	10	16.1%	62.0	15.4	33.0%	46.6
Total Invisalign revenues	295.2	9.4	3.3%	285.8	17.9	6.7%	$267.9
Other non-case revenues	17.1	(1.1)	(6.0%)	18.2	1.8	11.0%	16.4
Total net revenues	$312.3	$ 8.3	2.7%	$304.0	$ 19.7	6.9%	$284.3

Case volume data which represents Invisalign case shipments by channel, for the years ended December 31, 2009, 2008, and 2007 are as follows (in thousands):

	Years Ended December 31,						
Invisalign case volume	2009	Net Change	% Change	2008	Net Change	% Change	2007
North America:							
Ortho	73.0	2.4	3.4%	70.6	(2.3)	(3.2%)	72.9
GP	100.1	(3.4)	(3.3%)	103.5	1.5	1.5%	102.0
Total North American Invisalign	173.1	(1.0)	(0.6%)	174.1	(0.8)	(0.5%)	174.9
International Invisalign	47.5	9.6	25.3%	37.9	9.9	35.4%	28.0
Total Invisalign case volume	220.6	8.6	4.1%	212.0	9.1	4.5%	202.9

Invisalign revenues by product and other non-case revenues, which represents training, retainer and ancillary products, for the years ended December 31, 2009, 2008, and 2007 are as follows (in millions):

	Years Ended December 31,						
Net revenues	2009	Net Change	% Change	2008	Net Change	% Change	2007
Invisalign Full	$234.8	$(20.7)	(8.1%)	$255.5	$ 9.8	4.0%	$245.7
Invisalign Express	29.0	5.5	23.4%	23.5	1.3	5.9%	22.2
Invisalign Teen	25.9	19.7	317.7%	6.2	6.2	100.0%	—
Invisalign Assist	5.5	4.9	816.7%	0.6	0.6	100.0%	—
Other non-case revenues	17.1	(1.1)	(6.0%)	18.2	1.8	11.0%	16.4
	$312.3	$ 8.3	2.7%	$304.0	$ 19.7	6.9%	$284.3

Case volume data which represents Invisalign case shipments by product, for the years ended December 31, 2009, 2008, and 2007 are as follows (in thousands):

	Years Ended December 31,						
Invisalign case volume	2009	Net Change	% Change	2008	Net Change	% Change	2007
Invisalign Full	155.3	(17.1)	(9.9%)	172.4	0.4	0.2%	172.0
Invisalign Express	33.0	1.0	3.1%	32.0	1.1	3.6%	30.9
Invisalign Teen	25.9	19.1	280.9%	6.8	6.8	100.0%	—
Invisalign Assist	6.4	5.6	700.0%	0.8	0.8	100.0%	—
	220.6	8.6	4.1%	212.0	9.1	4.5%	202.9

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. We believe that, as a result of the economic downturn and continued economic uncertainty, many GPs focused their efforts on traditional dental procedures, and as a result, sales of Invisalign to these customers were negatively impacted compared to 2008. Depending on the customers' adoption of these products, our product mix may continue to gradually shift towards these newer products that have higher deferred revenues. 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.

Total net revenues increased in 2008 compared to 2007 primarily as a result of increased growth in our international Invisalign revenue and our North American GP revenue.

Net revenues from our North American Invisalign orthodontic channel decreased in 2008 compared to 2007 due to decreased case volume and higher revenue deferrals related to new products introduced in 2008 partially offset by lower participation in volume-based discount program rebates. Net revenues from our North American Invisalign GP channel increased due to higher case volume and lower participation in volume-based discount rebate programs. The increase in our International Invisalign revenues in 2008 compared to 2007 was predominately due to higher case volumes partially offset by unfavorable exchange rates and increased participation in volume-based discount programs.

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. Other revenues were lower in 2008 compared to 2007 due to North American training discount programs.

For 2010, we expect our total net revenues to grow compared to 2009 primarily due to the expected increases in case volumes from both the North American and International Invisalign channels. Quarterly revenues may be impacted by changes in product mix, the levels of promotional discounts, foreign exchange rates and other factors.

Cost of revenues and gross margin (in millions):

	Years Ended December 31,				
	2009	Change	2008	Change	2007
Cost of revenues	$ 78.8	$ (0.1)	$ 78.9	$ 3.9	$ 75.0
% of net revenues	25.2%		25.9%		26.4%
Gross profit	$233.5	$ 8.4	$225.1	$ 15.8	$209.3
Gross margin %	74.8%		74.1%		73.6%

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.

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 partially offset by $6.2 million of amortization of prepaid royalties relating to the Ormco litigation settlement.

Gross margin improved in 2008 compared to 2007 primarily due to an increase in case volume over our relatively fixed cost structure and improved operating efficiencies.

We believe that gross margin in 2010 will be higher than in 2009 due to an increase in revenue year over year as well as the cessation of the amortization of Ormco prepaid royalties. However, with our relatively fixed manufacturing cost structure, quarterly gross margin will fluctuate based on case volume and product mix. Additionally, the levels of promotional discounts, foreign exchange rates and several other factors can impact average selling prices, revenues, and gross margins.

Sales and marketing (in millions):

	Years Ended December 31,				
	2009	Change	2008	Change	2007
Sales and marketing	$112.5	$ (2.6)	$115.1	$ 16.9	$98.2
% of net revenues	36.0%		37.9%		34.5%

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 decreased during 2009 compared to 2008 due to a $4.8 million reduction in employee-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.

Sales and marketing expense increased during 2008 compared to 2007 due to higher payroll-related expenses of $7.0 million, including stock-based compensation of $1.1 million, as a result of the full year effect of additional headcount hired in the fourth quarter of 2007. We also incurred higher product marketing expenses of $9.0 million, associated with our new product launches and commercialization, professional marketing programs, clinical education and media costs.

General and administrative (in millions):

	Years Ended December 31,				
	2009	Change	2008	Change	2007
General and administrative	$61.7	$ (0.5)	$62.2	$ 8.9	$53.3
% of net revenues	19.8%		20.5%		18.7%

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

General and administrative expenses 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.

General and administrative expenses increased during 2008 compared to 2007 primarily due to higher payroll-related expenses of $4.5 million, including increased stock-based compensation expense of $2.6 million, resulting from additional headcount. 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 in the fourth quarter of 2008. In addition, legal and other professional fees were higher by $3.4 million compared to 2007 primarily due to a $1.6 million credit in 2007 from an insurance reimbursement we received associated with the OrthoClear litigation.

Research and development (in millions):

	Years Ended December 31,				
	2009	Change	2008	Change	2007
Research and development	$22.3	$ (3.9)	$26.2	$ 0.5	$25.7
% of net revenues	7.1%		8.6%		9.0%

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 expenses decrease in 2009 compared to the same period in 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.

Research and development expenses increased slightly in 2008 compared to the same period in 2007 primarily due to higher payroll-related expenses, including stock-based compensation, as a result of increased headcount in the first half of 2008, partially offset by lower consulting fees.

Restructurings (in millions):

	Years Ended December 31,				
	2009	Change	2008	Change	2007
Restructurings	$1.3	$ (4.9)	$6.2	$ 6.2	$—
% of net revenues	0.4%		2.1%	n/a	

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 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.

Litigation settlement (in millions):

	Years Ended December 31,				
	2009	Change	2008	Change	2007
Litigation settlement	$69.7	$ 69.7	$—	$ —	$—
% of net revenues	22.3%		0.0%	n/a	0.0%

On August 16, 2009, we entered into a litigation settlement with Ormco that ended all pending litigation between the parties and we agreed to make a cash payment of $13.2 million and issue a total of 7.6 million non-assessable shares of common stock. The shares issued to Danaher (an affiliate of Ormco) may not be resold except pursuant to an effective registration statement under the Securities Act or an available exemption from registration. We are not obligated to affect any such registration prior to August 16, 2010. The fair value of the unregistered shares was determined as of the market closing price on the dates the shares were issued less a 25% non-marketability discount, for a total value of $76.7 million, including the cash payment. The determination of the discount applied to the restricted stock is highly subjective and is based primarily on an analysis utilizing the Black-Scholes model to value a hypothetical put option to approximate the cost of hedging the restricted stock over the expected period of non-marketability. The table below provides for a sensitivity analysis if the discount rates were 1% and 5% higher or lower (in thousands, except percentages).

	20% (-5%)	24% (-1%)	25%	26% (+1%)	30% (+5%)
Total fair value of stock and cash consideration	80,899	77,512	76,665	75,818	72,430
Variance $	4,234	847	—	(847)	(4,234)
Variance %	5.5%	1.1%	0.0%	(1.1%)	(5.5%)

The value attributed to past infringement claims was recorded as litigation settlement costs and was based on case shipments from September 9, 2003 through August 16, 2009, totaling $69.7 million, which was recorded in operating expenses and $6.2 million was amortized to cost of sales for the year ended December 31, 2009. The remaining $0.8 million will be amortized based on case shipments during first quarter of 2010.

See *Note 7 "Ormco Litigation Settlement"* for additional information about the settlement accounting.

Patients First Program and settlement costs (in millions):

	Years Ended December 31,				
	2009	Change	2008	Change	2007
Patients First Program	$—	$ —	$—	$ 1.8	$(1.8)
Settlement costs	—	—	—	—	—
Total Patients First Program and settlement costs	$—	$ —	$—	$ 1.8	$(1.8)
% of net revenues	—		—		(0.6%)

As part of the OrthoClear Agreement in October 2006, OrthoClear agreed to stop the importation of aligners into the United States and discontinue all aligner business operations worldwide. As a result, most OrthoClear

patients were unable to complete their orthodontic treatment with OrthoClear. In an attempt to help minimize treatment disruptions for the OrthoClear patients and their doctors, we committed to make treatment available to these patients at no additional cost under the "Patients First Program". In the fourth quarter of 2006, we recorded an $8.3 million charge for the anticipated costs of completing this program. Subsequently, in the first quarter of 2007, we reduced our Patients First Program accrual by $1.8 million to reflect a reduction of our initial estimate to the number of cases actually received by the case submission deadline. We shipped all Patients First Program cases by June 30, 2007. There were no costs related to the Patients First Program in 2008 and 2009.

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

	Years Ended December 31,				
	2009	Change	2008	Change	2007
Interest income	$ 0.6	$ (2.5)	$ 3.1	$ (1.1)	$ 4.2
Interest (expense)	(0.1)	(0.1)	—	0.3	(0.3)
Other income (expense), net	(0.4)	1.1	(1.5)	(0.7)	(0.8)
Total interest and other income (expense), net	$ 0.1	$ (1.5)	$ 1.6	$ (1.5)	$ 3.1

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

Interest income net 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 established by the Federal Reserve during 2009. Other expense, net, decreased in 2009 compared to 2008 reflecting increases in foreign exchange gains during 2009.

Interest income, net in 2008 decreased by $1.1 million compared to 2007 primarily due to lower average cash, cash equivalents and marketable securities balances resulting from the $50.0 million stock repurchase program and lower interest rates. In 2008, we shifted our investments into more conservative instruments principally, U.S. government securities, which bear lower interest rates. We incurred no interest expense in 2008 compared to 2007. In 2007 we incurred interest expense on the outstanding balance of our line of credit during 2007 which was repaid during 2007. We had no outstanding borrowings as of December 31, 2009 and December 31, 2008.

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

	Years Ended December 31,				
	2009	Change	2008	Change	2007
Provision for (benefit from) income taxes	$(2.6)	$ 60.4	$(63.0)	$(64.2)	$1.2

We recorded income tax benefits of $2.6 million and $63.0 million for 2009 and 2008, respectively and an income tax provision of $1.2 million for 2007. These represented effective tax rates of (7.7%), (368.4%), and 3.3%, in 2009, 2008 and 2007, 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, the Company 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

The Company also considered the following negative evidence:

- history of operating losses in 2006 and prior to 2003
- cyclical nature of the business and price volatility

We believe 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 $6.2 million is related to capital loss and foreign net operating loss carryforwards as of December 31, 2008 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.

In February 2009, the California 2009-2010 budget legislation was signed into law. One of the major components of this legislation is 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 reversal pattern and 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 will decrease by approximately $0.6 million (net of federal benefit). The tax impact of $0.6 million has been recorded as a discrete item in the first quarter of 2009.

At December 31, 2009, we had net operating loss carryforwards of approximately $187.7 million for federal tax purposes and $68.1 million for California state tax purposes. If not utilized, these carryforwards will begin to expire in 2020 for federal purposes and 2011 for California purposes. The Internal Revenue Code imposes an annual limitation on the use of a corporation's tax attributes if a corporation undergoes an ownership change for tax purposes. If an ownership change is determined to have occurred, our ability to use the net operating loss carryforwards would be subject to an annual limitation. However, based on our current estimate of the total net operating losses at December 31, 2009 and our current estimate of the annual limitation, we do not expect our net operating loss carryforwards to be limited. At December 31, 2009, we had research credit carryforwards of approximately $4.4 million for federal purposes and $5.4 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 $8.8 million as of December 31, 2009 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, 2009 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, the proceeds of the sale of our common stock, and from occasional borrowings under our available credit facility. As of December 31, 2009, 2008 and 2007, we had the following cash and cash equivalents, restricted cash and short-term investments (in thousands):

	Years Ended December 31,		
	2009	2008	2007
Cash and cash equivalents	$ 166,487	$ 87,100	$ 89,119
Restricted cash	—	—	21
Short-term investments	19,978	23,066	38,771
Total	$ 186,465	$ 110,166	$ 127,911

Net cash provided by operating activities for the year ended December 31, 2009 was $74.2 million, resulting primarily from our net loss of $31.3 million adjusted for non-cash items including the litigation settlement with Ormco of $62.7 million and other non-cash expenses totaling $28.1 million, which included depreciation, amortization of intangibles, and stock-based compensation expense. The $34.4 million increase in cash provided by operating activities compared to the prior year was driven primarily by higher sales volume which also resulted in an increase in deferred revenue of $15.5 million due to increased sales of newer products that have higher deferred revenues.

Net cash provided by operating activities for the year ended December 31, 2008 was $39.7 million, resulting primarily from our net profit of $80.0 million and non-cash items totaling $32.7 million, which included depreciation, amortization of intangibles, option acceleration charges for terminated executives and stock-based compensation expense. Also included in non-cash items was an asset impairment charge of $1.7 million relating to management's decision to no longer invest in an internally developed software tool for business process management. These increases were offset by the release of a non-cash tax valuation allowance of $64.6 million on most of the deferred tax assets. Cash flows from operating activities also resulted from a $4.6 million increase in deferred revenue and a $0.9 million decrease in inventories. These increases in cash flows were offset by an $8.0 increase in accounts receivable and a decrease of $6.1 million in accounts payable and accrued liabilities.

Net cash provided by operating activities for the year ended December 31, 2007 was $52.8 million, resulting primarily from our net income of $35.7 million and non-cash items such as depreciation and amortization, stock-based compensation, and amortization of intangibles totaling $25.6 million. Additionally, a $2.7 million increase in accounts payable also contributed to the increase in net cash provided by operating activities. These increases in cash flows from operating activities were partially offset by a $10.7 million increase in accounts receivable.

Net cash used in investing activities was $1.6 million for the year ended December 31, 2009. The primary driver was $7.2 million used for the purchase of property and equipment in 2009 compared $14.3 million in 2008 offset by $6.0 million of net maturities from marketable securities as compared to $12.9 million in 2008. 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 $1.1 million for the year ended December 31, 2008 and consisted of $14.3 million for the purchase of property and equipment offset by $12.9 million of net maturities of marketable securities.

Net cash used in investing activities was $36.8 million for the year ended December 31, 2007, which largely consisted of $29.9 million of net purchases of short-term marketable securities and $7.4 million used for the purchase of capital assets.

Net cash provided in 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.

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 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 cash provided by financing activities was $17.5 million for the year ended December 31, 2007 and consisted of $29.0 million in proceeds from the issuance of our common stock, primarily from exercises of employee stock options. This increase was partially offset by the repayment of $11.5 million against the outstanding balance on our line of credit. Net cash provided by financing activities was $27.7 million for the year ended December 31, 2006 and consisted of $16.2 million in proceeds from the issuance of our common stock, primarily from exercises of employee stock options and $11.5 million in net borrowings from our line of credit.

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 2009, 2008, and 2007, we paid $0.5 million, $0.5 million, and $0.4 million of taxes related to RSUs that vested during the period for executive officers, respectively.

On December 5, 2008, we renegotiated and amended our existing credit facility with Comerica Bank. Under this revolving line of credit, we have $25.0 million of available borrowings with a maturity date of December 31, 2010. This credit facility requires a quick ratio covenant and also requires us to maintain a minimum unrestricted cash balance of $10.0 million. As of December 31, 2009, we had no outstanding borrowings and we were in compliance with the financial covenants of this credit facility.

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 2009.

Contractual Obligations/Off Balance Sheet Arrangements

The impact that our contractual obligations as of December 31, 2009 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	$8,574	$ 3,339	$4,229	$1,006	$ —

On January 26, 2010, we entered into an agreement for new corporate headquarters to lease approximately 129,024 square feet in San Jose, California. The lease agreement commences on the earlier of August 1, 2010 or the date we first commence conducting business in the premises, which is expected to be on or about June 28, 2010 and will continue for an initial term of seven years and two months. The lease agreement for our current office headquarters in Santa Clara, California, expires on June 30, 2010. See *Note 20 "Subsequent Event."*

We had no off-balance sheet arrangements as defined in Regulation S-K Item 303(a) (4) as of December 31, 2009.

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.

Revenues are deferred for certain products that include staged delivery. Depending on the product, revenues are recognized based on usage, case completion, ratably over a delivery period, or upon shipment of the final staged shipment. Invisalign Teen, which includes up to six replacement aligners, is delivered in a single shipment except for the replacement aligners. Currently, the revenue for Invisalign Teen is recognized upon shipment except for the six replacement aligners for which the fair market value is 100 percent deferred and recognized as the replacement aligners are shipped or when the case is completed. Although Invisalign Teen has been available since July 2008, we do not have sufficient evidence to support a usage rate less than 100 percent for the six replacement aligners at this time, however, we are continually gathering and evaluating our historical experience. If and when we gather sufficient historical experience to support a usage rate for the six replacement aligners less than 100 percent, we would adjust our deferred revenue balance to the estimated usage rate and prospectively apply this rate to future Invisalign Teen shipments. The Vivera retainer includes four shipments per year, and revenue is deferred upon the first shipment and recognized ratably over the one year delivery period. 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 11 "Stockholders' Equity" in the Notes to 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. 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. No intangible asset impairment was recorded for the periods presented.

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, 2009, 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 Consolidated Financial Statements* in *Item 8* for a full description of recent accounting pronouncements, including the expected dates of adoption and estimated effects on results of operations and financial condition, which is incorporated herein.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

In the normal course of business, we are exposed to foreign currency exchange rate and interest rate risks that could impact our financial position and results of operations.

Interest Rate Risk

Changes in interest rates could impact our anticipated interest income on our cash equivalents and investments in marketable securities. Our cash equivalents and investments are in fixed-rate, short-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, 2009, we had approximately $20.0 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, 2009 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.

Prior to January 1, 2007, the functional currency of Align and our subsidiaries was the U.S. dollar, and accordingly, gains and losses resulting from the remeasurement of monetary assets and liabilities denominated in Euros, Costa Rican Colones, and other currencies were reflected in other income (expense). During the first quarter of 2007, we analyzed the various economic factors of our international subsidiaries and determined that there had been a significant change in facts and circumstances to warrant a change in the functional currency for some of our European subsidiaries from the U.S. dollar to the local currency. Effective January 1, 2007, the adjustment from translating certain European subsidiaries' financial statements from the local currency into the U.S. dollar was recorded as a separate component of accumulated other comprehensive income, net in the stockholder's equity section of our Consolidated Balance Sheets.

ITEM 8. CONSOLIDATED FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Quarterly Results of Operations

	Three Months Ended							
	2009				2008			
	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	$86,616	$ 79,269	$76,316	$70,132	$74,125	$75,173	$79,902	$74,776
Gross profit(3)	63,806	59,001	57,978	52,707	53,892	56,407	59,659	55,168
Profit (loss) from operations(1)(3)	14,645	(60,194)	6,253	5,284	1,325	5,691	3,872	4,626
Net profit (loss)(1)(2)(3)	$11,492	$(49,942)	$ 4,545	$ 2,636	$65,496	$ 5,157	$ 4,030	$ 5,304
Net profit per share:								
Basic	$ 0.15	$ (0.72)	$ 0.07	$ 0.04	$ 0.99	$ 0.08	$ 0.06	$ 0.08
Diluted	$ 0.15	$ (0.72)	$ 0.07	$ 0.04	$ 0.98	$ 0.08	$ 0.06	$ 0.07
Shares used in computing net profit per share:								
Basic	74,482	69,528	66,285	65,983	66,440	67,367	68,581	69,053
Diluted	76,831	69,528	67,373	66,447	66,816	68,704	69,916	70,860

(1) March 2009 and June 2009 profit from operations and net profit included restructuring charges of $0.9 million and $0.4 million, respectively. September and December 2008 profit from operations and net profit included $2.2 million and $4.0 million, respectively, for restructuring charges. See *Note 19 "Restructurings" in the Notes to Consolidated Financial Statements* for additional information.

(2) December 2008 net profit included a $64.6 million benefit to income taxes as a result of the release of a tax valuation allowance on most of the deferred tax assets. See *Note 14 "Income Taxes" in the Notes to Consolidated Financial Statements* for additional information.

(3) Gross profit for the quarters ended September 30, 2009 and December 31, 2009 included the amortization of prepaid royalties of $1.9 million and $4.3 million, respectively, related to the litigation settlement with Ormco. In addition, loss from operations and net loss included a litigation settlement charge of $69.7 million, which was recorded in the third quarter of 2009. See *Note 7 "Ormco Litigation Settlement" in the Notes to Consolidated Financial Statements* for additional information.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF MANAGEMENT ON INTERNAL CONTROL OVER FINANCIAL REPORTING

Management of Align is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934. Align's 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 the company;
- 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
- 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. 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 Align's internal control over financial reporting as of December 31, 2009. 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, 2009, Align's 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.

The Company's internal control over financial reporting as of December 31, 2009 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 the Company's internal control over financial reporting as of December 31, 2009.

/s/ THOMAS M. PRESCOTT

Thomas M. Prescott
President and Chief Executive Officer

February 26, 2010

/s/ KENNETH B. AROLA

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

February 26, 2010

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, 2009 and 2008, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2009 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, 2009, 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, CA
February 26, 2010

ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except per share data)

	Years Ended December 31,		
	2009	2008	2007
Net revenues:			
Invisalign	$295,215	$285,798	$267,869
Non-case	17,118	18,178	16,463
Total net revenues	312,333	303,976	284,332
Cost of revenues:			
Invisalign	71,530	69,536	65,095
Non-case	7,311	9,314	9,940
Total cost of revenues	78,841	78,850	75,035
Gross profit	233,492	225,126	209,297
Operating expenses:			
Sales and marketing	112,542	115,062	98,231
General and administrative	61,718	62,154	53,280
Research and development	22,252	26,165	25,727
Patients First Program and settlement costs	—	—	(1,796)
Litigation settlement costs	69,673	—	—
Restructurings	1,319	6,231	—
Total operating expenses	267,504	209,612	175,442
Profit (loss) from operations	(34,012)	15,514	33,855
Interest income	579	3,052	4,195
Interest expense	(85)	(24)	(342)
Other expense	(375)	(1,466)	(758)
Net profit (loss) before provision for income taxes	(33,893)	17,076	36,950
Provision for (benefit from) income taxes	(2,624)	(62,911)	1,226
Net profit (loss)	$ (31,269)	$ 79,987	$ 35,724
Net profit (loss) per share:			
Basic	$ (0.45)	$ 1.20	$ 0.53
Diluted	$ (0.45)	$ 1.18	$ 0.50
Shares used in computing net profit (loss) per share:			
Basic	69,094	66,812	67,176
Diluted	69,094	68,064	71,444

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

ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS
(in thousands, except per share data)

	December 31, 2009	December 31, 2008
ASSETS		
Current assets:		
Cash and cash equivalents	$ 166,487	$ 87,100
Marketable securities, short-term	19,978	23,066
Accounts receivable, net of allowance for doubtful accounts of $1,033 and $612, respectively	54,537	52,362
Inventories, net	2,046	1,965
Prepaid expenses and other current assets	18,251	13,414
Total current assets	261,299	177,907
Property and equipment, net	24,971	26,979
Goodwill	478	478
Intangible assets, net	4,988	7,788
Deferred tax asset	61,535	61,696
Other assets	1,969	4,493
Total assets	$ 355,240	$ 279,341
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 6,122	$ 5,580
Accrued liabilities	42,822	38,282
Deferred revenues	32,299	16,710
Total current liabilities	81,243	60,572
Other long-term liabilities	961	229
Total liabilities	82,204	60,801
Commitments and contingencies (Notes 8 and 10)		
Stockholders' equity:		
Preferred stock, $0.0001 par value (5,000 shares authorized; none issued)	—	—
Common stock, $0.0001 par value (200,000 shares authorized; 74,568 and 65,633 shares issued, respectively; 74,568 and 65,633 shares outstanding, respectively)	7	7
Additional paid-in capital	525,073	439,494
Accumulated other comprehensive income, net	455	269
Accumulated deficit	(252,499)	(221,230)
Total stockholders' equity	273,036	218,540
Total liabilities and stockholders' equity	$ 355,240	$ 279,341

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

ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
For the years ended December 31, 2009, 2008 and 2007
(in thousands)

	Common Stock		Additional Paid in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total
	Shares	Amount				
Balances at December 31, 2006	64,859	$ 6	$ 408,921	$ 3	$ (325,374)	$ 83,556
Net profit					35,724	35,724
Net change in cumulative translation adjustment	—	—	—	703	—	703
Net change in unrealized loss from available-for sale securities	—	—	—	(49)	—	(49)
Comprehensive net income						36,378
Issuance of common stock relating to employee stock purchase plan	580	—	3,434	—	—	3,434
Issuance of common stock upon exercise of stock options	3,048	1	25,558	—	—	25,559
Issuance of common stock in settlement of restricted stock units, net of shares withheld for employees' taxes	155	—	(433)	—	—	(433)
Excess tax benefit from share based payment arrangements	—	—	449	—	—	449
Stock based compensation	—	—	12,211	—	—	12,211
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
Issuance of common stock relating to employee stock purchase plan	523	—	4,457	—	—	4,457
Issuance of common stock upon exercise of stock options	912	—	6,049	—	—	6,049
Issuance of common stock in settlement of restricted stock units, net of shares withheld for employees' taxes	216	—	(460)	—	—	(460)
Common stock repurchased	(4,660)		(38,571)		(11,567)	(50,138)
Excess tax benefit from share based payment arrangements	—	—	144	—	—	144
Stock based compensation	—	—	17,057	—	—	17,057
Acceleration of stock based compensation	—	—	678	—	—	678
Balances at December 31, 2008	65,633	7	439,494	269	(221,230)	218,540
Net loss	—	—	—	—	(31,269)	(31,269)
Net change in unrealized gain from available-for sale securities	—	—	—	18	—	18
Net change in cumulative translation adjustment	—	—		168	—	168
Comprehensive net loss						(31,083)
Issuance of common stock relating to employee stock purchase plan	545	—	3,676	—	—	3,676
Issuance of common stock upon exercise of stock options	586	—	4,421	—	—	4,421
Issuance of common stock in settlement of restricted stock units, net of shares withheld for employees' taxes	218	—	(487)	—	—	(487)
Shares issued for litigation settlement	7,586	—	63,518	—	—	63,518
Excess tax provision from share based payment arrangements	—	—	(637)	—	—	(637)
Stock based compensation	—	—	15,088	—	—	15,088
Balances at December 31, 2009	74,568	$ 7	$ 525,073	$ 455	$ (252,499)	$273,036

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

ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Years Ended December 31,		
	2009	2008	2007
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net profit (loss)	$ (31,269)	$ 79,987	$ 35,724
Adjustments to reconcile net profit (loss) to net cash provided by operating activities:			
Deferred taxes	(2,612)	(64,608)	—
Depreciation and amortization	10,204	9,964	10,176
Stock-based compensation	15,088	17,057	12,211
Acceleration of stock-based compensation	—	678	—
Amortization of intangibles	2,800	2,827	3,209
Litigation settlement costs and amortization of prepaid royalties	62,688	—	—
Provision for doubtful accounts	708	71	46
Loss on retirement and disposal of fixed assets	37	513	24
Loss on impairment of fixed assets	—	1,712	—
Excess tax provision for (benefit from) share-based payment arrangements	637	(144)	(449)
Changes in assets and liabilities, net of acquisition effect:			
Accounts receivable	(2,586)	(7,951)	(10,703)
Inventories	(85)	943	186
Prepaid expenses and other current assets	306	276	(1,480)
Accounts payable	(614)	(2,651)	2,738
Accrued and other long-term liabilities	3,336	(3,487)	(295)
Deferred revenues	15,527	4,559	1,390
Net cash provided by operating activities	74,165	39,746	52,777
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchase of property and equipment	(7,192)	(14,334)	(7,429)
Proceeds from sale of property and equipment	—	189	—
Restricted cash	—	21	77
Purchase of marketable securities	(42,923)	(75,050)	(64,686)
Maturities of marketable securities	48,893	87,926	34,797
Other assets	(334)	193	462
Net cash used in investing activities	(1,556)	(1,055)	(36,779)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from issuance of common stock	8,097	10,506	28,993
Payments on line of credit	—	—	(11,500)
Payments on short-term obligations	(136)	(407)	
Repurchases of common stock	—	(50,138)	—
Excess tax provision for (benefit from) share-based payment arrangements	(637)	144	449
Employees' taxes paid upon the vesting of restricted stock units	(487)	(460)	(433)
Net cash provided by (used in) financing activities	6,837	(40,355)	17,509
Effect of foreign exchange rate changes on cash and cash equivalents	(59)	(355)	499
Net increase (decrease) in cash and cash equivalents	79,387	(2,019)	34,006
Cash and cash equivalents, beginning of year	87,100	89,119	55,113
Cash and cash equivalents, end of year	$166,487	$ 87,100	$ 89,119

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

ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 1. Summary of Significant Accounting Policies

Business Description

Align Technology, Inc. ("Align" or the "Company") was incorporated in April 1997 and 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.

Basis of presentation and preparation

The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries after elimination of intercompany transactions and balances. Revenues and cost of revenues in prior period amounts have been reclassified to conform with the current period presentation. These reclassifications had no impact on previously reported gross profit or financial position.

In connection with the preparation of the consolidated financial statements, the Company evaluated events subsequent to the balance sheet date of December 31, 2009 through the financial statement issuance date and determined that all material transactions have been recorded and disclosed properly.

Use of estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires the Company's management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. Actual results could differ materially from those estimates.

Fair value of financial instruments

The carrying amounts of the Company's cash and cash equivalents, accounts receivable, accounts payable and other current liabilities approximate the fair value.

Cash equivalents and marketable securities

Cash equivalents consist of highly liquid instruments purchased with an original maturity of three months or less. The Company invests primarily in money market funds, commercial paper, and United States government securities, accordingly, these investments are subject to minimal credit and market risks.

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

The Company measures its cash equivalents and marketable securities at fair value. Fair value is the price that would be received from selling an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The fair value hierarchy prioritizes the inputs to valuation techniques used to measure fair value. This hierarchy requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value.

ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Foreign currency

The Company analyzes the functional currency for each of its international subsidiaries on an annual basis, or more often if necessary, to determine if a significant change in facts and circumstances indicate that the primary economic currency has changed. During the first quarter of 2007, the Company analyzed the various economic factors of its international subsidiaries and determined that some of its European subsidiaries had established a sufficient history of independent profitability and cash collections to warrant a change in the functional currency from the U.S. dollar to the local currency. Effective January 1, 2007, the adjustment from translating certain European subsidiaries' financial statements from the local currency to the U.S. dollar was recorded as a separate component of accumulated other comprehensive income (loss), net in the stockholders' equity section of the Consolidated Balance Sheets. This foreign currency translation adjustment reflects the translation of the balance sheet at period end exchange rates, and the income statement at an average exchange rate in effect during the period. As of December 31, 2009 and 2008, the Company had $0.5 million and $0.3 million, respectively, in accumulated other comprehensive income, net related to the translation of its foreign subsidiaries' financial statements. See *Note 16 "Comprehensive Income (Loss)"* for additional disclosures.

Align's other international entities operate in a U.S. dollar functional currency environment, and therefore, the foreign currency assets and liabilities are remeasured into the U.S. dollar at current exchange rates except for non-monetary assets and liabilities which are remeasured at historical exchange rates. Revenues and expenses are generally remeasured at an average exchange rate in effect during each period. Gains or losses from foreign currency remeasurement are included in other income (expense). Prior to January 1, 2007, all of Align's subsidiaries used the U.S. dollar as its functional currency, and accordingly, gains and losses resulting from remeasurement were included in other income (expense).

For the years ended December 31, 2009, 2008, and 2007, the Company included in other income (expense) a gain of $0.2 million, a loss of $0.4 million and a loss of $0.1 million, respectively.

Certain risks and uncertainties

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

Financial instruments which potentially expose the Company to concentrations of credit risk consist primarily of cash equivalents, marketable securities and accounts receivable. The Company invests excess cash primarily in money market funds of major financial institutions, commercial paper and notes and government securities. If the carrying value of the Company's investments exceeds the fair value, and the decline in fair value is deemed to be other-than-temporary, the Company will be required to write down the value of its investments, which could materially harm the Company's results of operations and financial condition. Moreover, the performance of certain securities in the Company's investment portfolio correlates with the credit condition of the U.S. financial sector. With the current unstable credit environment, the Company might incur significant realized, unrealized or impairment losses associated with these investments. The Company provides credit to customers in the normal course of business. Collateral is not required for accounts receivable, but ongoing evaluations of customers' credit worthiness are performed. The Company maintains reserves for potential credit losses and such losses have been within management's expectations. No individual customer accounted for 10% or more of the Company's accounts receivable at December 31, 2009 and 2008, or net revenues in 2009, 2008 and 2007.

ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

In the United States of America, the Food and Drug Administration ("FDA") regulates the design, manufacture, distribution, preclinical and clinical study, clearance and approval of medical devices. Products developed by the Company may require approvals or clearances from the FDA or other international regulatory agencies prior to commercialized sales. There can be no assurance that the Company's products will receive any of the required approvals or clearances. If the Company was denied approval or clearance or such approval was delayed, it may have a material adverse impact on the Company.

The Company has manufacturing operations located outside the United States of America. The Company currently relies on its manufacturing facilities in Costa Rica to prepare digital treatment plans using a sophisticated, internally developed computer-modeling program. In addition, the Company manufacturers its clear aligners at its facility in Juarez, Mexico. The Company's reliance on international operations exposes it to related risks and uncertainties, including difficulties in staffing and managing international operations, including difficulties in hiring and retaining qualified personnel; controlling production volume and quality of manufacture; political, social and economic instability, particularly as a result of increased levels of violence in Juarez, Mexico; interruptions and limitations in telecommunication services; product and material transportation delays or disruption; trade restrictions and changes in tariffs; import and export license requirements and restrictions; fluctuations in foreign currency exchange rates; and potential adverse tax consequences. If any of these risks materialize, the Company's international manufacturing operations, as well as its operating results, may be harmed.

The Company purchases certain inventory from sole suppliers. Additionally, the Company relies on a limited number of hardware manufacturers. The inability of any supplier or manufacturer to fulfill supply requirements of the Company could materially and adversely impact future operating results.

Inventories

Inventories are valued at the lower of cost or market, with cost computed on a first-in, first-out basis.

Property, equipment, long-lived assets, and finite purchased intangible assets

Property and equipment are stated at historical cost less accumulated depreciation and amortization. Depreciation and amortization are computed using the straight-line method over the estimated useful lives of the assets. Upon sale or retirement, the asset's cost and related accumulated depreciation are removed from the general ledger and any related gains or losses are reflected in the Consolidated Statements of Operations. Maintenance and repairs are expensed as incurred.

Other intangible assets primarily consist of intangible assets purchased as part of the OrthoClear Agreement. These assets are amortized using the straight-line method over their estimated useful lives of three to five years, reflecting the period in which the economic benefits of the assets are expected to be realized.

The Company evaluates long-lived assets (including intangible assets) for impairment whenever events or changes in circumstances indicate that the carrying amount of a long-lived asset may not be recoverable. An asset is considered impaired if its carrying amount exceeds the future net cash flows the asset is expected to generate. If an asset is considered to be impaired, the impairment to be recognized is calculated as the amount by which the carrying amount of the asset exceeds its fair market value which is estimated based on projected discounted future net cash flows. There were no impairments for long-lived and intangible assets as of December 31, 2009.

Development costs for internal use software

Costs relating to internal use software are accounted for in accordance with the provisions of accounting for the costs of computer software developed or obtained for internal use. As of December 31, 2009 and 2008,

capitalized internal use software at cost was $7.0 million and $5.3 million, respectively. The associated accumulated amortization was $5.3 million and $4.7 million as of December 31, 2009 and 2008, respectively. Capitalized software costs are amortized over the estimated useful lives of three years.

Goodwill

Goodwill represents the excess of the purchase price paid over the fair value of tangible and identifiable intangible net assets acquired in business combinations. Goodwill is reviewed annually in the fourth quarter and whenever events or circumstances occur which indicate that goodwill might be impaired. The Company completed its annual evaluation of goodwill during the fourth quarter of 2009 and determined that there was no impairment.

Product Warranty

The Company warrants its products against material defects until the Invisalign cases are completed. The Company accrues for product warranty in cost of revenues upon shipment of products. Product warranty costs are primarily based on historical experience as to product failures as well as current information on repair costs. Actual warranty costs could differ materially from the estimated amounts. The Company regularly reviews the accrued balances and updates these balances based on historical warranty cost trends. Actual warranty costs incurred have not materially differed from those accrued.

Allowance for Doubtful Accounts

The Company maintains an allowance for doubtful accounts for estimated losses resulting from the inability of the Company's customers to make payments. The Company periodically reviews these allowances, including an analysis of the customers' payment history and information regarding the customers' creditworthiness. Actual write-offs have not been materially differed from the estimated allowance.

Revenue Recognition

The Company recognizes revenue when persuasive evidence of an arrangement exists, delivery has occurred, the price is fixed or determinable, and collectability is reasonably assured. 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 process are recorded when the services are completed.

Align enters into arrangements that involve multiple future product deliverables. Included in the price of Invisalign Full, Invisalign Teen and Invisalign Assist, the Company offers 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. The Company uses vendor specific objective evidence of fair value to allocate revenue to the case refinement deliverable and recognizes the residual revenue upon shipment. The Company defers 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.

Revenues are deferred for certain products that include staged delivery. Depending on the product, revenues are recognized based on usage, case completion, ratably over a subscription period or upon shipment of the final staged shipment. Invisalign Teen which includes up to six replacement aligners, is delivered in a single shipment except for the replacement aligners. Currently, the revenue for Invisalign Teen is recognized upon shipment except for the six replacement aligners for which the fair market value is 100 percent deferred and recognized as

the replacement aligners are shipped or when the case is completed. Although Invisalign Teen has been available since July 2008, the Company does not have sufficient evidence to support a usage rate less than 100 percent for the six replacement aligners at this time, however, the Company is continually gathering and evaluating our historical experience. If and when Align gathers sufficient historical experience to support a usage rate for the six replacement aligners less than 100 percent, Align would adjust the deferred revenue balance to the estimated usage rate and prospectively apply this rate to future Invisalign Teen shipments. 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.

The Company estimates and records 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.

Shipping and Handling Costs

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

Research and development

Research and development costs are expensed as incurred.

Advertising costs

The cost of advertising and media is expensed as incurred. For the years ended December 31, 2009, 2008 and 2007 advertising costs totaled $18.1 million, $18.3 million, and $15.9 million, respectively.

Income taxes

The Company estimates income taxes based on the various jurisdictions where business is conducted. Significant judgment is required in determining the income tax provision. Deferred tax assets and liabilities are recognized for differing treatments of certain items for tax and accounting purposes. These differences result in deferred tax assets and liabilities. The Company must then assess the likelihood that its deferred tax assets will be realized. To the extent the Company believes that realization is not likely, it will establish a valuation allowance.

The Company accounts for the impact of an uncertain income tax position on the income tax return by recognizing the largest amount that is more-likely-than-not to be sustained upon audit by the relevant taxing authority under the guidance of Financial Accounting Standard Board (“FASB) Accounting Standards Codification (“ASC”) 740-10. Uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained.

Stock-based compensation

The Company recognizes 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. The Company estimates 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 the Company uses different assumptions, its stock-based compensation expense could be materially different in the future. See *Note 11 "Stockholders' Equity" for additional information*.

Comprehensive income (loss)

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

Recent Accounting Pronouncements

In April 2009, the FASB issued an update to ASC 820, "Determining Fair Value When the Volume and Level of Activity for the Asset or Liability Have Significantly Decreased and Identifying Transactions That Are Not Orderly", which provides guidance on determining fair value when there is no active market or where the price inputs being used represent distressed sales. This update to ASC 820 was effective for interim and annual periods ending after June 15, 2009 and was adopted by the Company in the second quarter of 2009. The adoption did not have a material impact on the Company's consolidated financial statements.

In April 2009, the FASB issued ASC 320, "Recognition and Presentation of Other-Than-Temporary Impairments", which was effective for the Company for the quarterly period beginning April 1, 2009. ASC 320 amends existing guidance for determining whether an other than temporary impairment of debt securities has occurred. Among other changes, the FASB replaced the existing requirement that an entity's management assert it has both the intent and ability to hold an impaired security until recovery with a requirement that management assert (a) it does not have the intent to sell the security, and (b) it is more likely than not it will not have to sell the security before recovery of its cost basis. The adoption of this pronouncement did not have a material effect on the Company's consolidated financial statements.

In April 2009, the FASB issued ASC 825, "Interim Disclosures about Fair Value of Financial Instruments." This pronouncement requires disclosures about the fair value of financial instruments for interim reporting periods of publicly traded companies as well as in annual financial statements and also requires those disclosures in summarized financial information at interim reporting periods. The disclosure requirements of ASC 825 were effective for interim and annual reporting periods ending after June 15, 2009. The Company has provided the required disclosures in *Note 2*.

In April 2009, the FASB issued ASC 805, "Accounting for Assets Acquired and Liabilities Assumed in a Business Combination that Arise from Contingencies." ASC 805 requires that assets acquired and liabilities assumed in a business combination that arise from contingencies be recognized at fair value if fair value can be reasonably estimated. If fair value of such an asset or liability cannot be reasonably estimated, the asset or liability would generally be recognized in accordance with ASC 450, "Accounting for Contingencies", and FASB Interpretation No. 14, "Reasonable Estimation of the Amount of a Loss." This pronouncement is effective for assets or liabilities arising from contingencies in business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008. The adoption of ASC 805 did not have a material effect on the Company's consolidated financial statements.

ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

In May 2009, the FASB issued ASC 855, "Subsequent Events". ASC 855 establishes general standards of accounting for and disclosure of events that occur after the balance sheet date but before financial statements are issued or are available to be issued. ASC 855, which includes a new required disclosure of the date through which an entity has evaluated subsequent events, was effective for interim or annual periods ending after June 15, 2009. The Company adopted this standard as of June 30, 2009; however, the adoption of ASC 855 had no impact to the Company's consolidated financial statements.

In June 2009, the FASB issued Accounting Standards Update ("ASU") 2009-16, "Transfers and Servicing (ASC 860): Accounting for Transfers of Financial Assets," which amends previous guidance to remove the concept of a qualifying special-purpose entity and its exemption from consolidation in the transferor's financial statements. This new standard also establishes conditions for reporting a transfer of a portion of a financial asset as a sale, modifies the financial-asset derecognition criteria, revises how interests retained by the transferor in a sale of financial assets are initially measured, removes the guaranteed mortgage securitization recharacterization provisions, and requires additional disclosures. The Company will adopt this pronouncement on January 1, 2010 and expects that there will be no significant impact on its consolidated financial statements.

In June 2009, the FASB issued ASU 2009-17, Consolidation (ASC 810) "Improvements to Financial Reporting by Enterprises Involved with Variable Interest Entities," which eliminates the quantitative approach previously required for determining the primary beneficiary of a variable interest entity and requires ongoing qualitative reassessments of whether an enterprise is the primary beneficiary of a variable interest entity. This new standard also requires additional disclosures about an enterprise's involvement in variable interest entities. The Company will adopt this pronouncement on January 1, 2010 and expects that there will be no significant impact on its consolidated financial statements.

In June 2009, the FASB issued ASC 105, "The FASB Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting Principles". ASC 105 establishes the FASB Accounting Standards Codification ("Codification"), as the single source of authoritative accounting and reporting standards in the United States for all non-government entities, with the exception of the Securities and Exchange Commission and its staff. It does not include any new guidance or interpretations of US GAAP, but merely eliminates the existing hierarchy and codifies the previously issued standards and pronouncements into specific topic areas. The Codification was adopted on July 1, 2009 for the Company's consolidated financial statements for the year ended December 31, 2009.

In September 2009, FASB amended the ASC as summarized in ASU 2009-13, "Revenue Recognition (ASC 605): Multiple-Deliverable Revenue Arrangements." Guidance in ASC 605-25 on revenue arrangements with multiple deliverables has been amended to require an entity to allocate revenue to deliverables in an arrangement using its best estimate of selling prices if the vendor does not have vendor-specific objective evidence or third-party evidence of selling prices, and to eliminate the use of the residual method and require the entity to allocate revenue using the relative selling price method. The new guidance also requires expanded quantitative and qualitative disclosures about revenue from arrangements with multiple deliverables. The update is effective for fiscal years beginning on or after June 15, 2010, with early adoption permitted. Adoption may either be on a prospective basis for new revenue arrangements entered into after adoption of the update, or by retrospective application. The Company is assessing the potential impact of the update on its consolidated financial statements and is planning to adopt the update effective January 1, 2011.

In January 2010, the FASB issued ASU 2010-06, "Fair Value Measurements and Disclosures (ASC 820): Improving Disclosures about Fair Value Measurements." This update will require (1) an entity to disclose separately the amounts of significant transfers in and out of Levels 1 and 2 fair value measurements and to describe the reasons for the transfers; and (2) information about purchases, sales, issuances and settlements to be

presented separately (i.e. present the activity on a gross basis rather than net) in the reconciliation for fair value measurements using significant unobservable inputs (Level 3 inputs). This guidance clarifies existing disclosure requirements for the level of disaggregation used for classes of assets and liabilities measured at fair value and requires disclosures about the valuation techniques and inputs used to measure fair value for both recurring and nonrecurring fair value measurements using Level 2 and Level 3 inputs. The new disclosures and clarifications of existing disclosure are effective for fiscal years beginning after December 15, 2009, except for the disclosure requirements for related to the purchases, sales, issuances and settlements in the rollforward activity of Level 3 fair value measurements. Those disclosure requirements are effective for fiscal years ending after December 31, 2010. The Company is still assessing the impact on this guidance and does not believe the adoption of this guidance will have a material impact to its consolidated financial statements.

Management does not believe that other recent accounting pronouncements issued by the FASB (including its Emerging Issues Task Force), the American Institute of Certified Public Accountants or the SEC have a material impact on the Company's present or future consolidated financial statements.

Note 2. Marketable Securities and Fair Value Measurements

The Company has the following short-term investments as of December 31, 2009 and 2008 (in thousands):

December 31, 2009	Amortized Costs	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. government notes and bonds	$ 18,972	$ 6	$ —	$ 18,978
Corporate bonds	1,000	—	—	1,000
Total	$ 19,972	$ 6	$ —	$ 19,978

December 31, 2008	Amortized Costs	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. government notes and bonds	$ 9,971	$ 25	$ —	$ 9,996
Corporate bonds and certificates of deposit	3,774	1	(24)	3,751
Agency bonds and discount notes	8,499	20	—	8,519
Commercial paper	800	—	—	800
Total	$ 23,044	$ 46	$ (24)	$ 23,066

As of December 31, 2009, all short-term investments have maturity dates of less than one year. For the years ended December 31, 2009 and 2008, realized losses were immaterial.

The Company had the following long-term investments as of December 31, 2008 (in thousands):

December 31, 2008	Amortized Costs	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Agency bonds	$ 1,000	$ 1	$ —	$ 1,001
Corporate bonds	1,897	—	(35)	1,862
Total	$ 2,897	$ 1	$ (35)	$ 2,863

The long-term marketable securities are included in Other assets in the consolidated balance sheets. As of December 31, 2009, the Company did not hold any long-term marketable securities.

ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Fair Value Measurements

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

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

The Company's Level 1 assets consist of U.S. government debt securities and money market funds. The Company did not hold any Level 1 liabilities as of December 31, 2009.

Level 2—Observable inputs other than quoted prices included in Level 1, such as quoted prices for similar assets or liabilities in active markets; quoted prices for identical or similar assets or liabilities in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the asset or liability.

The Company's Level 2 assets consist of corporate bonds. The Company did not hold any Level 2 liabilities as of December 31, 2009.

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

The Company did not hold any Level 3 assets or liabilities as of December 31, 2009.

The following table summarizes the Company's financial assets measured at fair value on a recurring basis as of December 31, 2009 (in thousands):

Description	Balance as of December 31, 2009	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)
Cash equivalents:			
Money market funds	$ 96,266	$ 96,266	$ —
Short-term investments:			
U.S. government debt securities	18,978	18,978	—
Corporate bonds	1,000	—	1,000
	$ 116,244	$ 115,244	$ 1,000

ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Note 3. Balance Sheet Components

Inventories consist of the following (in thousands):

	December 31,	
	2009	2008
Raw materials	$ 1,079	$ 1,066
Work in process	460	416
Finished goods	507	483
	$ 2,046	$ 1,965

Work in process includes costs to produce the Invisalign product. Finished goods primarily represent ancillary products that support the Invisalign system.

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

	Useful Life (in years)	December 31,	
		2009	2008
Clinical and manufacturing equipment	5	$ 46,620	$ 45,125
Computer hardware	3	13,895	13,548
Computer software	3	12,511	10,092
Furniture and fixtures	5	5,468	5,584
Leasehold improvements	Term of the lease	10,046	9,918
Construction in progress		6,437	4,075
		$ 94,977	$ 88,342
Less: Accumulated depreciation and amortization		(70,006)	(61,363)
		$ 24,971	$ 26,979

As of December 31, 2009, construction in progress consisted primarily of costs for capital equipment expected to be placed in service in the next year. Depreciation and amortization was $10.2 million, $10.0 million, and $10.2 million, for the years ended December 31, 2009, 2008 and 2007, respectively.

Accrued liabilities consist of the following (in thousands):

	December 31,	
	2009	2008
Accrued payroll and benefits	$ 25,847	$ 17,795
Accrued income taxes	2,920	2,492
Accrued sales and marketing expenses	1,954	2,449
Accrued sales rebate	2,610	2,205
Accrued sales tax and value added tax	2,392	1,823
Accrued warranty	2,376	2,031
Accrued professional fees	516	922
Accrued restructuring	—	2,501
Other	4,207	6,064
	$ 42,822	$ 38,282

ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Warranty accrual as of December 31, 2009 and 2008 consists of the following activity (in thousands):

Warranty accrual, December 31, 2007	$ 2,035
Charged to cost of revenues	2,484
Actual warranty expenditures	(2,488)
Warranty accrual, December 31, 2008	$ 2,031
Charged to cost of revenues	2,926
Actual warranty expenditures	(2,581)
Warranty accrual, December 31, 2009	$ 2,376

Note 4. Impairment of Long-Lived Assets

The Company evaluates the recoverability of property and equipment whenever events or changes in circumstances indicate that the carrying value of a long-lived asset may not be recoverable. The Company's management decided to cease further investment 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. The impairment indicators which management considered included the fact that this internally developed software tool was not completed and management concluded that no market participant would be willing to purchase an unfinished customized application, therefore the fair value was determined to be zero, and the capitalized amount of the software tool was written off. There were no impairment charges during 2009.

Note 5. Patients First Program and Settlement Costs

In October 2006, the Company entered into a formal agreement with OrthoClear, Inc., OrthoClear Holdings, Inc., and OrthoClear Pakistan Pvt. Ltd. ("OrthoClear"), together with certain individuals associated with OrthoClear (the "OrthoClear Agreement") to end all pending litigation between the parties. In addition, OrthoClear agreed to stop the importation of aligners into the United States and discontinue all aligner business operations worldwide. As a result, most OrthoClear patients were unable to complete their orthodontic treatment with OrthoClear. OrthoClear also agreed to assign and transfer to Align all intellectual property rights with application to the correction of malocclusion and certain OrthoClear principals also signed five year non-compete agreements. The Company evaluated this transaction under the provisions of FASB ASC 805 and concluded that this transaction was not a business acquisition and was accounted for as an asset purchase.

In an attempt to help minimize treatment disruptions for the OrthoClear patients and their doctors, the Company committed to make treatment available to these patients at no additional cost under the "Patients First Program." In 2006, the Company recorded an $8.3 million charge for the anticipated costs of completing this program. Subsequently, in the first quarter of 2007, the Company reduced its Patients First Program accrual by $1.8 million to reflect a reduction of its initial estimate of the number of cases actually received by the case submission deadline. During 2007, the Company shipped virtually all Patients First Program cases. The accrued Patients First Program balance as of December 31, 2008 was $0.1 million, which principally consisted of estimated future warranty and case refinement costs. There was no remaining balance related to the Patients First Program as of December 31, 2009.

The Company paid $20.0 million to OrthoClear in 2006 in accordance with the terms of the OrthoClear Agreement, of which $14.0 million was capitalized on the Company's balance sheet representing the fair value of the non-compete agreements and is being amortized over 5 years. The Company recorded the remaining $6.0 million as settlement costs in 2006.

ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Note 6. Intangible Assets

The intangible assets represent non-compete agreements received in conjunction with the October 2006 OrthoClear Agreement at gross value of $14 million. These assets are amortized on a straight-line basis over the expected useful life of five years. As of December 31, 2009 and December 31, 2008, the net carrying value of these non-compete agreements was $5.0 million (net of $9.0 million of accumulated amortization) and $7.8 million (net of $6.2 million of accumulated amortization), respectively.

For the years ended December 31, 2009, 2008 and 2007, total amortization expense for intangible assets was $2.8 million, $2.8 million and $3.2 million respectively. The total estimated annual future amortization expense for these intangible assets is as follows (in thousands):

Fiscal Year	
2010	$2,800
2011	2,188
Total	$4,988

Note 7. Ormco Litigation Settlement

On August 16, 2009, Align entered into three agreements with Ormco Corporation (“Ormco”), an affiliate of Danaher Corporation (“Danaher”): a Settlement Agreement, a Stock Purchase Agreement, and a Joint Development, Marketing and Sales agreement (“Collaboration Agreement”). The Settlement Agreement ended all pending litigation between the parties, and Align agreed to (1) make a cash payment of $13.2 million upon the execution of the agreement and (2) issue a total of 7.6 million non-assessable shares of common stock pursuant to the Stock Purchase Agreement. Under the Collaboration Agreement, Align and Ormco agreed to jointly develop and market an orthodontic product for the most complex orthodontic cases that combine the Invisalign system with Ormco’s orthodontic brackets and arch wire systems over the next seven years. Because the Company entered into several agreements with Ormco on the same date, the guidance related to multiple element arrangements was considered in determining the allocation of the total settlement amount to the various elements of this arrangement.

In accordance with the Collaboration Agreement, each party will retain ownership of its pre-existing intellectual property, and each party will be granted intellectual property licenses in their respective field for jointly-developed combination products. The Collaboration Agreement, among other things, ensures mutual and equal participation, and equal share of the risks, costs, and benefits associated with developing the combination product. With the assistance of a third party valuation firm, Align concluded there was no value on the execution date of this agreement, as the Company has not contributed any assets or tendered any consideration. In addition, as part of its long-term strategic plan, the Company had the intention of collaborating with other orthodontic industry leaders to offer Invisalign in combination with traditional wires and brackets therapy, and it believes that the terms of such an agreement would have been similar to those it reached with Ormco.

Upon execution of the Settlement Agreement, 5.6 million shares were issued to Danaher and the remaining 2.0 million shares were issued upon the expiration of the waiting period under the provisions of the Hart-Scott-Rodino Antitrust Improvements Act, which occurred on September 21, 2009. In addition to other provisions of the Settlement Agreement, these shares may not be resold except pursuant to an effective registration statement under the Securities Act or an available exemption from registration. The Company is not obligated to affect any such registration prior to the one year anniversary of this agreement. The fair value of the shares should reflect the value that market participants would demand because of the risk relating to the inability to access a public market for these securities for the specified period. The fair value of the unregistered shares was determined as of the market closing price on the dates the shares were issued less a 25% non-marketability discount, for a total value of $76.7 million, including the cash payment.

ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Align has concluded that 25% is an appropriate discount based primarily on an analysis utilizing the Black-Scholes model to value a hypothetical put option to approximate the cost of hedging the restricted stock over the expected period of non-marketability. This approach calculates the amount required to buy the right to sell the presently restricted stock at the then-current market price on the date the holder can count on the shares becoming salable on the public exchange. The assumptions input into the Black-Scholes option pricing model were based on the stock price on the dates of the share issuances, an expected term of 1 year, expected volatility of 70%, risk-free interest rate of 4.38% to 4.90% and no expected dividends.

The Company corroborated the conclusion indicated by the Black-Scholes model by assessing that the discount was generally consistent with the ranges noted from published restricted stock studies and comparable to discounts on restricted stock transactions completed by other companies operating in similar industries as Align.

In accordance with the Settlement Agreement, Ormco released Align from any and all past and future claims of infringement for the period September 9, 2003 through the expiration of the patent on January 19, 2010 (“infringement period”). In order to determine how to allocate the settlement value between past infringement and the future use of the patent, Align considered both past and estimated future case shipment volumes during the infringement period, and allocated the total settlement value across all case shipments. The value attributed to past infringement claims was recorded as litigation settlement costs and was based on case shipments from September 9, 2003 through August 16, 2009, totaling $69.7 million, which was recorded in operating expenses and $6.2 million in cost of sales for the year ended December 31, 2009. The remaining $0.8 million will be amortized based on case shipments during first quarter of 2010.

Note 8. Legal Proceedings

Consumer Class Action

On May 18, 2007, Debra A. Weber filed a consumer class action lawsuit against Align, 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 Align for breach of contract. The cause of action against the Company, titled “Breach of Third Party Benefit Contract” references Align’s agreement to make Invisalign treatment available to OrthoClear patients, alleging that the Company failed “to provide the promised treatment to Plaintiff or any of the class members”.

On July 3, 2007, the Company filed an answer to the complaint and asserted 17 affirmative defenses. On July 20, 2007, the Company filed a motion for summary judgment on the Third Cause of Action (the only cause of action alleged against Align). On August 24, 2007, Weber filed a motion for class certification. On October 1, 2007, the Company filed an opposition to the motion for class certification and it is currently awaiting rulings from the Court. OrthoClear has filed a motion to dismiss. The initial case management conference and all discovery has been stayed pending the Court’s decision on the motion for class certification, OrthoClear’s motion to dismiss and the Company’s motion for summary judgment. The Company believes the lawsuit to be without merit and intends to vigorously defend itself. Accordingly, the Company believes there is not sufficient evidence to conclude that a reasonable possibility exists that a loss had been incurred as of December 31, 2009.

Securities Litigation

In August 2009, Plaintiff Charles Wozniak filed a lawsuit against the Company and its 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 the common stock of Align 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

ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Securities Exchange Act of 1934. Specifically, the complaint alleges that during the class period Align failed to disclose that it had shifted the focus of the sales force to clearing backlog, causing a significant decrease in the number of new case starts. The Court has recently selected a lead plaintiff. The Company believes the lawsuit to be without merit and intends to vigorously defend itself. Accordingly, the Company believes there is not sufficient evidence to conclude that a reasonable possibility exists that a loss had been incurred as of December 31, 2009.

Note 9. Credit Facilities

On December 5, 2008, the Company renegotiated and amended its existing credit facility with Comerica Bank. Under this revolving line of credit, the Company has $25.0 million of available borrowings with a maturity date of December 31, 2010. This credit facility requires a quick ratio covenant and also requires the Company to maintain a minimum unrestricted cash balance of $10.0 million. The interest rate on borrowings will range from Libor plus 1.5% to 2.0% depending upon the amount of unrestricted cash the Company maintains at Comerica Bank above the $10.0 million minimum. As of December 31, 2009, the Company had no outstanding borrowings under this credit facility and is in compliance with the financial covenants.

Note 10. Commitments and Contingencies

Operating leases

Align rents its facilities and certain equipment and automobiles under non-cancelable operating lease arrangements. Facility leases expire at various dates through 2013 and thereafter and provides for pre-negotiated fixed rental rates during the terms of the lease.

In February 2005, the Company renewed its Santa Clara headquarters lease allowing it to utilize the security deposit of $1.3 million paid at the inception of the lease on July 1, 2000, to reduce the monthly rent payment by $11,000. By the end of the lease term on June 30, 2010, the security deposit balance will be reduced to $0.6 million.

The Company has a facility in San Jose, Costa Rica. The facility comprises approximately 63,000 square feet of manufacturing and office space. The monthly rent for the Costa Rica facility is approximately $84,000. The Company renewed the lease in March 2008 for an additional five year term, which commenced in October 2008 and expires in September 2013.

The Company also has a facility in Juarez, Mexico used to manufacture clear aligners. This facility comprises of approximately 68,000 square feet of manufacturing and office space with a monthly rent of approximately $30,000. This lease was assumed by the Company from IMS in December 2008 and will expire in July 2013.

The Company’s European headquarters are located in Amsterdam, The Netherlands. On August 3, 2007, the original lease agreement was amended to expand its Amsterdam facility to approximately 16,000 square feet of office space. This lease will expire in June 2012, with an option to renew for an additional five year term. The Company may also terminate this lease in June 2012 for a fee of approximately $125,000. The monthly rent for the Amsterdam facility is approximately $51,000.

The Company recognizes rent expense on a straight-line basis over the lease period, and has accrued for rent expense incurred but not paid. Total rent expense was $3.8 million, $3.8 million, and $3.4 million, for the years ended December 31, 2009, 2008 and 2007, respectively.

ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Minimum future lease payments for non-cancelable leases as of December 31, 2009, are as follows (in thousands):

Fiscal Year	
2010	$3,339
2011	2,449
2012	1,780
2013	1,006
Total	$8,574

On January 26, 2010, the Company entered into an agreement for new corporate headquarters. See *Note 20 "Subsequent Event."*

Note 11. Stockholders' Equity

Preferred Stock Rights Agreement

The Preferred Stock Rights Agreement (the "Rights Agreement") is intended to protect stockholders from unfair or coercive takeover practices. In accordance with the Rights Agreement, the Board of Directors declared a dividend distribution of one preferred stock purchase right (a "Right") for each outstanding share of Align's common stock to stockholders of record on November 22, 2005. Each Right entitles stockholders to buy one one-thousandth of a share of Align's Series A Participating Preferred Stock, par value $0.0001 per share, at an exercise price of $37.00, subject to adjustment. Rights will become exercisable upon the occurrence of certain events, including a person or group acquiring or the announcing the intention to acquire beneficial ownership of 15% or more of the then outstanding common stock without the approval of the Board of Directors. Each holder of a Right will have the right to receive, upon exercise, shares of common stock having a value equal to two times the purchase price. The Rights will expire on November 22, 2015 or upon the exercise of the Rights, whichever occurs earlier.

Common Stock

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

Employee Stock Purchase Plan

Align's Employee Stock Purchase Plan (the "Purchase Plan") consists of overlapping twenty-four month offering periods with four six-month purchase periods in each offering period, and expires on January 31, 2011. Employees purchase shares at 85% of the fair market value of the common stock at either the beginning of the purchase period or the end of the purchase period, whichever price is lower. The Purchase Plan provides that the number of shares of the Company's common stock reserved for issuance thereunder will automatically increase on the first trading day of January in each calendar year by an amount equal to three percent (3%) of the total number of shares of common stock outstanding on the last trading day in December of the immediately preceding calendar year, with this annual increase not to exceed 1,500,000 shares. The maximum number of shares that can be granted under the Purchase Plan in any one year is 800,000 shares of common stock.

During the year ended December 31, 2009, 545,151 shares were issued under the Purchase Plan. As of December 31, 2009, the Company had reserved 13,433,456 shares of common stock for future issuance and 10,124,732 shares remain available for future issuance.

ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

As of December 31, 2009, there was $1.4 million of total unamortized compensation costs related to employee stock purchases. These costs are expected to be recognized over a weighted average period of 0.3 years.

Stock Option Plans

In May 2005, the 2005 Incentive plan ("2005 Plan") replaced the 2001 stock incentive Plan ("2001 Plan"). The 2005 Plan, which expires December 31, 2010, provides for the granting of incentive stock options, non-statutory stock options, restricted stock units, stock appreciation rights, performance units and performance shares. Employees, non-employee directors and consultants are eligible to receive grants under the 2005 Plan. The options are granted for periods not exceeding ten years and generally vest over 4 years with 25% vesting one year from the date of grant and 1/48th each month thereafter. The Plan Administrator may, however, grant options with different vesting schedules.

The 2005 Plan has 9,983,379 shares of the Company's common stock reserved for issuance, plus up to an aggregate of 5,000,000 shares that have been or will be returned to the 2001 Plan as a result of termination of outstanding options or repurchase of shares granted under the 2001 Plan on or after March 28, 2005. As of December 31, 2009, 2,360,766 shares have been transferred to the 2005 Plan and 2,747,759 shares remain available for issuance under the 2005 Plan.

Activity for the years ended December 31, 2009, 2008 and 2007 under the stock option plans are set forth below (in thousands, except per share data):

	Stock Options			
	Number of Shares Underlying Stock Options (in thousands)	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2006	9,178	$ 8.86		
Granted	1,517	18.97		
Exercised	(3,048)	8.52		
Cancelled or expired	(514)	11.13		
Outstanding at of December 31, 2007	7,133	$ 10.99		
Granted	2,182	12.78		
Exercised	(912)	6.5		
Cancelled or expired	(1,094)	14.02		
Outstanding at December 31, 2008	7,309	$ 11.63		
Granted	1,134	8.62		
Exercised	(586)	7.05		
Cancelled or expired	(369)	12.45		
Outstanding at of December 31, 2009	7,488	$ 11.49	6.43	$ 48,825
Vested and expected to vest at December 31, 2009	7,325	$ 11.50	6.38	$ 47,747
Exercisable at December 31, 2009	4,875	$ 11.38	5.34	$ 32,689

ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

The aggregate intrinsic value in the table above represents the total pre-tax intrinsic value (the difference between Align's closing stock price on the last trading day in 2009 and the exercise price, multiplied by the number of in-the-money options) that would have been received by the option holders had all option holders exercised their options on the last day of each fiscal year. This amount will fluctuate based on the fair market value of Align's stock. The total intrinsic value of stock options exercised for the years ended December 31, 2009, 2008 and 2007 was $3.2 million, $5.2 million, and $43.1 million, respectively. The Company issues new shares upon the exercise of options.

As of December 31, 2009, there was $16.2 million of total unamortized compensation costs related to stock options and these costs are expected to be recognized over a weighted average period of 2.2 years. For the year ended December 31, 2009, the total recognized tax affect from exercised options was $0.6 million.

The options outstanding and exercisable by exercise price at December 31, 2009 are as follows:

	Options Outstanding			Options Exercisable	
Range of Exercise Prices	Shares	Weighted Average Remaining Contractual Term (in years)	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
$ 1.06 - $ 7.35	1,642,354	4.04	$ 6.17	1,631,253	$ 6.17
7.40 - 8.38	1,945,161	7.35	7.98	1,000,854	8.10
8.39 - 13.00	1,927,530	7.87	12.57	688,416	12.42
13.04 - 18.73	1,682,750	6.24	17.88	1,286,022	18.03
18.81 - 27.06	289,965	5.31	20.94	268,103	20.68
$ 1.06 - $27.06	7,487,760	6.43	$ 11.49	4,874,648	$ 11.38

Restricted Stock Units

In 2006, the Compensation Committee of the Board of Directors approved the grant of restricted stock units (contracts that give the recipients the right to receive shares as the units vest) to its employees and director(s) in addition to stock options. Each restricted stock unit award generally vests over 4 years with 25% on the one year anniversary of the date of grant and 6.25% vesting quarterly thereafter. Each grant of a restricted stock unit will reduce shares available for grant by two shares. In October 2007, the Compensation Committee of the Board of Directors approved a change in vesting for prospective grants of restricted stock units to 25% annually.

ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

The fair value of restricted stock units is based on the Company's closing stock price on the date of grant. A summary of the nonvested shares for the years ended December 31, 2009, 2008 and 2007 is as follows (in thousands, except per share amounts):

	Number of Shares Underlying RSUs (in thousands)	Weighted Average Grant Date Fair Value	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Nonvested as of December 31, 2006	419	$ 8.71		
Granted	480	19.17		
Vested and released	(178)	9.27		
Forfeited	(70)	13.31		
Nonvested as of December 31, 2007	651	15.78		
Granted	685	12.78		
Vested and released	(258)	15.55		
Forfeited	(206)	15.00		
Nonvested as of December 31, 2008	872	13.68		
Granted	326	8.56		
Vested and released	(257)	13.39		
Forfeited	(65)	12.44		
Nonvested as of December 31, 2009	876	$ 11.95	1.2	$ 15,617

The aggregate intrinsic value in the table above represents the total pre-tax intrinsic value (calculated by multiplying Align's closing stock price on the last trading day of 2009 by the number of non-vested RSUs) that would have been received by the unit holders had all RSUs been vested and released on the last day of each fiscal year. This amount will fluctuate based on the fair market value of Align's stock. During 2009, of the 257,536 shares vested and released, approximately 40,028 vested shares were withheld for executive RSU tax payments, resulting in a net issuance of 217,508 shares.

The total intrinsic value of RSUs vested and released during 2009, 2008 and 2007 was $2.9 million, $2.9 million and $3.4 million, respectively. As of December 31, 2009, there was $9.6 million of total unamortized compensation costs related to RSUs, and these costs are expected to be recognized over a weighted average period of 2.1 years.

ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Stock-based compensation

The Company measures and recognizes compensation expense for all share-based payment awards based on estimated fair values over the requisite service period. The fair value of stock options granted and the option component of the Purchase Plan shares were estimated at the grant date using the Black-Scholes option pricing model with the following weighted average assumptions:

	2009	2008	2007
Stock options:			
Expected term (in years)	4.4	4.4	4.5
Expected volatility	62.0%	60.0%	68.0%
Risk-free interest rate	1.6%	2.8%	4.4%
Expected dividend	—	—	—
Weighted average fair value at grant date	$4.32	$6.40	$10.82
Employee stock purchase plan:			
Expected term (in years)	1.3	1.2	1.2
Expected volatility	74.6%	67.2%	55.8%
Risk-free interest rate	0.6%	2.2%	4.8%
Expected dividend	—	—	—
Weighted average fair value at grant date	$3.78	$4.89	$ 9.42

The expected term of stock options represents the weighted-average period the stock options are expected to remain outstanding. The Company used a mid-point model to determine the expected term of stock options based on the Company's historical exercise, post-vesting cancellation experience, and the remaining contractual term of its outstanding options.

The Company uses its own historical volatility.

The risk-free interest rate is based on the implied yield on a U.S. Treasury zero-coupon issue with a remaining term equal to the expected term of the option.

The dividend yield reflects that the Company has not paid any cash dividends since inception and does not anticipate paying cash dividends in the foreseeable future.

Summary of Stock-based Compensation Expense

Stock-based compensation expense recognized in the Consolidated Statements of Operations for the years ended December 31, 2009, 2008 and 2007 is based on awards ultimately expected to vest, net of estimated forfeitures. Estimated forfeitures are based on historical experience at the time of grant and may be revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. The stock-based compensation expense related to all of the Company's stock-based awards and employee stock purchases for the years ended December 31, 2009, 2008, 2007 is as follows (in thousands):

	For the Years Ended December 31,		
	2009	2008	2007
Cost of revenues	$ 1,502	$ 1,753	$ 994
Sales and marketing	4,308	5,289	4,225
General and administrative	7,641	8,011	5,443
Research and development	1,637	2,004	1,549
Total stock-based compensation	$ 15,088	$ 17,057	$ 12,211

ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Note 12. Common Stock Repurchase Program

In April 2008, the Company's Board of Directors approved a common stock repurchase program authorizing management to repurchase up to $50 million of the Company's outstanding common stock. During 2008, the Company purchased approximately 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 and completed the stock repurchase program. The common stock repurchases reduced additional paid-in capital by $38.6 million and increased accumulated deficit by $11.6 million. All repurchased shares were retired, and there were no stock repurchases during 2009.

Note 13. Employee Benefit Plan

In January 1999, the Company adopted a defined contribution retirement plan under Section 401(k) of the Internal Revenue Code. This plan covers substantially all employees who meet minimum age and service requirements and allows participants to defer a portion of their annual compensation on a pre-tax basis. In 2009, the Company's Board of Directors authorized the Company to match equal 50% of the employee's salary deferral contributions up to a 6% based on the employee's eligible compensation effective 2010.

Note 14. Income Taxes

Deferred tax assets and liabilities were as follows (in thousands):

	Years Ended December 31,	
	2009	2008
Deferred tax assets, net:		
Net operating loss and capital loss carryforwards	$ 47,607	$ 48,583
Credit carryforwards	7,583	6,836
Reserves & accruals	8,947	4,807
Depreciation and amortization	6,196	6,100
Stock-based compensation	5,606	3,944
Other	785	2,433
	76,724	72,703
Deferred tax liabilities:		
Prepaid expenses	1,739	1,752
Translation gains	239	143
Other	1,344	—
	3,322	1,895
Net deferred tax assets before valuation allowance	73,402	70,808
Valuation allowance	(6,182)	(6,200)
Net deferred tax assets	$ 67,220	$ 64,608

With the exception of certain capital loss and foreign net operating loss carryforwards, the Company 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, 2009, the Company believed, except for the items noted above that it was more likely than not, that the amount of deferred tax assets recorded on the balance sheet will be realized. However, should there be a change in the Company's ability to recover its deferred tax assets, the tax provision would increase in the period in which it is more likely than not that the Company cannot recover its deferred tax assets.

ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

At December 31, 2009, the Company had net operating loss carryforwards of approximately $187.7 million for federal purposes and $68.1 million for California state tax purposes. If not utilized, these carryforwards will begin to expire beginning in 2020 for federal purposes and 2011 for California purposes.

The Company has research credit carryforwards of approximately $4.4 million for federal purposes and $5.4 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.

Effective January 1, 2007, the Company adopted FASB ASC 740 (formerly referenced as FASB Financial Interpretation No. 48, "Accounting for Uncertainty in Income Taxes—an interpretation of FASB Statement No. 109"). This interpretation clarifies the criteria for recognizing income tax benefits under the accounting provisions for income taxes, and requires additional disclosures about uncertain tax positions. The financial statement recognition of the benefit for a tax position is dependent upon the benefit being more-likely-than-not to be sustainable upon audit by the applicable taxing authority. If this threshold is met, the tax benefit is then measured and recognized at the largest amount that is greater than 50 percent likely of being realized upon ultimate settlement.

The following is a rollforward of the Company's total gross unrecognized tax benefit for 2009 (in thousands):

Balance as of January 1, 2009	$2,878
Tax positions related to current year:	
Additions for uncertain tax positions	1,691
Tax positions related to prior year:	
Additions for uncertain tax positions	1,738
Reductions for uncertain tax positions	(378)
Balance as of December 31, 2009	$5,929

During fiscal year 2009, the amount of unrecognized tax benefits was increased by $3.1 million. The total amount of unrecognized tax benefits was $5.9 million as of December 31, 2009, which would impact the Company's effective tax rate if recognized. The Company recognizes interest and penalties related to unrecognized tax benefits as a component of income tax expense. Interest and penalties are immaterial at the date of adoption and are included in the unrecognized tax benefits.

The Company is subject to taxation in the U.S. and various states and foreign jurisdictions. All of the Company's tax years will be open to examination by the U.S. federal and most state tax authorities due to the Company's net operating loss and overall credit carryforward position. With few exceptions, the Company is no longer subject to examination by foreign tax authorities for years before 2005.

ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

The differences between income taxes using the federal statutory income tax rate of 35% and the Company's effective tax rate were as follows:

	Years Ended December 31,		
	2009	2008	2007
U.S. federal statutory income tax rate	35.00%	35.00%	35.00%
State income taxes, net of federal tax benefit	1.89	7.74	5.04
Deferred tax benefits utilized	—	(67.04)	(44.53)
Foreign losses not benefited	—	4.16	2.40
Impact of differences in foreign tax rates	(14.99)	(8.13)	(7.23)
Amortization of stock-based compensation	(6.53)	32.30	7.89
Non-deductible foreign exchange losses	—	(0.91)	—
Non-deductible meals & entertainment charges	(1.31)	3.21	1.21
Valuation allowance release	—	(378.34)	—
Other items not individually material	(6.40)	3.57	3.54
	7.66%	(368.44%)	3.32%

The domestic and foreign components of income (loss) before provision for income taxes were as follows (in thousands):

	Years ended December 31,		
	2009	2008	2007
Domestic	$(23,075)	$13,333	$30,928
Foreign	(10,818)	3,743	6,022
Total	$(33,893)	$17,076	$36,950

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 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 2009. Because Costa Rica incurred a net loss in 2009, no tax benefit was realized from these incentives in 2009. In order to receive the benefit of the incentives, the Company must hire specified numbers of employees and maintain minimum levels of fixed asset investment in Costa Rica. If the Company does not fulfill these conditions for any reason, our incentive could lapse and its income in Costa Rica would be subject to taxation at higher rates, which could have a negative impact on the Company's operating results.

ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

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

	Years Ended December 31,		
	2009	2008	2007
Federal			
Current	$(1,196)	$ 268	$ 276
Deferred	(1,437)	(56,934)	—
	(2,633)	(56,666)	276
State			
Current	(96)	784	309
Deferred	(1,115)	(7,674)	—
	(1,211)	(6,890)	309
Foreign			
Current	1,280	645	641
Deferred	(60)	—	—
	1,220	645	641
Provision for (benefit from) income taxes	$(2,624)	$(62,911)	$1,226

The Company has not provided additional U.S. income taxes on undistributed earnings from non- U.S. operations as of December 31, 2009 because such earnings are intended to be reinvested indefinitely outside of the United States.

Note 15. Net Profit (Loss) per Share

Basic net profit (loss) per share is computed using the weighted average number of shares of common stock during the year less unvested common shares subject to repurchase. Diluted net profit (loss) per share is computed using the weighted average number of shares of common stock, adjusted for the dilutive effect of potential common stock. Potential common stock, computed using the treasury stock method, includes options, restricted stock units, and the dilutive component of Purchase Plan shares.

The following table sets forth the computation of basic and diluted net profit (loss) per share attributable to common stock (in thousands, except per share amounts):

	Years Ended December 31,		
	2009	2008	2007
Numerator:			
Net profit (loss)	$(31,269)	$79,987	$35,724
Denominator:			
Weighted-average common shares outstanding, basic	69,094	66,812	67,176
Dilutive effect of potential common stock	—	1,252	4,268
Total shares, diluted	69,094	68,064	71,444
Net profit (loss) per share, basic	$ (0.45)	$ 1.20	$ 0.53
Net profit (loss) per share, diluted	$ (0.45)	$ 1.18	$ 0.50

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

For the years ended December 31, 2009, 2008, and 2007, stock options, restricted stock units, and employee stock purchases totaling 9.3 million, 5.1 million, and 1.0 million, respectively, were excluded from diluted net profit (loss) per share because of their anti-dilutive effect.

Note 16. Comprehensive Income (Loss)

Comprehensive income (loss) includes net profit (loss), foreign currency translation adjustments and unrealized gains and losses on available-for-sale securities. The components of comprehensive income (loss) are as follows (in thousands):

	Years Ended December 31,		
	2009	2008	2007
Net profit (loss)	$(31,269)	$79,987	$35,724
Foreign currency translation adjustments	168	(421)	703
Change in unrealized gain/(loss) on available-for-sale securities	18	33	(49)
Comprehensive income (loss)	$(31,083)	$79,599	$36,378

Note 17. Supplemental Cash Flow Information

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

	Years Ended December 31,		
	2009	2008	2007
Taxes paid	$ 2,004	$1,510	$1,632
Interest paid	$ 84	$ —	$ 415
Non-cash investing and financing activities:			
Fixed assets acquired with accounts payable, accrued liabilities, or through financing	$ 1,790	$1,322	$1,135
Stock component of litigation settlement costs	$63,518	$ —	$ —

Note 18. Segments and Geographical Information

Segments

The Company reports segment data based on the management approach which designates the internal reporting that is used by management for making operating decisions and assessing performance as the source of the Company's reportable operating segments. During all periods presented, the Company operated as a single business segment.

ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Geographical Information

Net revenues and long-lived assets are presented below by geographic area (in thousands):

	For the Years Ended December 31,		
	2009	2008	2007
Net revenues:			
North America	$ 237,033	$ 240,210	$ 236,758
Europe	72,245	61,652	45,047
Other international	3,055	2,114	2,527
Total net revenues	$ 312,333	$ 303,976	$ 284,332

	As of December 31,		
	2009	2008	2007
Long-lived assets:			
North America	$ 91,548	$ 99,086	$ 35,632
Europe	1,018	960	1,081
Other international	1,375	1,388	1,531
Total long-lived assets	$ 93,941	$ 101,434	$ 38,244

Note 19. Restructurings

During 2008, the Company announced restructuring plans in July and October to increase efficiencies across the organization and lower the overall cost structure. In July 2008, the Company implemented a restructuring plan to reduce its full time headcount by 67 employees including a phased-consolidation of order acquisition operations from its 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 as the Company moves its customer care, accounts receivable, credit and collections, and customer event registration organizations, in Santa Clara, California to existing facilities in Costa Rica.

In 2008, the Company incurred approximately $6.2 million in restructuring expenses relating to these actions which included $0.7 million related to the acceleration of stock option vesting and $5.5 million related to severance and termination benefits, of which $3.0 million was paid during the year.

In 2009, the Company incurred approximately $1.3 million of costs related to severance and termination benefits.

Activity and liability balances related to restructuring activity for the year ended December 31, 2009 are as follows (in thousands):

	Severance and Benefits
Balance at January 1, 2009	$ 2,501
Restructuring accrual	1,319
Cash payments	(3,820)
Balance at December 31, 2009	$ —

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Note 20. Subsequent Event

On January 26, 2010, the Company entered into an agreement to lease new corporate headquarters of approximately 129,024 square feet in San Jose, California. The lease agreement commences on the earlier of August 1, 2010 or the date the Company first commences conducting business in the premises, which is expected to be on or about June 28, 2010 and will continue for an initial term of seven years and two months. The agreement for the Company's current corporate headquarters in Santa Clara, California, expires on June 30, 2010. The expected future cash payments for the new property are presented in the following table (in thousands):

Fiscal Year	
2010	$ 519
2011	1,572
2012	1,619
2013	1,716
2014 and thereafter	7,100
Total	$ 12,526

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of disclosure controls and procedures.

Under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, we have evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). Based upon that evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that our disclosure controls and procedures are effective as of December 31, 2009 to provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our Chief Executive Officer and our Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure, and that such information is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission rules and forms.

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

See "Report of Management on Internal Control over Financial Reporting" on page 52 of this Annual Report on Form 10-K, which is incorporated herein by reference.

Changes in internal control over financial reporting.

There have been no changes in our internal control over financial reporting during the year ended December 31, 2009 that have materially affected or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

PART III

Certain information required by Part III is omitted from this Form 10-K because we intend to file a definitive Proxy Statement for our 2010 Annual Meeting of Stockholders (the "Proxy Statement") not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K, and certain information to be included therein is incorporated herein by reference.

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by Item 401 of Regulation S-K concerning our directors is incorporated by reference to the Proxy Statement under the section captioned "Election of Directors." The information required by Item 401 of Regulation S-K concerning our executive officers is set forth in *Item 1—"Business" of this Annual Report on Form 10-K*. The information required by Item 405 of Regulation S-K is incorporated by reference to the section entitled "Section 16(a) Beneficial Ownership Reporting Compliance" contained in the Proxy Statement. The information required by Item 407(d)(5) of Regulation S-K is incorporated by reference to the Proxy Statement under the section entitled "Corporate Governance—Board of Directors & Committee Meetings—Audit Committee".

Code of Ethics

We have a code of ethics that applies to all of our employees, including our principal executive officer, principal financial officer and principal accounting officer. This code of ethics is posted on our Internet website. The Internet address for our website is *www.aligntech.com*, and the code of ethics may be found on the "Corporate Governance" section of our "Investor Relations" webpage.

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

ITEM 11. EXECUTIVE COMPENSATION

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

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by Item 403 of Regulation S-K is incorporated by reference to the Proxy Statement under the section captioned "Security Ownership of Certain Beneficial Owners and Management."

Equity Compensation Plan Information

The following table provides information as of December 31, 2009 about our common stock that may be issued upon the exercise of options and rights granted to employees, consultants or members of our Board of Directors under all existing equity compensation plans, including the 1997 Equity Incentive Plan, the Employee Stock Purchase Plan, the 2001 Stock Incentive Plan and the 2005 Incentive Plan, each as amended, and certain individual arrangements.

Plan Category	Number of securities to be issued upon exercise of outstanding options and restricted stock units(a)	Weighted average exercise price of outstanding options(b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column(a))
Equity compensation plans approved by security holders	8,364,135(1)(2)	$ 11.49	2,747,759(3)
Equity compensation plans not approved by security holders	—	—	—
Total	8,364,135	$ 11.49	2,747,759

(1) This number reflects the number of securities to be issued upon exercise of outstanding options and restricted stock units under the 1997 Equity Incentive Plan, the 2001 Stock Incentive Plan, and the 2005 Incentive Plan. The 876,375 restricted stock units included in this number have an exercise price of zero.

(2) We are unable to ascertain with specificity the number of securities to be issued upon exercise of outstanding rights under the Employee Stock Purchase Plan or the weighted average exercise price of outstanding rights under the Employee Stock Purchase Plan.

(3) This number reflects securities available for future issuance under the 2005 Stock Incentive Plan and the Employee Stock Purchase Plan. In January 2001, all outstanding options under the 1997 Equity Incentive Plan were subsumed under the 2001 Stock Incentive Plan. Since that date no options have been granted under the 1997 Equity Incentive Plan. In May 2005, stockholder approval was obtained for the 2005 Incentive Plan and the 2001 Stock Incentive Plan was terminated. Since that date, no further options have been granted under the 2001 Stock Incentive Plan. The 2005 Incentive Plan has 9,983,379 shares of common stock reserved for issuance, plus up to an aggregate of 5,000,000 shares that are or would have been returned to the 2001 Stock Incentive Plan as a result of termination of outstanding options or repurchase of shares granted under the 2001 Stock Incentive Plan after March 28, 2005. As of December 31, 2009, 2,360,766 shares have been transferred to the 2005 Incentive Plan. As of December 31, 2009, the number of shares available for future issuance under the 2005 Incentive Plan was 2,747,759. Any grants of restricted stock units will reduce shares available for grant at a 2:1 ratio. The Employee Stock Purchase Plan provides that the number of shares of our common stock reserved for issuance thereunder will automatically increase on the first trading day of January in each calendar year by an amount equal to three percent (3%) of the total number of shares of common stock outstanding on the last trading day in December of the immediately preceding calendar year, with this annual increase not to exceed 1,500,000 shares. The maximum number of shares that can be granted under the Employee Stock Purchase Plan in any one year is 800,000 shares of common stock. As of December 31, 2009, the total number of shares of our common stock available for future issuance under the Employee Stock Purchase Plan was 10,124,732.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

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

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

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

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

(a) Financial Statements

1. Consolidated Financial Statements

The following documents are filed as part of this Annual Report on Form 10-K:

2. The following financial statement schedule is filed as part of this Annual Report on Form 10-K:

Schedule II—Valuation and Qualifying Accounts and Reserves

All other schedules have been omitted as they are not required, not applicable, or the required information is otherwise included.

SCHEDULE II: VALUATION AND QUALIFYING ACCOUNTS AND RESERVES

	Balance at Beginning of Period	Additions (reductions) to Costs and Expenses	Write offs (in thousands)	Reclass from Other Accounts	Balance at End of Period
Allowance for doubtful accounts:					
Year ended December 31, 2007	$ 844	$ 46	$(184)	$ 54	$ 760
Year ended December 31, 2008	$ 760	$ 71	$(184)	$ (35)	$ 612
Year ended December 31, 2009	$ 612	$ 708	$(305)	$ 18	$ 1,033
Allowance for deferred tax assets:					
Year ended December 31, 2007	$102,153	$ (8,996)	$ —	$ —	$ 93,157
Year ended December 31, 2008	$ 93,157	$ (86,957)	$ —	$ —	$ 6,200
Year ended December 31, 2009	$ 6,200	$ (18)	$ —	$ —	$ 6,182
Allowance for excess and obsolete inventory and abandoned product:					
Year ended December 31, 2007	$ 188	$ 47	$ (19)	$ —	$ 216
Year ended December 31, 2008	$ 216	$ 110	$(188)	$ —	$ 138
Year ended December 31, 2009	$ 138	$ 73	$(107)	$ —	$ 104

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

Exhibit Number	Description	Form	Date	Exhibit Number Incorporated by reference herein	Filed herewith
3.1	Amended and Restated Certificate of Incorporation of registrant.	Form S-1, as amended (File No. 333-49932)	12/28/2000	3.1	
3.2	Amended and Restated Bylaws of registrant.	Form S-1, as amended (File No. 333-49932)	12/28/2000	3.2	
3.2A	Amendment to Amended and Restated Bylaws of registrant.	Form 8-K (item 5.03 only)	12/18/2007	3.1	
3.3	Certificate of Designations of Rights, Preferences and Privileges of Series A Participating Preferred Stock registrant.	Form 8-K	10/27/2005	3.1	
4.1	Form of Specimen Common Stock Certificate.	Form S-1, as amended (File No. 333-49932)	01/17/2001	4.1	
4.2	Preferred Stock Rights Agreement dated October 25 between the registrant and EquiServe Trust Company, N.A.	Form 8-K	10/27/2005	4.1	
10.1	Lease Agreement by and between James Lindsey and registrant, dated June 20, 2000, for office space located at 881 Martin Avenue, Santa Clara, CA.	Form S-1, as amended (File No. 333-49932)	11/14/2000	10.4	
10.2	First Amendment to Lease Agreement dated February 2, 2005 for office space located at 881 Martin Avenue, Santa Clara, CA.	Form 8-K	02/09/2005	10.1	
10.3	Lease Agreement dated August 30, 2001 by and between James S. Lindsey and registrant for office space located at 821 Martin Avenue, Santa Clara, CA.	Form 10-K	03/27/2003	10.28	
10.4	First Amendment to Lease Agreement dated February 2, 2005 for office space located at 821 Martin Avenue, Santa Clara, CA.	Form 8-K	02/09/2005	10.3	
10.5	Lease Agreement dated March 4, 2004 by and between James S. Lindsey and registrant for office space located at 831 Martin Avenue, Santa Clara, CA.	Form 10-Q	05/06/2004	10.40	
10.6	First Amendment to Lease Agreement dated February 2, 2005 for office space located at 831 Martin Avenue, Santa Clara, CA.	Form 8-K	02/09/2005	10.2	
10.8	Amended and Restated Loan and Security Agreement dated December 16, 2005 between registrant and Comerica Bank.	Form 8-K.	12/19/2005	10.1	

Exhibit Number	Description	Form	Date	Exhibit Number Incorporated by reference herein	Filed herewith
10.8A	Amendment to Amended and Restated Loan and Security Agreement dated March 7, 2007 between registrant and Comerica Bank.	Form 10-K	03/12/2007	10.8A	
10.8B	Amendment to Amended and Restated Loan and Security Agreement dated March 7, 2007 between registrant and Comerica Bank.	Form 8-K	04/29/2008	10.1	
10.8C	Amendment to Amended and Restated Loan and Security Agreement dated March 7, 2007 between registrant and Comerica Bank.	Form 8-K	01/13/2009	10.1	
10.10†	Registrant's 2001 Stock Incentive Plan.	Form S-1 as amended (File No. 333-49932)	12/28/2000	10.13	
10.11†	Form of option agreement under Align's 2001 Stock Incentive Plan.	Form 10-Q	11/05/2004	10.13.1	
10.12†	Registrant's Employee Stock Purchase Plan.	Form S-8	02/05/2001	99.2	
10.13†	Form of Indemnification Agreement by and between registrant and its Board of Directors and its executive officers.	Form S-1 as amended (File No. 333-49932)	01/17/2001	10.15	
10.14†	Amended and restated 2005 Incentive Plan.	Form 10-K	03/12/2007	10.14	
10.14A†	Form of restricted stock unit award agreement under registrant's 2005 Incentive Plan (General Form; Officer Form: Director Form).	Form 10-Q	11/05/2007	10.1A, 10.1B, 10.1C	
10.14B†	Form of option award agreement under registrant's 2005 Incentive Plan.	Form 10-Q	08/04/2005	10.4	
10.14C†	Form of restricted stock unit award agreement under registrant's 2005 Incentive Plan with Thomas M. Prescott.	Form 10-K	03/12/2007	10.14C	
10.14D†	Form of restricted stock unit award agreement amendment under registrant's 2005 Incentive Plan with Thomas M. Prescott.	Form 10-K	03/12/2007	10.14D	
10.15†	Amended and Restated Employment Agreement dated May 5, 2008 between Thomas M. Prescott and registrant.	Form 10-Q	04/08/2008	10.4	
10.16†	Form of Employment Agreement entered into by and between registrant and each of executive officer (other than CEO).	Form 10-Q	05/08/2008	10.3	

Exhibit Number	Description	Form	Date	Exhibit Number Incorporated by reference herein	Filed herewith
10.17†	Amended and Restated Employment Agreement between registrant and Thomas M. Prescott dated May 5, 2008.	Form 10-Q	05/08/2008	10.4	
10.20	Lease Agreement dated February 26, 2003 between KPMG FIDES (Costa Rica) S.A., Parque Global S.A.A. and registrant.	Form 10-Q	05/13/2003	10.36	
10.20A	Omnibus Amendment to Lease and Service Agreement between KPMG FIDES (Costa Rica) S.A., Parque Global S.A. and Align dated June 24, 2008.	Form 8-K	06/26/2008	10.1	
10.21	Lease Agreement between Schootsepoort Onroerendgoed Beheer, for Stichting Philips Pensioenfonds and Align.	Form 10-Q	08/05/2004	10.41	
10.21A	Amendment to Lease Agreement between Align Technology, B.V. and TT Amsterdam Project Company (formerly Stichting Philips Pensioenfonds).	Form 10-Q	08/03/2007	10.4	
10.22	Lease Agreement between International Manufacturing Solutions Operaciones, S.R.L. and Elamex de Juarez, S.A. de C.V. dated July 31, 2008 (assigned to Align as Lessee effective April 1, 2009).	Form 8-K	12/22/2008	10.1	
10.23†	Summary of 2009 Incentive Awards for Named Executive Officers.	Form 8-K	02/08/2010	Item 5.02 only	
10.24†	Summary of Executive Officer Annual Incentive Plan.	Form 8-K/A Form 8-K	05/27/2009 08/08/2010	Item 5.02 only	
10.25	Lease Agreement between Align and Carr N.P. Properties, L.L.C. dated January 26, 2010	Form 8-K	01/29/2010		
10.26	Settlement Agreement dated as if August 16, 2009 between Align Technology, Inc. and Ormco Corporation.	Form 10-Q/A	02/24/2010		
10.27	Stock Purchase Agreement dated as of the 16th day of August by and between Align Technology, Inc. and Danaher Corporation.	Form 10-Q	11/05/2009		
10.28††	Joint Development, Marketing and Sales Agreement entered in as of August 16, 2009 by and between Align Technology, Inc. and Ormco Corporation	Form 10-Q/A	02/24/2010		

Exhibit Number	Description	Form	Date	Exhibit Number Incorporated by reference herein	Filed herewith
21.1	Subsidiaries of Align Technology, Inc.				*
23.1	Consent of PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firm.				*
31.1	Certifications of Chief Executive Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2003.				*
31.2	Certifications of Chief Financial Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2003.				*
32	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2003.				*

† Management contract or compensatory plan or arrangement filed as an Exhibit to this form pursuant to Items 14(a) and 14(c) of Form 10-K.
†† Portions of the exhibit have been omitted pursuant to a request for confidential treatment. The confidential portions have been filed with the SEC.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, on February 26, 2010.

ALIGN TECHNOLOGY, INC.

By: /s/ THOMAS M. PRESCOTT
Thomas M. Prescott
President and Chief Executive Officer

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

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

Signature	Title	Date
/s/ THOMAS M. PRESCOTT **Thomas M. Prescott**	President and Chief Executive Officer (Principal Executive Officer)	February 26, 2010
/s/ KENNETH B. AROLA **Kenneth B. Arola**	Chief Financial Officer and Vice President, Finance (Principal Financial Officer and Principal Accounting Officer)	February 26, 2010
/s/ DAVID E. COLLINS **David E. Collins**	Director	February 26, 2010
/s/ JOSEPH LACOB **Joseph Lacob**	Director	February 26, 2010
/s/ C. RAYMOND LARKIN **C. Raymond Larkin**	Director	February 26, 2010
/s/ GEORGE J. MORROW **George J. Morrow**	Director	February 26, 2010
/s/ DAVID C. NAGEL **David C. Nagel**	Director	February 26, 2010
/s/ GREG J. SANTORA **Greg J. Santora**	Director	February 26, 2010
/s/ WARREN S. THALER **Warren S. Thaler**	Director	February 26, 2010

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10.27	Stock Purchase Agreement dated as of the 16th day of August by and between Align Technology, Inc. and Danaher Corporation.	Form 10-Q	11/5/09		

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Exhibit Number	Description	Form	Date	Exhibit Number Incorporated by reference herein	Filed herewith
10.28††	Joint Development, Marketing and Sales Agreement entered in as of August 16, 2009 by and between Align Technology, Inc. and Ormco Corporation	Form 10-Q/A	02/24/2010		
21.1	Subsidiaries of Align Technology, Inc.				*
23.1	Consent of PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firm.				*
31.1	Certifications of Chief Executive Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2003.				*
31.2	Certifications of Chief Financial Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2003.				*
32	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2003.				*

† Management contract or compensatory plan or arrangement filed as an Exhibit to this form pursuant to Items 14(a) and 14(c) of Form 10-K.

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

Exhibit 21.1

Subsidiaries of Align Technology, Inc.

The registrant's principal subsidiaries as of December 31, 2009, are as follows:

- Align Technology De Costa Rica, SRL, Costa Rica
- Align Technology, B.V., The Netherlands
- Aligntech de Mexico, S. de R.L. de C.V.

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statement on Form S-8 (No. 333-55020, No.333-134477, No. 333-143319, No. 333-161054, No. 333-82874, No. 333-116912, and No. 333-125586) of Align Technology, Inc. of our report dated February 26, 2010, relating to the financial statements, financial statement schedule, and the effectiveness of internal control over financial reporting, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP
San Jose, California
February 26, 2010

Exhibit 31.1

CERTIFICATIONS

I, Thomas M. Prescott, certify that:

1. I have reviewed this annual report on Form 10-K of Align Technology, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 26, 2010

/s/ THOMAS M. PRESCOTT

Thomas M. Prescott
President and Chief Executive Officer

Exhibit 31.2

I, Kenneth B. Arola, certify that:

1. I have reviewed this annual report on Form 10-K of Align Technology, Inc.;

2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (c) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 26, 2010

/s/ KENNETH B. AROLA

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

Exhibit 32

906 Certification

CERTIFICATION OF CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER
PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2003

I, Thomas M. Prescott, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2003, that the Annual Report of Align Technology, Inc. on Form 10-K for the fiscal year ended December 31, 2009 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in this Form 10-K fairly presents in all material respects the financial condition and results of operations of Align Technology, Inc.

Date: February 26, 2010

By: /s/ THOMAS M. PRESCOTT
Name: **Thomas M. Prescott**
Title: ***President and Chief Executive Officer***

I, Kenneth B. Arola, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2003, that the Annual Report of Align Technology, Inc. on Form 10-K for the fiscal year ended December 31, 2009 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in this Form 10-K fairly presents in all material respects the financial condition and results of operations of Align Technology, Inc.

Date: February 26, 2010

By: /s/ KENNETH B. AROLA
Name: **Kenneth B. Arola**
Title: ***Chief Financial Officer and Vice President, Finance***