ALIGN TECHNOLOGY INC
Form 10-K
February 27, 2009

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# SECURITIES AND EXCHANGE COMMISSION

**Washington, D.C. 20549**

# FORM 10-K

**(Mark One)**

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

**For the fiscal year ended December 31, 2008**

**Or**

o **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 ý No o

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 o No ý

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

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. o

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

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

The aggregate market value of the registrant's common stock held by non-affiliates of the registrant was $601,665,751 as of June 30, 2008 based on the closing sale price of the registrant's common stock on the NASDAQ Global Market on such date. Shares held by persons who may be deemed affiliates have been excluded. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

On February 18, 2009, 66,055,143 shares of the registrant's common stock were outstanding.

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the registrant's definitive Proxy Statement relating to its 2009 Annual Stockholders' Meeting to be filed pursuant to Regulation 14A within 120 days after the registrant's fiscal year end of December 31, 2008 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, 2008**

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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, statements concerning our expectations regarding the expected 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 relocation of several customer facing organizations from our Santa Clara, California facility to our facility in Costa Rica, including the timing of such relocation, our expectation that our utilization rate will improve over time, our expectations regarding our average selling prices and gross profits in 2009, the expected timing of the completion of our transition from our reliance on a shelter service provider in Juarez, Mexico to a direct manufacturer of our product, our expectations regarding the continued growth of our international markets, our expectations regarding the impact of increased consumer marketing programs in Europe, our expectations that the decline in general economic conditions in 2009 may result in a decline in our product volumes and revenues compared to 2008, 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. Orthodontists and GPs must complete an Invisalign training course in order to provide the Invisalign treatment solution to their patients. The Invisalign system is sold in North America, Europe, Asia Pacific, Latin America and Japan. We use a distributor model for the sale of our products in parts of the Asia Pacific and Latin American region.

We were incorporated in Delaware in April 1997. Our headquarters are located at 881 Martin Avenue, Santa Clara, California 95050, and our telephone number is 408-470-1000.

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**Industry Background**

*Malocclusion*

Malocclusion, or the misalignment of teeth, is one of the most prevalent clinical dental conditions, affecting over 195 million individuals, or approximately 65% of the U.S. population. Approximately 2.1 million people annually elect treatment by orthodontists in the U.S. 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 cement 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. Because of the length of time between visits, the dental professional must tighten the braces to a degree sufficient to achieve sustained tooth movement during the interval. In a final visit, the dental professional removes each bracket and residual cement 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. In addition, dental professionals commonly charge a premium for lingual or ceramic alternatives. 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. Many adults associate braces with adolescence. As a result of these and other limitations, relatively few adults with malocclusion elect traditional orthodontic treatment annually.

*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.

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*Poor oral hygiene.* Braces compromise oral hygiene by making it more difficult to brush and floss. These problems can result in tooth decay and periodontal damage. 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, braces 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 people with malocclusion elect traditional orthodontic treatment. Accordingly, we believe there is a large unmet need for an orthodontic system that addresses these patient concerns. We also believe there is an unmet need among dental professionals for a treatment system that increases the predictability and efficiency of treatment and enhances practice profitability.

**The Align 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 digital treatment plans using proprietary software known as ClinCheck, and the manufacturing of customized Invisalign aligners.

*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. Manufacturing services are currently provided by International Manufacturing Solutions Operaciones, S.R.L., or IMS, a third party shelter services provider in Juarez, Mexico. On December 22, 2008, we notified IMS of our intention to terminate this shelter services arrangement effective April 2009. At that time, we will become a direct manufacturer of our clear aligners at the 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

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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 facilities 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 customized, 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 ClinCheck 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.

*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. IMS currently manufactures the molds and then uses these molds to fabricate the patient's aligners. As stated above, in April 2009, we will become a direct manufacturer of our clear aligners at the facility in Juarez, Mexico.

*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 custom-manufactured, thin, clear plastic, removable dental appliances that are 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. In certain cases, we provide an aligner-like template to the dental professionals to aid the placement of bonding attachments to the patient's teeth. Also, in cases where interproximal reduction, or IPR, is

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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. New 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.

*Invisalign Full.* Commercial sales of Invisalign Full commenced in the U.S. in July 1999. Our traditional, 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. In fiscal 2008, approximately 85% of our net revenues were generated by the sale of Invisalign Full.

*Invisalign Express.* In the third quarter of 2005, we launched Invisalign Express, 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.

*Retention.* In addition to our traditional single retainer product, in January 2008, we launched 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.

*Invisalign Teen.* In July 2008, we launched Invisalign Teen to meet the specific needs of the non-adult comprehensive or teen treatment market. Invisalign Teen includes features such as an aligner wear indicator to help gauge patient compliance and specially engineered aligner features to address lingual root control issues and 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.* In October 2008, we launched Invisalign Assist. Invisalign Assist is designed specifically for GPs who want an integrated approach to selecting, monitoring and finishing Invisalign cases. Intended to help newly-trained and low 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, new 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. We believe Invisalign Assist will help GPs increase their confidence in prescribing Invisalign treatment.

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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.

*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.

**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 treatment and likely outcomes.* ClinCheck enables dental professionals to preview a course of treatment and the likely 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.

*Begin using Invisalign with minimal additional training.* The biomechanical principles that underlie treatment with the Invisalign system are consistent with those of traditional orthodontics. Dental professionals can complete our initial training in one day. We provide additional clinical support following the initial training and encourage dental professionals to attend continuing education classes, seminars and workshops.

*Expanded patient base.* We believe that Invisalign has the potential to transform the practice of orthodontics. Currently, approximately 2.1 million people annually elect treatment by orthodontists in the U.S. As of December 31, 2008, our share of the 2.1 million case starts is approximately 3 percent. 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 abrasive than traditional braces.

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*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 tooth decay and periodontal damage during treatment, which may result from traditional 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.

*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.

**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 is generally a turn-around time of a month or more before the corresponding aligners are delivered. 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 occurred. 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**

Approximately 2.1 million people annually elect treatment by orthodontists in the U.S., of which approximately 1.2 million have mild to moderate malocclusion and are applicable to Invisalign our served market. Twenty-six percent of these patients, or approximately 300 thousand, have mature dentition (adults and older teens), with fully-erupted second molars and substantially completed jaw growth. Seventy-four percent, or approximately 850 thousand, have erupting dentition (non-adult comprehensive, or younger teens), with partially-erupted second molars, cuspid and second bicuspid teeth. As of December 31, 2008, our share of the 2.1 million case starts is approximately 3% and approximately 6% of the 1.2 million patients of our served market.

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

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2008, we now offer a product designed to meet the needs of the non-adult comprehensive, or younger teen, treatment market. Even though we have not previously marketed our product to treat younger patients, approximately 18% of our total case starts since 2007 were with individuals younger than 19. Launching 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.

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, 2008, approximately 944,000 patients 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 21%, 17% and 16% of our net revenues in 2008, 2007 and 2006, respectively. A geographic breakdown of our net revenues is summarized in Note 17 "Segments and Geographic Information" in the Notes to our Consolidated Financial Statements. We operate as one reportable segment  the design, development, manufacturing and marketing of Invisalign, a proprietary method for treating malocclusion, or the misalignment of teeth.

No single customer accounted for 10% or more of our total net revenues in 2008, 2007 and 2006.

**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 four key objectives: driving product innovation, enhancing the customer experience, generating consumer demand and expanding our international markets.

*Product innovation and enhancements to existing products.* We believe that product performance and innovation is a cornerstone to our future long-term goal to drive and sustain product adoption. Until 2008, the Invisalign system was a single offering used by our primary channels  GPs and orthodontists  each with distinct and separate needs. In 2008, we launched additional products to better meet those distinct 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, in July 2008, we announced the release of Invisalign Teen, predominantly marketed to the orthodontist. In October 2008, we announced the release of Invisalign Assist, predominantly marketed to the GP.

With the introduction of Invisalign Teen, our Invisalign product family now includes a product designed to meet the specific needs of the non-adult comprehensive or younger teen market. Invisalign Teen features include an aligner wear indicator to help gauge patient compliance and specially engineered aligner features to address the natural eruption of key teeth and lingual root control. Predominantly marketed to orthodontists who treat the vast majority of malocclusion in teen patients, these features make it easier and more efficient for orthodontists to treat those younger patients. 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. We expect that orthodontists will adopt Invisalign Teen slowly, after they experience multiple successful treatment outcomes. As a result, we anticipate that Invisalign Teen volume may increase gradually and will not constitute a significant portion of our total product mix in the near-term.

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Our most recently launched product, Invisalign Assist, is intended to help newly-trained and low 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 addition, GPs can plan and submit cases efficiently, manage appointments with suggested tasks, and receive batch shipments of aligners based on treatment progress. We believe Invisalign Assist will help GPs increase their confidence in prescribing Invisalign treatment.

We believe continuing to introduce new products and product features as well as enhancing the user experience will keep us at the forefront of the market and increase adoption of Invisalign. The recent launch of Invisalign Teen and Invisalign Assist and other future products will rely on new features, tools and delivery options to meet specific clinical demands while providing a family of end-to-end solutions for our customers. Enhanced product performance and innovation should continue to drive the adoption and frequency of use (what we call utilization). Although we believe new product introduction to be a cornerstone to our future long-term growth, we expect that adoption of these new products will increase gradually over a number of years.

*Enhancing the customer experience.* 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 are focused on improving our pre-selection process in order to attract new doctors that are motivated to become Invisalign providers and committed to making Invisalign a key part of their practices and strengthening our training programs in order to increase the rate that these newly trained customers submit Invisalign cases, as well as increase the rate that they move up the adoption curve to ultimately become leading Invisalign providers, or what we call promoters.

*Improving Training Programs.* Increasing the number of Invisalign trained doctors and ensuring that these 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 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. 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.

*Moving from Invisalign provider to a leading Invisalign provider.* Once a doctor is trained, our goal is to assist the doctor to move up the adoption curve to ultimately become a leading Invisalign provider, or a promoter. In order to increase the number of Invisalign promoters, we provide additional services to help our customers increase their confidence in using the Invisalign system through continuing education and clinical support as well as improving their practice management skills. In early 2008, we announced the introduction of 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. Lastly, as trained Invisalign

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providers grow their case starts with Invisalign, programs such as the Advantage Program provide tiered benefits including volume rebates, dedicated clinical support and a premium website position on the Invisalign Doctor Locator website to those leading providers. By participating in these programs and the various events and educational offerings, we believe that our customers will emerge with a better understanding of the product and its applicability, and with a greater aptitude for starting and finishing Invisalign cases successfully.

*Consumer demand generation for Invisalign.* 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, we will for the first time direct our communication efforts directly to teens and their parents. Despite the continuing challenges in the U.S. economy and weak consumer spending, 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 through our traditional TV advertising, as well as digital online media. In 2009, we will focus our efforts on the introduction of a new public relations program for Invisalign Teen intended to access print, TV and online media. We also have a teen specific website and will increasingly leverage widgets, social media and blogs to directly target teens.

*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 domestic market, our objective internationally is to increase the number of doctors that are motivated to becoming an Invisalign provider and committed to making Invisalign a key part of their practices. Through December 31, 2008, we have trained over 14,000 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 October 2008, we launched Invisalign Express in Europe expanding our international product offerings. In Europe, the vast majority of orthodontic case starts are children and teens. With the introduction of Invisalign Teen in Europe, planned for mid-2009, 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 that was first launched in March 2007. 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. 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 2008, our international sales increased from 17% of net revenues to 21% of net revenues, an increase of approximately 34%.

**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 manufacturing facilities are located outside of the U.S, in San Jose, Costa Rica and Juarez, Mexico. As of

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December 31, 2008, our manufacturing and operations staff in the U.S. and Costa Rica consisted of 747 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 treatment plan by the dental professional, these plans are then transmitted electronically to Juarez, Mexico. These digital files form the basis of ClinCheck and 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 currently conducted by International Manufacturing Solutions Operaciones, S.R.L., or IMS, a third party shelter services provider in Juarez, Mexico. On December 22, 2008, we notified IMS of our intention to terminate IMS' shelter services arrangement effective April 2009. At that time, we will become a direct manufacturer of our clear aligners at the facility in Juarez, Mexico. Upon the completion of this transition, we will directly employ approximately 500 people in Mexico, each of whom is currently employed by IMS. 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 and of the Council of Canada. 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

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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 Invisalign's benefits to dental professionals through our training programs, mail campaigns, trade shows, trade journals and print media, and to consumers through a nationwide advertising campaign. 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. In order to serve anticipated demand, we continue to train a broad base of dental professionals.

*Professional Marketing*

Our sales and support staff has been engaged in marketing Invisalign to orthodontists since July 1999. In 2001, we began marketing Invisalign to GPs in our North American market. As of December 31, 2008 our North American sales organization consisted of 161 people, of which 134 were direct sales representatives and 27 were sales administration and management. Internationally, we had 41 people engaged in sales and sales support as of December 31, 2008. We continually evaluate cost effective ways to support our customers in smaller markets. For instance, during 2007, we transitioned the sales of our products in part of the Asia Pacific and Latin American regions to a distributor model. 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.

We provide training, marketing and clinical support to orthodontists and GPs in the U.S. and Canada, which we consider our North American market, and internationally. As of December 31, 2008, we had trained 55,510 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 8,670 orthodontists and 32,660 GPs cumulatively through the end of 2008.

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.

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*Consumer Marketing*

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

- an orthodontist;
- a GP;
- consumer marketing and advertising;
- our website, which can be accessed at either *www.invisalign.com* or *www.aligntech.com;*
- direct-to-consumer mail advertising and public relations efforts; and
- other Invisalign patients.

In 2009, we expect higher marketing spending in Europe with a focus on consumer advertising, including television and print media to raise the profile of Invisalign and drive more consumers to our most experienced doctors. We will continue to incur additional costs related to commercialization and launch of new products to market in the United States and Europe.

**Research and Development**

Our research and development effort is focused on extending the range of dental 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 $26.2 million for 2008, $25.7 million for 2007, and $18.5 million for 2006.

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, 2008, we had 118 issued U.S. patents, 181 pending U.S. patent applications, and numerous foreign issued patents, as well as 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."

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**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. 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 Company, 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). See *Item 3 "Legal Proceedings"* for a summary of our litigation with Ormco. 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.

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**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. Our aligners are currently manufactured by IMS, a third party shelter services provider based in Juarez, Mexico. IMS is registered with the FDA as a medical device manufacturer and is certified to ISO 13485:2003 under Align's quality management system. We have also ensured that our quality system procedures and processes have been implemented at IMS to comply with the FDA's Quality Systems standards. IMS has dedicated an area in its facilities and trained personnel in the manufacture and distribution of Invisalign. We and IMS 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. On December 22, 2008, we notified IMS of our intention to terminate IMS' shelter services arrangement effective April 2009. At that time, we will become a direct manufacturer of our clear aligners at the facility in Juarez, Mexico.

If the FDA determines that we or IMS 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

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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, 2008, we had 1,394 employees, including 747 in manufacturing and operations, 339 in sales and marketing, 137 in research and development and 171 in general and administrative functions. We had 503 employees in North America, 721 employees in Costa Rica, 160 employees in Europe 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*.

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**Executive Officers of the Registrant**

The following table sets forth certain information regarding our executive officers as of February 26, 2009:

| Name | Age | Position |
|---|---|---|
| Thomas M. Prescott | 53 | President and Chief Executive Officer |
| Kenneth B. Arola | 53 | Vice President, Finance and Chief Financial Officer |
| Dana Cambra | 51 | Vice President, Research & Development and Information Technology |
| Dan S. Ellis | 57 | Vice President, North American Sales |
| Roger E. George | 43 | Vice President, Legal and Corporate Affairs General Counsel and Corporate Secretary |
| Len M. Hedge | 51 | Senior Vice President, Business Operations |
| Gil Laks | 43 | Vice President, International |
| Emory Wright | 39 | 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 Interventional Rhythm Management, 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

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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.

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

Although we maintained profitability in 2008, 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, 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;

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;

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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 as a result of the introduction of new products such as Invisalign Assist and Invisalign Teen;

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.

**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 a decline 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 adoption of Invisalign at a lower rate than we expect, as well as the risk related to declining average selling prices are described more fully below.

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*Consumers may not adopt Invisalign as rapidly as we anticipate due to a variety of factors including a continued decline 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 both 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. 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.*

Our success depends upon increasing acceptance and frequency of use of the Invisalign system by dental professionals (what we refer to as utilization). Invisalign requires orthodontists, GPs and their staff to undergo special training and learn to interact with patients in new ways. Increasing adoption and cumulative use by orthodontists and GPs will depend on factors such as the capability, safety, efficacy, ease of use, price, quality and reliability of our products, our ability to provide effective sales support, training and service and the availability of competing products, technologies and alternative treatments. In addition, unanticipated poor clinical performance of Invisalign could result in significant adverse publicity and, consequently, reduced acceptance by dental professionals. Also 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. In addition, we provide volume based discount programs to our doctors. If we are to introduce any price reductions or expand our discount programs in the future or if participation in these programs increases, our revenues, gross margin and net profits (losses) may be adversely affected. 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 as a result 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.

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**We may experience unexpected problems and expenses associated with the phased-relocation of our customer facing organizations to Costa Rica.**

In October 2008, we announced a restructuring plan to increase efficiencies across the organization and lower our overall cost structure. In addition to headcount reduction, the restructuring plan included the phased-relocation of our customer care, accounts receivable, credit and collections and customer event registration organizations currently located in Santa Clara, California, to our facility in Costa Rica. We expect this relocation to be completed by the end of July 2009. This relocation is accompanied by a number of risks and uncertainties that may affect our results of operations and statement of cash flows, including:

- failure to successfully coordinate and phase the relocation of these customer facing organizations may cause our customers to experience decrease in service levels;
- the relocation may absorb significant management and key employee attention and resources that would otherwise be available for the ongoing business operations;
- failure to retain key employees who possess specific knowledge or expertise and upon whom we are depending upon for the timely and successful transition to Costa Rica; and
- difficulties in hiring employees in Costa Rica with the necessary skills to perform these customer facing functions.

If any of these risks materialize in the future, our operating results, statement of operations and cash flows may be adversely affected.

**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. 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

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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 the 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 October 2008, we announced the phased-consolidation of our customer-care, accounts receivable, credit and collections and customer event registration organizations, which are currently located in Santa Clara, California, to our facility in Costa Rica. We expect this relocation to be completed by the end of July 2009. Our increasing 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;
- 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.

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**We currently are transitioning from reliance on a shelter service arrangement to become a direct manufacturer of our products. If we fail to successfully manage this transition, our business may be harmed.**

We currently rely on IMS, a third party shelter services provider located in Juarez, Mexico, for order acquisition, to fabricate aligner molds as well as finished aligners and to ship the completed product to customers. On December 22, 2008, we announced the termination of our shelter services arrangement with IMS effective April 1, 2009. In addition to the risks related to international operations described in the risk factor above, any difficulties encountered by us with respect to a transition from a third party shelter services arrangement to manufacture, including difficulties hiring and retaining qualified personnel could disrupt our ability to deliver our products in a timely manner which could harm our business. In addition, any delay in completing the transition could result in increased transition costs, which could decrease the amount of expected savings.

**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, ClinCheck setup 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. We are also transitioning our customer facing operations from Santa Clara, California to Costa Rica. In addition, 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 or manufacture and ship our aligners could be compromised which could result in our customers experiencing a significant delay in receiving their completed aligners. 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 Company 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

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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, 2008, we had 118 issued U.S. patents, 181 pending U.S. patent applications, and 47 issued foreign patents, and 142 pending foreign patent applications.

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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. During fiscal 2005 and 2006, requests were filed with the United States Patent and Trademark Office ("USPTO") by a San Francisco, California law firm, acting on behalf of an unnamed party and in some instances acting on behalf of OrthoClear, requesting re-examination of a number of our patents. 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. Management does not believe that the ultimate outcome of these other legal proceedings and claims will have a material adverse effect on our financial position or results of operations. In addition, 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

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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.

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**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, 2008, our North American sales organization consisted of 161 people, of which 134 were direct sales representatives and 27 were sales administration and regional sales management. Internationally, we had 41 people engaged in sales and sales support as of December 31, 2008. 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 or the failure of IMS 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.

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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. 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.

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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.

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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. In the past, class action litigation has often been brought against the issuing company following periods of volatility in the market price of a company's securities. If a securities class action suit is filed against us in the future, we would incur substantial legal fees, and our management's attention and resources would 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

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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 addition, we have negotiated tax incentives with the Costa Rica Ministry of Foreign Trade, an agency of the Government of Costa Rica. Under these incentives, all of the income we earn in Costa Rica during these eight to 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 2010. The Costa Rica corporate income tax rate that would apply, absent the incentives, is 30% for 2009. As a result of these incentives, income taxes decreased by $1.3 million in 2008. 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

Our headquarters are located in Santa Clara, California. We lease approximately 127,000 square feet of space where we house our research and development and administrative personnel. We lease our Santa Clara facilities under four leases, which expire in June 2010. The combined monthly rent for the Santa Clara facilities is approximately $64,000. Commencing July 1, 2005 and continuing on the first day of each calendar month thereafter, $11,000 will be deducted from the $1.3 million security deposit previously paid by us to the lessor and such amount will be applied against the monthly base rent for the Santa Clara facilities.

We operate 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 $78,000. We renewed the lease in March 2008 for an additional five year term, which commenced in October 2008 and expires in September 2013. Our European headquarters are located in Amsterdam, The Netherlands. On August 3, 2007, we entered into an amendment to the original lease agreement to expand the 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. We may also terminate this lease in June 2012 for a fee of $125,000. The monthly rent for the Amsterdam facility is approximately $48,000.

On December 22, 2008, we notified IMS of our intention to terminate IMS' shelter services arrangement effective April 2009. At that time, we will become a direct manufacturer of our clear

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aligners at the facility in Juarez, Mexico and we will also assume IMS' lease with its landlord. The monthly rent for this 68,000 square foot facility is $30,000 and the lease expires in July 2013.

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

***Ormco***

On January 6, 2003, Ormco Corporation ("Ormco"), a division of Sybron Dental Specialties (a Danaher Corporation subsidiary), filed suit against us in the United States District Court for the Central District, Orange County Division, asserting infringement of U.S. Patent Nos. 5,447,432, 5,683,243 and 6,244,861. The complaint sought unspecified monetary damages and injunctive relief. Also in 2003, we counterclaimed for infringement of our U.S. Patent No. 6,398,548, seeking unspecified monetary damages and injunctive relief. Ormco filed a first amended complaint for infringement of U.S. Patent No. 6,616,444 and we filed an answer to Ormco's first amended complaint and a counterclaim for invalidity and non-infringement of U.S. Patent No. 6,616,444 and for infringement of U.S. Patent No. 6,554,611.

In connection with these claims, in 2004, the Court granted five motions for summary judgment that we filed. First, the Court granted our motion for summary judgment of non-infringement, finding that our Invisalign system does not infringe any of the asserted Ormco patents (5,447,432, 5,683,243, 6,244,861 and 6,616,444). Second, the Court granted in part our motion for summary judgment of infringement, finding that Ormco and its subsidiary, Allesee Orthodontic Appliances, Inc. ("AOA") infringe certain, but not all, claims of our patents Nos. 6,398,548 and 6,554,611 through the manufacture and sale of Red, White & Blue appliances. Third, the Court granted our motion for summary judgment of invalidity of Ormco's asserted patents claims (5,447,432, 5,683,243, 6,244,861 and 6,616,444). As noted above, the Court earlier found that we do not infringe these patents. In addition, the Court also denied Ormco's and AOA's motion for summary judgment seeking a finding of invalidity of our asserted patent claims (6,398,548 and 6,554,611). Fourth, the Court granted our summary judgment motion that our asserted patent claims are not invalid based on the evidence currently before the Court. Although the Court granted that motion, it reopened discovery on two additional invalidity arguments Ormco and AOA asserted. Fifth, the Court also granted our summary judgment motion that our patents are not unenforceable and granted Ormco's and AOA's summary judgment motion that Ormco and AOA did not willfully infringe our patents.

On February 24, 2005, the Court, on further summary judgment, confirmed the validity of all of the asserted claims of our 6,554,611 patent and two of the asserted claims of our 6,398,548 patent. The Court also found certain claims of our 6,398,548 patent to be invalid in view of prior use evidence. On May 26, 2005, the Court issued a permanent injunction (the "Permanent Injunction") to enjoin Ormco and AOA from further infringement of Claims 10 and 17 of our 6,398,548 patent and Claims 1-3 and 7 of our 6,554,611 patent. On May 31, 2005, Ormco and AOA filed a notice of appeal with the Federal Circuit from the Permanent Injunction.

There have been two appeals. After the Permanent Injunction was entered, Ormco and AOA appealed that injunction and the orders of the District Court on summary judgment on which the injunction was based. In April 2006, the U.S. Court of Appeals for the Federal Circuit ("CAFC") issued a ruling declaring two out of a total of seventy-one claims in our US Patent No. 6,398,548 and four out of a total of ten claims in US Patent No. 6,554,611 to be invalid as "obvious." The CAFC's decision reverses the California District Court summary judgment order of validity.

The 6,398,548 patent consists of 71 claims; only claims 10 and 17 were at issue in the first appeal and CAFC ruling. These two claims are directed to a system of appliances and method of repositioning

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teeth from an initial to a final tooth arrangement where at least some of the appliances are marked to show order of use. These claims contain further limitations requiring instructions as to the order in which the appliances are to be worn and use of the appliances in intervals of 2-20 days.

The 6,554,611 patent consists of ten claims directed to a system for repositioning teeth that includes one or more intermediate appliances and a final appliance, provided in a single package, as well as instructions which set forth the order in which the appliances are to be worn. The CAFC's ruling pertains only to claims 1, 2, 3 and 7 in the patent.

The second appeal was from the final judgment. Ormco appealed the ruling of the District Court that 92 claims in four of its patents are not infringed by us and that the asserted claims are invalid. We appealed the ruling of the District Court that certain claims of our 6,398,548 patent which were found to be infringed by Ormco's and AOA's Red, White & Blue appliances were invalid. The CAFC issued a ruling on August 24, 2007, affirming the District Court's ruling that 86 out of 92 claims in Ormco's 5,447,432, 5,683,243, 6,244,861 and 6,616,444 patents are invalid and not infringed by us. The CAFC reversed the District Court's non-infringement and invalidity rulings on six claims in Ormco's 6,616,444 patent. Ormco filed a petition for review with the U.S. Supreme Court with respect to the portion of the CAFC's opinion that affirmed the District Court's ruling of non-infringement and non-enablement of Ormco's 86 claims. The Supreme Court denied Ormco's petition, and the case on the six claims in Ormco's 6,616,444 patent were returned to the District Court for a determination of validity and infringement of those claims. The District Court issued orders construing the claim terms at issue and granting our motion to amend our answer and counterclaim to assert Ormco's 6,616,444 patent is unenforceable due to inequitable conduct. The parties are currently completing fact discovery.

On February 25, 2009, the District Court issued rulings on various Summary Judgment and expert related motions. In summary, the District Court granted one of Ormco's motions on one theory of infringement and granted our motion on two theories of non-infringement. Our invalidity argument supported by over fifty prior art references was unaffected. The District Court also ruled that one of our inequitable conduct theories should be resolved at trial. A finding of inequitable conduct at trial could render the six claims at issue and possibly the family of Ormco patents related to the 6,616,444 patent unenforceable.

Trial on liability issues is scheduled for June 2, 2009. Despite the District Court's ruling of infringement on one of Ormco's theories, if the jury finds Ormco's six claims to be invalid or unenforceable, there can be no liability for infringement. We intend to vigorously pursue our invalidity and inequitable conduct counterclaims at trial.

***Other matters***

*USPTO*

During fiscal 2005 and 2006, requests were filed with the United States Patent and Trademark Office ("USPTO") by a San Francisco, California, law firm, acting on behalf of an unnamed party, requesting Ex Parte re-examination of our patents. A Reexamination Certificate has been issued regarding the 6,309,215, 6,398,548, 6,705,863, 6,217,325, 6,722,880, 6,318,994 and 5,975,893 patents and

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therefore these patents are no longer in reexamination. We received an Action Closing Prosecution on the 6,685,469 patent. The status of the 6,629,840 patent is as follows:

| Patent No. | Request for Reexamination Granted? | Initial Office Actions Received? | Status |
|---|---|---|---|
| 6,629,840 | Yes | Yes | In this initial Office Action dated June 13, 2006, the examiners confirmed the validity of eight of the eleven claims of U.S. Patent No. 6,629,840 (the '840 patent) without amendment and preliminarily rejected the remaining claims of the patents. The non-final initial Office Action presented us with the first opportunity to respond to the USPTO's review and interpretation of the prior art. On September 13, 2006, we submitted a response to the initial Office Action. A petition seeking a waiver was filed on February 15, 2007 and was granted on April 17, 2007, granting a single interview. The interview was held on May 22, 2007, and an Interview Summary was filed with the USPTO on June 21, 2007. We are awaiting further action by the USPTO. |

As part of the OrthoClear Agreement, OrthoClear agreed to take no further action with respect to the Inter Parte Requests, including the 6,629,840 patent.

*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.

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 2008.

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## PART II

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

*Price Range of Common Stock*

Our common stock is 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, 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 |
| Year Ended December 31, 2007: | | |
| Fourth quarter | $28.70 | $14.69 |
| Third quarter | $27.69 | $22.55 |
| Second quarter | $24.89 | $15.74 |
| First quarter | $17.88 | $13.35 |

On February 18, 2009, the closing price of our common stock on the NASDAQ Global Market was $8.03 per share. As of February 18, 2009 there were approximately 184 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".*

*Issuer Purchases of Equity Securities*

Following is a summary of stock repurchases for the three months ended December 31, 2008 (1):

| Period | Total Number of Shares Repurchased | Average Price Paid per Share | Total Number of Shares Repurchased as Part of Publicly Announced Program | Approximate Dollar Value of Shares that May Yet Be Repurchased Under the Program |
|---|---|---|---|---|
| November 1, 2008 to November 30, 2008 | 1,064,021 | $ 6.83 | 1,064,021 | $ 3,431,000 |
| December 1, 2008 to December 31, 2008 | 477,500 | $ 7.22 | 477,500 | $ |
| Total | 1,541,521 | $ 6.95 | 1,541,521 | |

In April 2008, our Board of Directors approved a common stock repurchase program authorizing management to purchase up to $50.0 million of our outstanding shares of common stock. Purchases under the program were made, from time to time, in the open market. As of December 31, 2008, we had repurchased approximately 4.7 million shares of common stock at an average price of $10.76 per

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share. In December 2008, we completed the stock repurchase program, and all repurchased shares have been retired.

(1) All shares were repurchased pursuant to the publicly announced repurchase program described above.

*Performance Graph*

*Notwithstanding any statement to the contrary in any of our previous or future filings with the SEC, the following information relating to the price performance of our common stock shall not be deemed "filed" with the SEC or "Soliciting Material" under the Securities Exchange Act of 1934, as amended, or subject to Regulation 14A or 14C, or to liabilities of Section 18 of the Exchange Act except to the extent we specifically request that such information be treated as soliciting material or to the extent we specifically incorporate this information by reference.*

The 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. and a peer group that reflects the labor market in which we compete. The comparison for each of the periods assumes that $100 was invested on January 1, 2003 in our common stock, the stocks in the NASDAQ Stock Market US Index, and the stocks in the peer group index, and that all dividends were reinvested.

**COMPARISON OF 5 YEAR CUMULATIVE TOTAL RETURN***

Among Align Technology, Inc., The NASDAQ Composite Index
And A Peer Group

*$100 invested on 12/31/03 in stock & index-including reinvestment of dividends.
Fiscal year ending December 31.

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Our peer group consists of 13 companies that are predominantly (although not exclusively) located in the San Francisco Bay Area, the geographic location in which we operate and compete for executive talent. In addition to geographic location, these companies were chosen using the following principles:

- companies that are close industry competitors;
- medical device companies that are generally between 0.5 to 2.5 times Align's revenue (with Align at approximately the median); and
- technology companies with similar growth potential and technology development needs for software and enterprise system designers.

The following companies made up the peer group for 2008:

| | |
|---|---|
| Advanced Medical Optics Inc.* | Natus Medical Inc. |
| American Medical Systems Holdings Inc. | Nektar Therapeutics |
| Ansys Inc. | Nuvasive Inc. |
| ArthroCare Corp. | Sirona Dental Systems Inc. |
| Integra Lifesciences Holdings Corp. | Sonosite |
| Intuitive Surgical Inc. | Vital Images Inc. |
| Mentor Corp.* | |

* Each of these companies was acquired in 2008 and will no longer form part of our peer group as public information for these companies are no longer publicly available.

**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, 2008. 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 50 to 78 and "Management's Discussion and Analysis of Financial Condition and Results of Operations" beginning on page 35. We have derived the statement of operations data for the years ended December 31, 2008, 2007 and 2006 and the balance sheet data as of December 31, 2008 and 2007 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, 2005 and 2004 and the balance sheet data as of December 31, 2006, 2005 and 2004 were derived from the consolidated audited financial statements that are not included in this Annual Report on Form 10-K.

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**SELECTED CONSOLIDATED FINANCIAL DATA**

**(in thousands, except per share data)**

| | Years Ended December 31, | | | | |
|---|---|---|---|---|---|
| | **2008** | **2007** | **2006** | **2005** | **2004** |
| **Consolidated Statement of Operations Data:** | | | | | |
| Net revenues | $303,976 | $284,332 | $206,354 | $207,125 | $172,830 |
| Gross profit | $225,126 | $209,297 | $141,579 | $143,341 | $115,304 |
| Profit (loss) from operations(1)(2) | 15,514 | 33,855 | (37,536) | 2,446 | 9,765 |
| Other income (expense), net | 1,562 | 3,095 | 3,401 | 283 | (3) |
| Net profit (loss) before provision for (benefit from) income taxes(1)(2) | 17,076 | 36,950 | (34,135) | 2,729 | 9,762 |
| Provision for (benefit from) income taxes | (62,911) | 1,226 | 828 | 1,316 | 994 |
| Net profit (loss)(1)(2)(3) | $ 79,987 | $ 35,724 | $ (34,963) | $ 1,413 | $ 8,768 |
| Net profit (loss) per share | | | | | |
| Basic | $ 1.20 | $ 0.53 | $ (0.55) | $ 0.02 | $ 0.15 |
| Diluted | $ 1.18 | $ 0.50 | $ (0.55) | $ 0.02 | $ 0.14 |
| Shares used in computing net profit (loss) per share: | | | | | |
| Basic | 66,812 | 67,176 | 63,246 | 61,644 | 59,963 |
| Diluted | 68,064 | 71,444 | 63,246 | 63,152 | 64,089 |

| | December 31, | | | | |
|---|---|---|---|---|---|
| | **2008** | **2007** | **2006** | **2005** | **2004** |
| **Consolidated Balance Sheet Data:** | | | | | |
| Working capital | $117,335 | $123,058 | $ 40,306 | $ 62,978 | $ 61,886 |
| Total assets | 279,341 | 222,761 | 151,558 | 142,110 | 130,712 |
| Total long-term liabilities | 229 | 148 | 219 | 64 | 25 |
| Stockholders' equity | $218,540 | $161,154 | $ 83,556 | $ 93,438 | $ 85,739 |

(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 18 "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 13 "Income Taxes" in the Notes to Consolidated Financial Statements* for additional information.

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

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

**Overview**

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, which was launched in July 2008, is designed to meet the specific needs of the non-adult comprehensive or teen treatment market. Invisalign Assist, launched in October 2008, is intended to help newly-trained and low 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, 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 during the remainder of 2009 and beyond.

*Impact on consumer spending due to a decline 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 as well as an uncertain economic outlook have adversely affected consumer spending habits. As a result of the decline in general economic conditions, we expect that our product volumes and revenues may decline in 2009 compared to 2008. In addition, the decline in general economic conditions may further have the impact of decreasing the number of orthodontic case starts overall.

*Utilization Rates.* Our goal is to establish Invisalign as the standard method for treating malocclusion ultimately driving increased product adoption and frequency of use by dental

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professionals, or utilization. Our quarterly utilization rates from the years ended December 31, 2008, 2007 and 2006 are as follows:

**Utilization Rates***

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

As set forth in the chart above, year over year utilization rates declined slightly for our domestic channel in each quarter of 2008 compared to the same quarter in 2007. We believe that the continued economic slowdown has negatively impacted many of our North America customers. International utilization rates for the same periods, however, increased slightly.

*Impact of new products on deferred revenue.* We launched three new products in 2008: Vivera retainers in January 2008, Invisalign Teen in July 2008, and Invisalign Assist in October 2008. As a result of and depending upon customer adoption of these new products, we expect our mix of products to begin shifting gradually. Key features of these new products include staged delivery of retainers with Vivera, up to six free individual replacement aligners with Invisalign Teen and staged delivery of aligners with Invisalign Assist. As a result of these features, these new products will have a significantly higher amount of deferred revenue as a percentage of their average selling prices compared to Invisalign Full.

The Vivera retainer includes four shipments per year, and revenue is deferred upon the first shipment and then recognized as each shipment occurs. Revenue for the six replacement aligners included in Invisalign Teen will be deferred based on their fair market value until the earlier of the replacement aligners being used or until the case is completed. For Invisalign Assist, when the progress tracking feature is selected, aligners are shipped to the dental professional after every nine stages. As a result, for these cases, revenue will be deferred upon the first staged shipment and will be recognized upon shipment of the final staged shipment. In addition, included in the price of Invisalign Full treatment, we offer case refinement, which is a finishing tool used to adjust a patient's teeth to the desired final position. Invisalign Teen, Invisalign Assist, and Invisalign Full include a deferral for case refinement. As these new products increase as a percentage of our total case volume, deferred revenue on our balance sheet will increase.

*Reliance on international manufacturing operations.* Our manufacturing efficiency has been and will continue to be an important factor in our future profitability. Currently, two of our key production steps are performed in operations located outside of the U.S. At our facility in Costa Rica, dental technicians use a sophisticated, internally developed computer-modeling program to prepare digital treatment plans. We currently rely on IMS, a third party shelter services provider located in Juarez, Mexico, for order acquisition, to fabricate aligner molds as well as finished

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aligners and to ship the completed product to customers. On December 22, 2008, we notified IMS of our intention to terminate this shelter services arrangement effective in April 2009. At that time, we will become a direct manufacturer of our clear aligners at the facility in Juarez, Mexico. Our success will depend in part on the efforts and abilities of management to effectively manage these international operations, including any difficulties encountered by us with respect to a transition from a third party shelter services arrangement to a direct manufacturer, including difficulties hiring and retaining qualified personnel. If our management fails in any of these respects, we could experience production delays and lost or delayed revenue. In addition, even if we have case submissions, we may not have a sufficient number of trained dental technicians in Costa Rica to create the ClinCheck treatments, or if we are unable to ship our product to our customers on a timely basis, our revenue will be delayed or lost, which will cause our operating results to fluctuate. *See Part I, Item 1A "Risk Factors" for risks related to our international operations as well as risks related to transitioning from reliance on shelter service arrangement to independent manufacturer.*

*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. These seasonal trends have caused and will likely 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.

*Restructurings.* During 2008, we announced restructuring plans in July and October to increase efficiencies across the organization and lower the overall cost structure. In July 2008, we implemented a restructuring plan to reduce our full time headcount by 67 employees including initiating 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 as we create a new shared services organization in our existing Costa Rica facility that will consolidate customer care, accounts receivable, credit and collections, and customer event registration organizations, which are currently located in Santa Clara, California. We anticipate phasing the relocation to Costa Rica in an attempt to minimize disruptions to customer service levels and expect the relocation to be completed by the end of July 2009. These actions resulted in a restructuring charge of approximately $6.2 million in 2008, and we expect to incur additional restructuring charges of approximately $1.8 million over the first half of 2009. We expect to reinvest the annualized savings of these two restructurings in the execution of our key strategic initiatives. *See Part I, Item 1A "Risk Factors" for risks related to the October restructuring, including the phased-relocation of our customer facing operations to Costa Rica.*

*Review of our investment portfolio and policies.* Our cash equivalent and short-term investment portfolio as of the date of this Form 10-K consisted of U.S. government notes and bonds, corporate bonds and certificates of deposits, agency bonds and discount notes and commercial paper. We follow an established investment policy and set of guidelines to monitor, manage and

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limit our exposure to interest rate, liquidity and credit risk. The policy sets forth credit quality standards and limits our exposure to any one issuer, as well as our maximum exposure to various asset classes. As a result of current adverse financial market conditions, investments in some financial instruments, such as structured investment vehicles, sub-prime mortgage-backed securities and collateralized debt obligations, may pose risks arising from liquidity and credit concerns. As of the date of this Form 10-K, we had no direct holdings in these categories of investments and our indirect exposure to these financial instruments through our holdings in money market mutual funds was immaterial. As of the date of this Form 10-K, we had no impairment charge associated with our short-term investment portfolio relating to such adverse financial market conditions. 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. See *Part I, Item 1A "Risk Factors" for risks related to global financial and securities markets.*

Our short-term marketable securities as of December 31, 2008 are as follows (in thousands):

| 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 |

Our long-term marketable securities as of December 31, 2008 are as follows (in thousands):

| September 30, 2008 | Amortized Costs | Gross Unrealized Gains | Gross Unrealized Losses | Fair Value |
|---|---|---|---|---|
| Agency bonds | $ 1,000 | $ 1 | | $ 1,001 |
| Corporate bonds | 1,897 | 0 | (35) | 1,862 |
| Total | 2,897 | 1 | (35) | 2,863 |

*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.

*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.

*Stock-based compensation.* We implemented Statement of Financial Accounting Standards ("FAS") No. 123 (revised 2004), "Share-based Payment" ("FAS 123R") in 2006, and we expect stock-based compensation to increase until at least 2010, which corresponds to our standard 4-year vesting term. Thereafter, new grants will be expensed over the vesting period, however, this expense may be offset by fully vested grants that are no longer expensed. For the years

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ended December 31, 2008, 2007 and 2006, stock-based compensation expense recognized in accordance with FAS 123R is as follows (in thousands):

| | Year Ended December 31, 2008 | | Year Ended December 31, 2007 | | Year Ended December 31, 2006 | |
|---|---|---|---|---|---|---|
| | Stock-based Compensation | % of net revenues | Stock-based Compensation | % of net revenues | Stock-based Compensation | % of net revenues |
| Cost of revenues | $ 1,753 | 0.6% | $ 994 | 0.4% | $ 700 | 0.3% |
| Sales and marketing | 5,289 | 1.7% | 4,225 | 1.5% | 2,862 | 1.4% |
| General and administrative | 8,011 | 2.6% | 5,443 | 1.9% | 4,054 | 2.0% |
| Research and development | 2,004 | 0.7% | 1,549 | 0.5% | 1,294 | 0.6% |
| Total stock-based compensation expense | $ 17,057 | 5.6% | $ 12,211 | 4.3% | $ 8,910 | 4.3% |

**Results of Operations**

**Comparison of Years Ended December 31, 2008, 2007 and 2006:**

*Net revenues:*

Invisalign product revenues by channel and other revenues, which represent training and sales of ancillary products for the years ended December 31, 2008, 2007 and 2006, are as follows:

| | Years Ended December 31, | | | | | | |
|---|---|---|---|---|---|---|---|
| Net revenues | 2008 | Net Change | % Change | 2007 | Net Change | % Change | 2006 |
| | (in millions) | | | | | | |
| North America: | | | | | | | |
| Ortho | $ 89.5 | $ (0.8) | (0.9)% | $ 90.3 | $ 21.7 | 31.7% | $ 68.6 |
| GP | 140.2 | 5.7 | 4.2% | 134.5 | 40.6 | 43.2% | 93.9 |
| Total North American Invisalign | 229.7 | 4.9 | 2.2% | 224.8 | 62.3 | 38.3% | 162.5 |
| International Invisalign | 61.9 | 15.3 | 32.8% | 46.6 | 14.5 | 45.1% | 32.1 |
| Total Invisalign revenues | 291.6 | 20.2 | 7.4% | 271.4 | 76.8 | 39.5% | 194.6 |
| Other revenues | 12.4 | (0.5) | (3.9)% | 12.9 | 1.1 | 10.3% | 11.8 |
| Total net revenues | $304.0 | $ 19.7 | 6.9% | $284.3 | $ 77.9 | 37.8% | $206.4 |

Case volume data which represents Invisalign case shipments by channel, for the years ended December 31, 2008, 2007 and 2006 are as follows:

| | Years Ended December 31, | | | | | | |
|---|---|---|---|---|---|---|---|
| Invisalign case volume | 2008 | Net Change | % Change | 2007 | Net Change | % Change | 2006 |
| | (in thousands) | | | | | | |
| North America: | | | | | | | |
| Ortho | 70.6 | (2.3) | (3.2)% | 72.9 | 17.4 | 31.3% | 55.5 |
| GP | 103.5 | 1.5 | 1.5% | 102.0 | 26.6 | 35.3% | 75.4 |
| Total North American Invisalign | 174.1 | (0.8) | (0.5)% | 174.9 | 44.0 | 33.6% | 130.9 |
| International Invisalign | 37.9 | 9.9 | 35.4% | 28.0 | 8.8 | 46.1% | 19.2 |
| Total Invisalign case volume | 212.0 | 9.1 | 4.5% | 202.9 | 52.8 | 35.2% | 150.1 |

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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.

Revenues from both our North American orthodontic and GP channels increased in 2007 compared to 2006 primarily as a result of an overall increase in case volume and a favorable product mix shift towards Invisalign Full. This product mix shift towards Invisalign Full began in the fourth quarter of 2006 after we removed the cancellation fees on Invisalign Full cases prior to ClinCheck approval and clarified clinical protocols surrounding what is an appropriate Invisalign Express case. The increase in Invisalign Full revenues is partially offset by increased participation in our volume-based discount programs.

The increase in our international Invisalign revenues in 2008 compared to 2007 was predominantly due to higher case volumes partially offset by unfavorable exchange rates and increased participation in volume-based discount programs.

The increase in our international Invisalign revenues in 2007 compared to 2006 was attributable to an increase in case volume. Additionally, our international revenues benefited from favorable exchange rates in 2007. These increases were partially offset by increased participation in volume-based discount programs.

Other revenues, consisting of training fees and sales of ancillary products, were lower in 2008 compared to 2007 primarily due to North American training discount programs. Other revenues were higher in 2007 compared to 2006 as a result of an increased number of doctors trained year over year.

For 2009, we expect our total net revenues to decrease compared to 2008 primarily due to case volume decreases in North America partially offset by expected growth in international revenue. We expect our mix of products to continue to shift in 2009 due to the introduction of new products during the second half of 2008. These new products have a significantly higher amount of deferred revenue as a percentage of their average selling price compared to Invisalign Full.

*Cost of revenues and gross margin:*

| | Years Ended December 31, | | | | |
|---|---|---|---|---|---|
| | **2008** | **Change** | **2007** | **Change** | **2006** |
| | | | **(in millions)** | | |
| Cost of revenues | $ 78.9 | $ 3.9 | $ 75.0 | $ 10.2 | $ 64.8 |
| % of net revenues | 25.9% | | 26.4% | | 31.4% |
| Gross profit | $225.1 | $ 15.8 | $209.3 | $ 67.7 | $141.6 |
| Gross margin % | 74.1% | | 73.6% | | 68.6% |

Cost of revenues includes salaries for staff involved in the production process, costs incurred by IMS, a third party shelter service provider in Juarez, Mexico, 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 in 2008 compared to 2007 primarily due to an increase in case volume over our relatively fixed cost structure and improved operating efficiencies.

Gross margin improved in 2007 compared to 2006 primarily as a result of increased case volume over our relatively fixed cost structure resulting in decreases in our per unit standard cost. Additionally,

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cost reductions from improved operating efficiencies also contributed to the increase in 2007 gross margin.

We believe that gross margin in 2009 will be slightly lower than in 2008 as we expect overall case volume to decrease year over year partially offset by a benefit from our transition from a third party shelter arrangement to direct manufacturing in Juarez, Mexico effective April 2009. However, with our relatively fixed manufacturing cost structure, quarterly gross margin will fluctuate based on case volume and product mix. In addition, should we experience continuing unfavorable exchange rates, our gross margin may be adversely affected.

*Sales and marketing:*

| | Years Ended December 31, | | | | |
|---|---|---|---|---|---|
| | 2008 | Change | 2007 | Change | 2006 |
| | (in millions) | | | | |
| Sales and marketing | $115.1 | $ 16.9 | $98.2 | $ 16.2 | $82.0 |
| % of net revenues | 37.9% | | 34.5% | | 39.7% |

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

Sales and marketing expense increased 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.

Our sales and marketing expense increased during 2007 compared to 2006 predominantly as a result of a $10.3 million increase in media, advertising and product marketing expenses and an increase in payroll-related expenses of $5.1 million, of which $3.7 million was attributable to additional headcount and $1.4 million to stock-based compensation.

We expect sales and marketing expense levels in 2009 to be comparable to 2008. In 2009, we expect to invest in our international channel, including consumer advertising and sales force expansion, and continue commercialization of new products in North America, offset by benefits from the transition of our shared services organizations to Costa Rica, beginning in the second half of 2009.

*General and administrative:*

| | Years Ended December 31, | | | | |
|---|---|---|---|---|---|
| | 2008 | Change | 2007 | Change | 2006 |
| | (in millions) | | | | |
| General and administrative | $62.2 | $ 8.9 | $53.3 | $ (11.0) | $64.3 |
| % of net revenues | 20.5% | | 18.7% | | 31.2% |

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

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

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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.

General and administrative expense decreased in 2007 compared to 2006 largely due to a $20.6 million decline in external legal fees following the settlement of the OrthoClear litigation in the fourth quarter of 2006. As mentioned above, our 2007 legal expense included a $1.6 million credit for an insurance reimbursement of legal costs also associated with the OrthoClear litigation. This decrease was partially offset by a $3.5 million increase in additional headcount and incentive compensation, a $1.7 million increase in consulting fees, and a $1.4 million increase in stock-based compensation expense. Additionally, amortization expense increased $2.2 million in 2007 compared to 2006 related to the amortization of the non-compete agreements we received in connection with the OrthoClear settlement.

We expect general and administrative expense in 2009 to be lower than 2008 levels as we begin to benefit from the transition of our shared services organizations to Costa Rica, beginning in the second half of 2009.

*Research and development:*

| | Years Ended December 31, | | | | |
|---|---|---|---|---|---|
| | 2008 | Change | 2007 | Change | 2006 |
| | (in millions) | | | | |
| Research and development | $26.2 | $ 0.5 | $25.7 | $ 7.2 | $18.5 |
| % of net revenues | 8.6% | | 9.0% | | 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 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.

Research and development expense increased in 2007 compared to 2006 predominantly from a $5.0 million increase resulting from higher headcount and incentive compensation. Additionally, a $1.5 million increase in outside services also contributed to the increase in 2007 research and development costs.

We expect research and development expense in 2009 to be lower than 2008 levels as a result of lower headcount and reduced consulting expenses.

*Restructurings:*

| | Years Ended December 31, | | | | |
|---|---|---|---|---|---|
| | 2008 | Change | 2007 | Change | 2006 |
| | (in millions) | | | | |
| Restructurings | $6.2 | $ 6.2 | $ | $ | $ |
| % of net revenues | 2.1% | n/a | | | |

During 2008, we announced restructuring plans in July and October to increase efficiencies across the organization and lower the overall cost structure. 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 as we move customer care, accounts

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receivable, credit and collections, and customer event registration organizations in Santa Clara, California to our existing facilities in Costa Rica.

In 2008, we incurred approximately $6.2 million in restructuring expenses relating to these actions which includes $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.

We are phasing in the relocation to Costa Rica of our shared services group in an attempt to minimize disruptions to customer service levels and expect the relocation to be completed by July 2009. We expect to incur additional restructuring charges of approximately $1.8 million during the first half of 2009.

*Patients First Program and settlement costs:*

| | Years Ended December 31, | | | | |
|---|---|---|---|---|---|
| | 2008 | Change | 2007 | Change | 2006 |
| | (in millions) | | | | |
| Patients First Program | $ | $ 1.8 | $ (1.8) | $ (10.1) | $ 8.3 |
| Settlement costs | | | | (6.0) | 6.0 |
| Total Patients First Program and settlement costs | $ | $ 1.8 | $ (1.8) | $ (16.1) | $ 14.3 |
| % of net revenues | | | (0.6)% | | 7.0% |

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.

We paid $20.0 million to OrthoClear during the fourth quarter of 2006 in accordance with the terms of the OrthoClear Agreement, of which $14.0 million was capitalized on our balance sheet representing the fair value of the non-compete agreements and is being amortized over 5 years. In accordance with Emerging Issues Task Force 04-01 "Accounting for Pre-existing Contractual Relationships between the Parties to a Purchase Business Combination" ("EITF 04-01"), we recorded the remaining $6.0 million as settlement costs in the fourth quarter of fiscal 2006.

*Interest and other income (expense), net:*

| | Years Ended December 31, | | | | |
|---|---|---|---|---|---|
| | 2008 | Change | 2007 | Change | 2006 |
| | (in millions) | | | | |
| Interest income | $ 3.1 | $ (1.1) | $ 4.2 | $ 1.0 | $ 3.2 |
| Interest (expense) | | 0.3 | (0.3) | | (0.3) |
| Other income (expense), net | (1.5) | (0.7) | (0.8) | (1.3) | 0.5 |
| Total interest and other income(expense), net | $ 1.6 | $ (1.5) | $ 3.1 | $ (0.3) | $ 3.4 |

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

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, 2008.

Other income (expense), net, increased in 2008 compared to 2007 reflecting increases in foreign currency translation losses.

Interest income, net increased in 2007 compared to 2006 primarily due to higher average cash, cash equivalents and marketable securities balances in 2007.

Other income (expense), net, decreased in 2007 compared to 2006 reflecting the decrease in foreign currency translation gains. In January 2007, we began to record the adjustments from translating certain European subsidiaries' financial statements from the local currency into the U.S. dollar as a separate component of shareholders' equity on our Consolidated Balance Sheets. See *Item 7A "Quantitative And Qualitative Disclosures About Market Risk" under the heading "Currency Rate Risk"* for additional information on the change in functional currency.

*Provision for (benefit from) income taxes:*

| | Years Ended December 31, | | | | |
|---|---|---|---|---|---|
| | 2008 | Change | 2007 | Change | 2006 |
| | (in millions) | | | | |
| Provision for (benefit from) income taxes | $(63.0) | $(64.2) | $1.2 | $ 0.4 | $0.8 |

We recorded an income tax benefit of $63.0 million for 2008 and income tax provisions of $1.2 million and $0.8 million for 2007 and 2006, respectively. These represented effective tax rates of (368.4)%, 3.3%, and (2.4)%, in 2008, 2007 and 2006, 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 available positive 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 as we cannot forecast sufficient future capital gains or foreign source income to realize these deferred tax assets. Therefore, we recorded a tax valuation allowance release of $64.6 million in 2008. The remaining valuation allowance of approximately $6.2 million relating to capital loss and foreign net operating loss carryforwards as of December 31, 2008, will result in an income tax benefit if and when we conclude it is more likely than not that the related deferred tax assets will be realized.

At December 31, 2008, we had net operating loss carryforwards of approximately $191.1 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 2010 for California purposes. FAS 123R 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 $7.5 million as of December 31, 2008 and will be accounted for as a credit to additional paid-in capital, if and when realized through a reduction in income taxes

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payable. 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, 2008 and our current estimate of the annual limitation, we do not expect our net operating loss carryforwards to be limited. At December 31, 2008, we had research credit carryforwards of approximately $3.5 million for federal purposes and $4.3 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.

We have not provided additional U.S. income taxes on undistributed earnings from non- U.S. operations as of December 31, 2008 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, 2008, 2007 and 2006, we had the following cash and cash equivalents, restricted cash and short-term investments:

| | Years Ended December 31, | | |
|---|---|---|---|
| | 2008 | 2007 | 2006 |
| | (in thousands) | | |
| Cash and cash equivalents | $ 87,100 | $ 89,119 | $55,113 |
| Restricted cash | | 21 | 93 |
| Short-term investments | 23,066 | 38,771 | 8,931 |
| Total | $110,166 | $127,911 | $64,137 |

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 operating activities for the year ended December 31, 2006 was $14.0 million, resulting primarily from our net loss of $35.0 million and non-cash items such as depreciation and amortization, stock-based compensation, and amortization of intangibles totaling $19.2 million. Additionally, a $6.4 million increase in current assets and a $5.8 million reduction in deferred revenue partially offset by a $14.3 million increase in accounts payable and accrued liabilities also contributed to the cash used in operating activities. The increase in accrued liabilities was primarily due to the

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$6.8 million accrual as of December 31, 2006 for the anticipated costs of completing the Patients First Program.

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. As a result of current adverse financial market conditions, investments in some financial instruments may pose risks arising from liquidity and credit concerns. 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 $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 used in investing activities was $32.8 million for the year ended December 31, 2006, primarily due to a $14.0 million purchase of intangible assets resulting from the OrthoClear Agreement, $10.0 million for the purchase of capital assets and $8.9 million for net purchases of short-term marketable securities.

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

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, 2008, we had no outstanding borrowings and we were in compliance with the financial covenant 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.

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***Contractual Obligations/Off Balance Sheet Arrangements***

The impact that our contractual obligations as of December 31, 2008 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 | $ 9,687 | $ 3,234 | $4,205 | $2,248 | $ |
| Computer support services | 388 | 388 | | | |
| Total | $10,075 | $ 3,622 | $4,205 | $2,248 | $ |

In July 2008, we entered into an agreement in favor of and for the benefit of Elamex de Juarez, S.A. DE C.V., or Elamex, landlord to IMS, our third party shelter services provider. Under this agreement, we guarantee IMS' lease payments for its facility located in Juarez, Mexico. The monthly rent for this 68,000 square foot facility is $30,000 and the lease expires in July 2013. Pursuant to the guarantee, we are obligated to pay Elamex for any rental payments in default by IMS. During the year ended December 31, 2008, there were no rental payment defaults by IMS.

On December 22, 2008, we notified IMS of our intention to terminate IMS' shelter services arrangement effective April 2009. At that time, we will become a direct manufacturer of our clear aligners at the facility in Juarez, Mexico and we will also assume IMS' lease with Elamex.

We had no off-balance sheet arrangements as defined in Regulation S-K Item 303(a) (4) as of December 31, 2008.

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.

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*Revenue Recognition*

We recognize revenue in accordance with SEC Staff Accounting Bulletin No. 104 "Revenue Recognition" ("SAB 104"), and Emerging Issues Task Force ("EITF") No. 00-21 "Revenue Arrangements with Multiple Deliverables" ("EITF 00-21"). SAB 104 requires that four basic criteria must be met before revenue can be recognized: persuasive evidence of an arrangement exists, delivery has occurred, the price is fixed or determinable, and collectibility 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.

We enter into arrangements that involve multiple product deliveries in the future. 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 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 utilization. We believe that the use of a breakage factor is reasonable and appropriate because of the relative stability of case refinement utilization since case refinement was first offered. Actual utilization 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. Revenue for the six replacement aligners included in Invisalign Teen is deferred based on the fair market value until the earlier of replacement aligners being used or until the case is completed. 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 adopted the fair value recognition provisions of Statement of Financial Accounting Standards ("FAS") No. 123 (revised 2004), "Share-Based Payment" ("FAS 123R") in 2006. Accordingly, we recognize 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. Prior to FAS 123R adoption, we accounted for share-based payment awards under Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to

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Employees" ("APB 25") and its related interpretations. *See Note 10 "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. Long-lived assets are reviewed for impairment in accordance with Statement of Financial Accounting Standards No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets" ("FAS 144"). 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, 2008, 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

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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, 2008, we had $23.1 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, 2008 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 country. 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 in accordance with FAS 52 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.

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## ITEM 8. CONSOLIDATED FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

**Quarterly Results of Operations**

| | Three Months Ended | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | 2008 | | | | 2007 | | | |
| | 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 | $74,125 | $75,173 | $79,902 | $74,776 | $72,517 | $71,451 | $76,603 | $63,761 |