ALIGN TECHNOLOGY INC
Form 10-K
February 26, 2008

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PART IV

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, 2007

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, including Zip Code)

(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 $1,370,873,964 as of June 30, 2007 based on the closing sale price of the registrant's common stock on the NASDAQ Global Market on such date. Shares held by person who may be deemed officers have been excluded. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

On February 20, 2008, 69,155,844 shares of the registrant's common stock were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement relating to its 2008 Annual Stockholders' Meeting to be filed pursuant to Regulation 14A within 120 days after the registrant's fiscal year end of December 31, 2007 are incorporated by reference into Part III of this Annual Report on Form 10-K.

ALIGN TECHNOLOGY, INC.

FORM 10-K

For the Year Ended December 31, 2007

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Invisalign, Align, ClinCheck, Invisalign ClinAssist, Invisalign Teen and Vivera, amongst others, are trademarks belonging to Align Technology, Inc. and are pending or registered in the United States and other countries.

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 release of ClinAssist, Invisalign Teen and Vivera including anticipated product release dates, product features and the expected impact these new products and product enhancements will have on doctor utilization and our market share, our expectations regarding product mix, our expectations regarding the existence and impact of seasonality, our expectation that our utilization rate will improve over time, our expectations regarding our average selling prices and gross margins in 2008, our intention to continue the integration of Invisalign into the curriculums of additional universities, our expectations regarding the benefit of increased consumer marketing programs, our expectations regarding case shipment volume in 2008, our expectation regarding the anticipated level of our operating expenses in 2008, 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 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. was incorporated in April 1997 under the laws of the state of Delaware. We design, manufacture and market the Invisalign system, a proprietary method for treating malocclusion, or the misalignment of teeth. Invisalign corrects malocclusion using a series of clear, nearly invisible, removable appliances that gently move teeth to a desired final position. Because it does not rely on the use of metal or ceramic brackets and wires, Invisalign significantly reduces the aesthetic and other limitations associated with traditional metal arch wires and brackets, commonly referred to as braces. Invisalign is appropriate for treating adults and teens with mature dentition. We received 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 solution to their patients. The Invisalign system is sold in North America, Europe, Asia-Pacific, Latin America and Japan. In parts of the Asia-Pacific and Latin-American region, we recently transitioned the sales of our product to a distributor model.

On the Financial Information page within the Investor Relations section of our corporate website, which can be accessed at either *www.aligntech.com* or *www.invisalign.com*, we make our Annual Report 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 available as soon as reasonably practicable after they are electronically filed with or furnished to the Securities and Exchange Commission, or SEC. All such filings are available free of charge. The information in, or that can be accessed through, our website is not part of this report.

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 2.3 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, if covered at all. 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.

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 electronic treatment plans using ClinCheck, and the manufacturing of 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 Santa Clara, California facility.

Preparation of three-dimensional computer models of the patient's initial malocclusion. Upon receipt, we use the treatment data to construct digital models of the patient's dentition. Using computed tomography, known as CT scanning, we scan the PVS impression to develop a digital, three-dimensional computer model of the patient's current dentition. We then transmit this initial computer model together with the dental professional's prescription and supplemental materials electronically to our 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 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. International Manufacturing Solutions Operaciones, S.R.L., or IMS, a third party shelter services provider in Juarez, Mexico, manufactures the molds and then uses these molds to fabricate the patient's aligners.

Manufacture of aligners and shipment to the dental professional. From these molds, IMS fabricates aligners 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. For each of our current products, aligners are manufactured and then delivered to the dental professionals in a single shipment. 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 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 Vivera retainers, a clear aligner set designed for ongoing retention. Vivera is a subscription-based program that delivers new replacement retainers to patients every three months over the one year subscription period.

Our Products

The vast majority of our revenues are generated from the sales of full Invisalign and Invisalign Express treatments.

Full Invisalign Treatment. Commercial sales of full Invisalign treatment commenced in the U.S. in July 1999. Our traditional, full Invisalign treatment option 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 full Invisalign, aligners are manufactured and then delivered to the dental professionals in a single shipment. In fiscal 2007, approximately 88% of our net revenues were generated by the sale of full Invisalign treatment.

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 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. In fiscal 2007, approximately 8% of our net revenues were generated by the sale of Invisalign Express.

Vivera. In November 2007, we introduced Vivera retainers, a subscription-based program that delivers 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. Vivera was fully launched to our North American sales force in the first quarter of 2008.

Invisalign Teen. In January 2008, we announced the planned release of Invisalign Teen. Invisalign Teen is designed to meet the specific needs of the non-adult comprehensive or teen treatment market. Planned 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 root control issues common in teen patients. As part of Invisalign Teen, we will include up to three free replacement aligners during active treatment to cover potential aligner loss. For Invisalign Teen, aligners (other than the three replacement aligners) will be manufactured and then delivered to the dental professionals in a single shipment. We anticipate that Invisalign Teen will be available in late 2008.

Invisalign ClinAssist. In January 2008, we announced the planned release of Invisalign ClinAssist. ClinAssist is intended to be used as a complete treatment for a broad range of malocclusions similar to full Invisalign. ClinAssist, however, will also include a consultative approach to Invisalign treatment for doctors who want a highly efficient treatment process with built-in monitoring tools and progress checks. Planned features include a simplified submission process, case monitoring support by us to help doctors keep cases on track, and staged shipment of aligners based on treatment progress. For Invisalign ClinAssist, aligners will be shipped to the dental professionals in a series of staged deliveries as treatment progresses. We anticipate that Invisalign ClinAssist will be available in late 2008 or early 2009.

Statements concerning our expectations regarding new products in development, ClinAssist and Invisalign Teen, and expectations related to their anticipated release, are not guarantees of the date of availability, which may be delayed or cancelled, or of the availability of the features mentioned, which may be changed or removed prior to release. Actual results may differ materially and adversely from those expressed in any forward-looking statement. See *Item 1A "Risk Factors"* for a more complete discussion of factors that might cause such differences.

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 4% of our 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 2.3 million people annually elect treatment by orthodontists in the U.S. As of December 31, 2007, our share of the 2.3 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.

Decreased dental professional and staff time. Invisalign eliminates the need for time-intensive processes such as bonding appliances to the patient's teeth, adjusting arch wires during the course of treatment and removing the appliances at the conclusion of treatment. As such, use of Invisalign reduces dental professional and staff chair time and can increase practice capacity.

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 office space and staff time, 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.

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 2.3 million people annually elect treatment by orthodontists in the U.S., of which approximately 40% of these patients, or approximately 900 thousand, have mature dentition, with fully-erupted second molars and substantially completed jaw growth with mild to moderate malocclusions. Historically, Invisalign has predominately been marketed to treat patients with fully-erupted mature dentition (adults and older teens). As of December 31, 2007, our share of the 2.3 million case starts is approximately 3% and approximately 8% of the 900 thousand patients with mature dentition, our served market. 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 and therefore

represent our most immediate market expansion opportunity. However, with the planned launch of Invisalign Teen in the latter half of 2008, we will for the first time offer a product designed to meet the needs of the non-adult comprehensive, or teen, treatment market. Specifically, those individuals who have shed their "baby" teeth but do not yet have fully-erupted mature dentition. Even though we have not previously marketed our product to treat younger patients, approximately 15% of our total case starts in 2007 were with individuals younger than 19. Launching a teen-specific product will make the Invisalign system 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 non-adult comprehensive, or 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, 2007, approximately 732,000 patients worldwide have started treatment using Invisalign. The Invisalign system is sold in North America, Europe, Asia-Pacific, Latin America and Japan. In 2007, international sales accounted for 16% of our net revenues. A geographic breakdown of our net revenues is summarized in Note 15 "Segments and Geographic Information" in the Notes to our Consolidated Financial Statements.

For 2007, 2006 and 2005, no single customer accounted for 10% or more of our total net revenues.

Business Strategy

Our goal is to establish Invisalign as the standard method for treating malocclusion by focusing on the following key objectives: driving product innovation, increasing customer adoption and frequency of use (what we call utilization) by training dental professionals and focusing on education and customer support, and stimulating consumer demand.

Product innovation New products and enhancements to existing products. We believe that product performance and innovation is a cornerstone to our future long-term growth by driving and sustaining product adoption, enhancing the user experience and thereby increasing utilization growth. Currently, the Invisalign system is a single system used by both GPs and orthodontists. We are committed to delivering new products and introducing new product features to better meet the needs of our two customers orthodontists and GPs each with distinct and separate needs. Orthodontists want a more robust set of tools for greater predictability, wider applicability and more flexibility in the use of the Invisalign system. On the other hand, typical GPs want greater ease of use, more efficient and simplified diagnostic tools, guidance through the case set-up process, minimal treatment intervention and self-help tools designed to simplify treatment of cases of mild to moderate malocclusion. Based on this knowledge, we announced the anticipated release of two products Invisalign Teen in the latter half of 2008 and Invisalign ClinAssist in the latter half of 2008 or early 2009. Invisalign Teen will include features such as an aligner wear indicator to help gauge patient compliance and specially engineered aligner features to address the natural eruption of key teeth and root control issues common in teen patients. Predominately 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. Invisalign ClinAssist is the first phase of our GP-specific product platform which is being designed as a turnkey, consultative approach to Invisalign treatment for doctors who want a highly efficient treatment process with built-in monitoring tools and progress tracking. 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 demand for Invisalign. The planned roll out of Invisalign ClinAssist and Invisalign Teen 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. We believe enhanced product performance and innovation will continue to drive the adoption and frequency of use (what we call utilization), and increase customer productivity resulting in increased demand for Invisalign and market share expansion.

Increase customer adoption and utilization. By first increasing adoption through the expansion of our customer base and then increasing utilization by offering new products and feature enhancements to meet the needs of orthodontists and GPs, we believe the overall market for Invisalign and our share of that market will increase.

Training new orthodontists and general practitioners. Expanding our customer base through training is a key part of our strategy. Through the end of 2007, we have trained 27,480 GPs and 8,310 orthodontists in the United States and 12,340 doctors internationally. In addition, 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. Currently, we have incorporated the Invisalign technique into the curriculum of 38 university programs. We expect additional dental schools to integrate the Invisalign technique into their curricula in the future.

Focus on education and customer support. In order to build long-term relationships with our customers and increase utilization, we focus on providing ongoing training, support and services. In early 2008, we announced the introduction of the Aligntech Institute program brand, which consolidates our extensive clinical education programs under a new interactive website that will provide clinical education and practice development training opportunities for our Invisalign trained doctors on demand. These practice development training opportunities will 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. By participating in these events, 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. The cornerstone of our clinical education program is *www.aligntechinstitute.com*, which provides information and registration for our training workshops, conference calls and seminars and provides an extensive range of case studies, best practices, testimonials and online coursework to ensure treatment success and improve practice economics. 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.

Stimulate demand for Invisalign treatment increasing our patient base. 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 vast majority of people with malocclusion who desire treatment do not elect traditional treatment because of 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 Invisalign treatment annually. In 2008, we expect to increase our overall marketing spending in the United States with a focus on programs such as advertising and digital online media, designed to raise the profile of Invisalign and drive more consumers to our most experienced doctors. We also intend to initiate similar consumer marketing efforts, but on a smaller scale, in key European countries. We believe that this increased consumer awareness of Invisalign will increase the overall market acceptance of our products.

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.

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 become 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.

As of December 31, 2007, our manufacturing and operations staff in the U.S. and Costa Rica consisted of 641 people. Manufacturing is coordinated in Santa Clara, California. Digital dental modeling is processed in our 63,000 square foot facility in San Jose, Costa Rica. The operations team in Costa Rica creates ClinCheck treatments using simulation software. SLA (stereolithography) molds and aligners are manufactured, packaged and distributed at IMS, an outsourced, third party shelter services provider based in Juarez, Mexico. Information regarding risks associated with our manufacturing process and foreign operations may be found in Item 1A of this Annual Report on Form 10-K under the heading "Risk Factors."

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 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 and mail campaigns, 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, 2007 our North American sales organization consisted of 163 people, of which 136 were direct sales representatives and 27 were sales administration and management. Internationally, we have over 30 people engaged in sales and sales support as of December 31, 2007. 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, 2007, we had trained 48,130 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 8,310 orthodontists and 27,480 active GPs cumulatively through the end of 2007.

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 will 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, establishing an Internet connection and familiarizing them with our website. 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.

In 2008, we expect to increase marketing spending in the United States related to bringing new products to market, such as Vivera, Invisalign Teen and Invisalign ClinAssist, including spending related to pilot testing and the actual launch of such products.

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 2008, we expect to increase marketing spending in the United States with a focus on programs designed to raise the profile of Invisalign and drive more consumers to our most experienced doctors. We believe that this increased consumer awareness of Invisalign will increase demand for our product.

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 Teen and Invisalign ClinAssist. Our research and development expenses were $25.7 million for 2007, $18.5 million for 2006, and $18.6 million for 2005.

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 Ortho-specific and GP-specific platforms to meet the needs of our customers to increase adoption and utilization of Invisalign. We will continue to invest in ongoing product enhancements and software tools development.

Intellectual Property

We believe our intellectual property position represents a substantial business advantage. As of December 31, 2007, we had 98 issued U.S. patents, 167 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."

Seasonality

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 computer-simulated 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. In May 2006, Danaher Corporation purchased Sybron Dental Specialties. 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.

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. 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 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 9001:2000 requirements. 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.

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. 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 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 principally the responsibility of the hospital, physician or other healthcare provider, we are required to maintain the confidentiality of patient information when providing technical services and when handling patient information and records. We have designed our product and service offerings to be consistent with the requirements of the Privacy and Security standards under HIPAA and applicable corresponding state laws and regulations. Maintaining systems that are consistent with these laws and regulations is costly and could require complex changes in the way we do business or provide services to our patients. Additionally, our success may be dependent on the success of healthcare participants in dealing with HIPAA requirements.

Other Federal and State Laws. As a participant in the health care industry we are subject to extensive and frequently changing regulation under many other laws administered by governmental entities at the federal, state and local levels, some of which are, and others of which may be, applicable to our business. 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 are applicable to our financial relationships with, and any marketing or other promotional activities involving, our dental professional customers. Finally, various states regulate the operation of an advertising and referral service for dentists, and may require registration of such services with a state agency as well as compliance with various requirements and restrictions on how they conduct business and structure their relationships with participating dentists. Violations of any of these laws or regulations could subject us to a variety of civil and criminal sanctions.

Employees

As of December 31, 2007, we had 1,307 employees, including 641 in manufacturing and operations, 340 in sales and marketing, 154 in research and development and 172 in general and administrative functions. We had 576 employees in the U.S., 586 employees in Costa Rica, 134 employees in Europe and 11 employees in Japan.

Executive Officers of the Registrant

The following table sets forth certain information regarding our executive officers as of February 26, 2008:

Name	Age	Position
Thomas M. Prescott	52	President and Chief Executive Officer
Kenneth B. Arola	52	Vice President, Finance and Chief Financial Officer
Afsaneh Azadeh	48	Vice President, Information Technology and Chief Information Officer
Sonia Clark	43	Vice President, Human Resources
Dan S. Ellis	56	Vice President, North American Sales
Roger E. George	42	Vice President, Legal and Corporate Affairs General Counsel and Corporate Secretary
Len M. Hedge	50	Senior Vice President, Business Operations
Gil Laks	42	Vice President, International
Emory Wright	38	Vice President, Operations
Darrell Zoromski	43	Vice President, Global Marketing and Chief Marketing Officer

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

Afsaneh Azadeh has served as our Vice President, Information Technology and Chief Information Officer since October 2007. Prior to joining us, Ms. Azadeh was Senior Vice President, Information Technology for Agile Software Corporation, a product life cycle management software provider, from February 2005 to October 2007. From 1985 to 2005, Ms. Azadeh was at ZiLOG, Inc., where she held various positions, most recently as Chief Information Officer.

Sonia Clark has served as our Vice President, Human Resources since September 2006. During 2006, Ms. Clark was with Avago Technologies, a recent spin-off of the Semiconductor Products Group (SPG) of Agilent Technologies. Prior to Avago, Ms. Clark was at Agilent Technologies from October 2004 to December 2005 as its Chief Learning Officer-Networking Solutions. From July 2001 to August 2004, Ms. Clark served as Vice President, Human Resources at Cadence Design Systems, an electronic design automation company. Her experience also includes positions of increasing responsibilities in Human Resources at Black & Decker, Colgate Palmolive and several startups.

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

Roger E. George has served as our Vice President, Legal and Corporate Affairs, General Counsel and Corporate Secretary since July 2002. Prior to joining us, Mr. George was the Chief Financial Officer, Vice President of Finance and Legal Affairs and General Counsel of SkyStream Networks, a privately held broadband and broadcast network equipment company. Prior to SkyStream, Mr. George was a partner at Wilson Sonsini Goodrich & Rosati, P.C. in Palo Alto, California.

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

Gil Laks has served as our Vice President, International since September 2005, and served as our Vice President, Europe since June 2001. Prior to joining us, Mr. Laks was Vice President, Business Development for the diagnostic imaging division of Singapore Technologies, from November 1999 to May 2001. He also served as Director of International for ISIX, Ltd., an educational computing services firm, from October 1996 to October 1999.

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.

Darrell Zoromski has served as our Vice President, Global Marketing and Chief Marketing Officer since December 2005. Prior to joining us, Mr. Zoromski most recently held the position of Vice President and General Manager of CZV Labs at Carl Zeiss Vision, a global manufacturer and distributor of optical lenses to eye care physicians and chain retailers, where he worked from January 2002 to December 2005. From December 1999 to January 2002, Mr. Zoromski was Director, Breakfast Foods Division at Pillsbury Company and from December 1992 to November 1999, he served in management positions at S.C. Johnson & Son, Inc., most recently as Director, Home Cleaning Division. Prior to joining S.C. Johnson & Son, Mr. Zoromski was a brand manager at Procter & Gamble Company from 1989 to 1991.

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.

While we returned to profitability in 2007, we experienced a net loss in each quarter of 2006. 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 2007, we experienced negative cash flow in 2006. 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;
- 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;
- changes in product mix;
- seasonal fluctuations in the number of doctors in their offices and available to take appointments;
- success of marketing programs from quarter to quarter;
- changes in the timing of revenue recognition with the introduction of new products such as Invisalign ClinAssist and Invisalign Teen;
- 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 or 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 as it has in the past, our operating results would be harmed. Factors that could cause Invisalign not to achieve market acceptance at the rate at which we expect, as well as the risk related to declining average selling prices are described more fully below.

Dental professionals 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. In addition, because Invisalign has only been in clinical testing since July 1997 and commercially available only since July 1999, orthodontists and GPs may be reluctant to adopt it until more historical clinical results are available. Also, 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.

Consumers may not adopt Invisalign in sufficient numbers or as rapidly as we anticipate.

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. In addition, consumers may not comply with recommended treatment guidelines for Invisalign, which could compromise the effectiveness of their 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. Furthermore, consumers may not respond to our direct marketing campaigns or we may be unsuccessful in reaching our target audience. Adoption by consumers may also be affected by general macroeconomic conditions in North America and internationally, which fluctuate and could be affected by unstable global economic, political or other conditions.

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, in November 2005, we reduced the list price of full Invisalign cases and in the third quarter of 2005 we introduced Invisalign Express, a lower-cost solution for less complex cases. In addition, in the fourth quarter of 2005, we expanded our volume based discount program to all doctors. As a result of these programs, the blended average selling price of our products declined in 2006 compared to 2005. Additionally in Europe, we introduced new pricing initiatives in the first quarter of 2006 which resulted in a lower average selling price. Although our blended average selling prices increased in 2007 compared to 2006 primarily as a result of a product mix shift towards full Invisalign and an increasing number of lower volume GPs, who did not attain volume discount levels, if we are to introduce any similar discount programs in the future or if participation in these programs increases, our revenues, gross margin and net profits (losses) may be adversely affected.

Our future success may depend on our ability to develop and successfully introduce new products.

Our future success may depend on our ability to develop, obtain regulatory approval or clearance of, manufacture and market new products. We announced the anticipated launch of Invisalign Teen in the latter half of 2008 and Invisalign ClinAssist in the latter half of 2008 or early 2009. 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.

We are dependent on our international operations, which exposes us to foreign operational, political and other risks that may harm our business.

Currently, two of 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 electronic treatment plans, which are transmitted electronically back to the U.S. These electronic files form the basis of ClinCheck and are used to manufacture aligner molds. IMS, our third party shelter services provider located in Juarez, Mexico fabricates the aligner molds, the aligners and ships the completed products to our customers. 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 Costa Rica and Moscow, Russia. 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, including our relationship with IMS, our third party shelter services provider;
- 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;
- 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.

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 electronic 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. In addition, our aligner molds and finished aligners are fabricated by IMS, our third party shelter services provider located 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 currently rely on third parties to provide key inputs to our manufacturing process, and if our access to these inputs is diminished, our business may be harmed.

We currently outsource key portions of our manufacturing process. We rely on IMS, a third party shelter services provider located in Juarez, Mexico, to fabricate aligner molds as well as finished aligners and to ship the completed product to customers. If IMS fails to deliver its components or if we lose its services, we may be unable to deliver our products in a timely manner, and our business may be harmed. Any difficulties encountered by IMS with respect to hiring and retaining qualified personnel, and maintaining acceptable manufacturing standards, controls, procedures and policies could disrupt our ability to deliver our products in a timely manner. Finding a substitute manufacturer may be expensive, time-consuming or impossible.

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 Corporate 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 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 produce 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 additional functionality into our business enterprise systems and intend to continue this effort for the foreseeable future, which will more efficiently integrate these systems with our other system applications, such as customer facing and manufacturing tools. 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, 2007, we had 98 issued U.S. patents, 167 pending U.S. patent applications, and numerous foreign issued patents, as well as pending foreign patent applications.

We intend to rely on our portfolio of issued and pending patent applications in the U.S. and in other countries to protect a large part of our intellectual property and our competitive position. However, our currently pending or future patent filings may not result in the issuance of patents. Additionally, any patents issued to us may be challenged, invalidated, held unenforceable, circumvented, or may not be sufficiently broad to prevent third parties from producing competing products similar in design to our products. 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. *See Item 3 of this Annual Report on Form 10-K for a summary of the USPTO proceedings.* 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. For example, we are currently involved in a patent infringement lawsuit with Ormco. In addition, during 2005 and 2006 we were involved in several lawsuits with OrthoClear, Inc. and other parties related to OrthoClear, including a patent infringement action against OrthoClear filed in the Western District of Wisconsin (Madison). We settled this lawsuit in October 2006, however, the potential effects on our business operations resulting from similar 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 Item 3 of this Annual Report on Form 10-K for a summary of our material pending legal proceedings.*

While we believe we currently have adequate internal control over financial reporting, we are required to assess our internal control over financial reporting on an annual basis and any future adverse results from such assessment could result in a loss of investor confidence in our financial reports and have an adverse effect on our stock price.

Pursuant to the Sarbanes-Oxley Act of 2002 and the rules and regulations promulgated by the SEC, we are required to furnish in our Form 10-K an Annual Report by our management regarding the effectiveness of our internal control over financial reporting. The report includes, among other things, an assessment of the effectiveness of our internal control over financial reporting as of the end of our fiscal year, including a statement as to whether or not our internal control over financial

reporting is effective. This assessment must include disclosure of any material weaknesses in our internal control over financial reporting identified by management. While we currently believe our internal control over financial reporting is effective, the effectiveness of our internal controls to future periods is subject to the risk that our controls may become inadequate because of changes in conditions, and, as a result, the degree of compliance of our internal control over financial reporting with the policies or procedures may deteriorate. If we are unable to assert that our internal control over financial reporting is effective in any future period (or if our auditors are unable to express an opinion on the effectiveness of our internal controls or conclude that our internal controls are ineffective), we could lose investor confidence in the accuracy and completeness of our financial reports, which could have an adverse effect on our stock price.

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

We are highly dependent on the key employees in our clinical engineering, technology development, sales and marketing personnel and management teams. The loss of the services of 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.

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, we are committed to purchasing all of our resin from a single-source and our scanning and stereolithography equipment are provided by single suppliers. 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 these items, our business and growth prospects may be harmed.

We have experienced rapid growth, and our failure to manage this growth could harm our business.

We have expanded rapidly since we commenced commercial sales in 1999. Our headcount increased from approximately 50 employees as of December 31, 1999 to 1,307 employees as of December 31, 2007. This expansion will continue to place significant demands on our management and other resources and will require us to continue to develop and improve our operational, financial and other internal controls, both in the U.S. and internationally. In particular, growth increases the challenges involved in a number of areas, including recruiting and retaining sufficiently skilled personnel, providing adequate training and supervision to maintain our high quality standards, and preserving our culture and values. Our inability to effectively manage growth could harm our business.

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, 2007, our North American sales organization consisted of 163 people, of which 136 were direct sales representatives and 27 were sales administration and regional sales management. Internationally, we have over 30 people engaged in sales and sales support as of December 31, 2007. We do not have any long-term employment contracts with the members of our direct sales force. The loss of the services of 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 reestablish 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, manufacture 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.

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.

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, Canada, Mexico, Brazil, Australia, Hong Kong 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 market conditions.

In addition, the stock market in general, and the market for technology and medical device companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated to or disproportionate to the operating performance of those companies. These broad market and industry factors may seriously harm the market price of our common stock, regardless of our operating performance. 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 while at the same time maximizing yields without significantly increasing risk. To achieve this objective, a majority of our marketable investments are investment grade, liquid, short-term fixed-income securities and money market instruments denominated in U.S. dollars. If the carrying value of our investments exceeds the fair value, and the decline in fair value is deemed to be other-than-temporary, we will be required to write down the value of our investments, which could materially harm our results of operations and financial condition. Moreover, the performance of certain securities in our investment portfolio correlates with the credit condition of the U.S. financial sector. With the current unstable credit environment, we might incur significant realized, unrealized or impairment losses associated with these investments.

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

Our board of directors has the authority to issue up to 5,000,000 shares of preferred stock and to determine the rights, preferences, privileges and restrictions of such shares without any further vote or action by our shareholders. To date, our board of directors has designated 200,000 shares as Series A participating preferred stock in connection with our shareholder rights' plan. The issuance of preferred stock under certain circumstances could have the effect of delaying or preventing an acquisition of the company or otherwise adversely affecting the rights of the holders of our stock. The shareholder rights' plan may have the effect of rendering more difficult or discouraging an acquisition of our company which is deemed undesirable by our board of directors. The shareholder rights' plan may cause substantial dilution to a person or group attempting to acquire us on terms or in a manner not approved by our board of directors, except pursuant to an offer conditioned on the negation, purchase or redemption of the rights issued under the shareholder rights' plan.

Our effective tax rate may vary significantly from period to period, and we could owe significant taxes even during periods when we experience low operating profit or operating losses.

We have negotiated tax incentives with the Costa Rica Ministry of Foreign Trade, an agency of the Government of Costa Rica. Under the 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 fiscal years beginning in fiscal 2010. The Costa Rica corporate income tax rate that would apply, absent the incentives, is 30% for fiscal year 2007. As a result of these incentives, income taxes decreased by $2 million in fiscal year 2007. 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 cause our operating results to be harmed.

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 customer support, operations, 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 $75,000. 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 $71,000. The lease for this facility expires at the end of 2008 with an option to renew for an additional five year term. We expect this lease will be renewed beyond 2008.

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 $34,000.

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") 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. Ormco is a division of Sybron Dental Specialties. In May 2006, Danaher Corporation acquired Sybron Dental Specialties. The complaint sought unspecified monetary damages and injunctive relief. On February 18, 2003, we answered the complaint and asserted counterclaims seeking a declaration by the Court of invalidity and non-infringement of the asserted patents. In addition, we counterclaimed for infringement of our U.S. Patent No. 6,398,548, seeking unspecified monetary damages and injunctive relief. Ormco filed a reply to our counterclaims on March 10, 2003 and asserted counterclaims against us seeking a declaration by the Court of invalidity and non-infringement of U.S. Patent No. 6,398,548. We amended our counterclaim to add Allesee Orthodontic Appliances, Inc. ("AOA"), a wholly-owned subsidiary of Ormco, as a counterdefendant in regard to our counterclaim of infringement of U.S. Patent No. 6,398,548. The Court then permitted Ormco to amend its Complaint and permitted us to amend our counterclaim to add an additional patent each. Ormco filed a first amended complaint for infringement of U.S. Patent No. 6,616,444 on October 15, 2003. On October 27, 2003, 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, the Court granted five motions for summary judgment that we filed. First, on May 14, 2004, 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, on July 2, 2004, the Court granted in part our motion for summary judgment of infringement, finding that Ormco and 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, on August 26, 2004, 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 December 20, 2004, we filed a further summary judgment motion that our asserted claims are not invalid based on Ormco's and AOA's new evidence. Ormco and AOA filed a counter-summary judgment motion that our asserted claims are invalid based on this new evidence. The motions were heard by the Court on February 7, 2005. On February 24, 2005, the Court granted our motion in part, confirming 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 granted Ormco's and AOA's motion in part, finding certain claims of our 6,398,548 patent to be invalid in view of prior use evidence. On March 10, 2005, Ormco and AOA moved for reconsideration of the Court's ruling that Claims 10 and 17 of our U.S. Patent No. 6,398,548 are not invalid. On April 8, 2005, the Court ruled that it would adhere to its previous ruling that Claims 10 and 17 of our 6,398,548 patent are not invalid.

On March 28, 2005, we filed a motion for permanent injunction to prevent Ormco and AOA from selling the infringing Red, White & Blue system. 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. Oral argument took place on April 3, 2006. Following oral argument, 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 seventy-one 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 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, which will be returned to the District Court for a determination of validity and infringement of those claims. The Court has denied Ormco's petition for rehearing with respect to the portion of the Federal Circuit's opinion that affirmed the District Court's ruling of non-infringement and non-enablement of the 86 claims.

On our cross-appeal, the CAFC affirmed the District Court's finding that six claims in our 6,398,548 patent (claims 1-3 and 11-13) are invalid. These six claims are directed to a system of appliances and method of repositioning teeth from an initial to a final tooth arrangement where at least some of the appliances are marked to show the order of use. The majority of the claims in the 6,398,548 patent, including claims that address methods of fabricating aligners, digital data sets or

computer-generated models to fabricate appliances, are unaffected by the second appeal and the CAFC's ruling.

We previously entered into a settlement agreement (the "Settlement Agreement") with Ormco and AOA pursuant to which Ormco and AOA were required to pay into escrow, pending the completion of the appeals process as discussed above, $884,000 to resolve the issues of past damages, willfulness and attorneys' fees for the adjudged infringement of two of our patents (the "Align Patents") through the manufacture and sale of Ormco's and AOA's Red, White & Blue appliances. Our receipt of the payments out of escrow was contingent upon the Court, in a final, non-appealable judgment, finding that Ormco or AOA infringes at least one of the claims in the Align Patents. As discussed above, the CAFC has now issued a final, non-appealable judgment of invalidity with respect to each asserted claim of the Align Patents, and therefore all funds in the escrow account will be returned to Ormco and AOA.

Ormco has filed a petition with the U.S. Supreme Court asking for an extension of time in which to file a petition for review by 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 the 86 claims. The Supreme Court granted Ormco's petition for an extension of time. On February 14, 2008, Ormco filed with the U.S. Supreme Court a petition for review of the Federal Circuit's ruling that 86 of Ormco's patent claims are not infringed and are invalid. We will have an opportunity to respond to Ormco's petition.

Other matters

USPTO

Ex Parte Requests:

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. As noted below, a Reexamination Certificate has been issued regarding the 6,309,215, 6,398,548, 6,705,863, 6,217,325 and 6,318,994 patents and therefore these patents are no longer in reexamination. We are awaiting Reexam Certificates regarding the

6,685,469 and the 5,975,893 patents. We are awaiting a communication from the Patent Office regarding the 6,629,840 patent. The status of USPTO proceedings are as follows:

U.S. Patent No.	Request for Reexamination Granted?	Initial Office Actions Received?	Status
5,975,893	Yes	Yes	On January 26, 2006, a first office action was issued rejecting all claims of U.S. Patent No. 5,975,893 (the '893 patent). We responded to this initial office action. A Final Office Action was issued by the USPTO on June 23, 2006 rejecting the pending claims of Align's response. On August 23, 2006, we filed an amendment and on February 14, 2007 we filed a supplementary amendment each in response to this Final Office Action, which included claims discussed in an interview with the Examiners. On June 27, 2007, we field a supplemental amendment per examiner's recommendations which corrected certain informalities noted by the examiners in a May 22, 2007 interview. We have received a Notice of Intent to Issue an Ex Parte Reexam Certificate dated September 18, 2007.
6,398,548	Yes	Yes	We filed a preliminary amendment and a supplementary preliminary amendment on July 16, 2006 and February 14, 2007, respectively. On June 28, 2007, we filed a supplemental amendment per examiner's recommendations based on a May 22, 2007 interview. An Ex Parte Reexam Certificate was issued on November 20, 2007.
6,309,215	Yes	Yes	On July 27, 2006, after submitting amendments, affidavits, declarations or other documents as evidence of patentability, we received an action entitled "Notice of Intent to Issue Ex Parte Reexamination Certificate" with respect to U.S. Patent No. 6,309,215 (the '215 patent). With this Notice, the USPTO has closed prosecution on the merits in reexamination and affirmed the patentability of all of our claims pending in reexamination in the '215 patent. While the '215 patent entered the reexamination proceedings with 16 claims, 26 additional claims were added in the reexamination by us and the '215 patent leaves the proceedings as a valid and enforceable patent with 42 claims. An Ex Parte Reexamination Certificate was issued on March 20, 2007.
6,705,863	Yes	Yes	We filed a preliminary amendment and a supplementary preliminary amendment on May 26, 2006 and February 14, 2007, respectively. On June 28, 2007, we filed a supplemental amendment per examiner's recommendations based on a May 22, 2007 interview. An Ex Parte Reexam Certificate was issued on January 8, 2008.

6,217,325	Yes	Yes	On July 25, 2006, we received an Office Action in U.S. Patent No. 6,217,325 (the '325 patent) confirming the patentability of 32 claims. While the '325 patent entered the reexamination proceedings with 26 claims, 15 additional claims were added by us in the reexamination. On September 25, 2006, we filed an amendment in response to the final Office Action with respect to the claims that were not allowed. On June 27, 2007, we filed a supplemental amendment per examiner's recommendations based on a May 22, 2007 interview. An Ex Parte Reexam Certificate was issued on January 15, 2008.
6,722,880	No	N/A	On December 23, 2005, in a non-appealable, final Order, the USPTO denied the request for re-examination with respect to all twenty-one claims of U.S. Patent No. 6,722,880 (the '880 patent). Accordingly, the validity of all twenty-one claims of the '880 patent stand reaffirmed by the USPTO. On January 23, 2006, a Petition Seeking Review of Denial of Request for Reexamination of the '880 patent was filed by the same San Francisco, California law firm. The Petition was denied and the denial of the request for Reexamination is final.
6,318,994	Yes	Yes	The USPTO has granted the requests for reexamination of the U.S. Patent No. 6,318,994. On February 15, 2007 we filed a preliminary amendment. We had an interview on this case on May 22, 2007. An Ex Parte Reexam Certificate was issued on November 6, 2007.

Inter Parte Requests made by OrthoClear

As part of the OrthoClear Agreement, OrthoClear agreed to take no further action with respect to the Inter Parte Requests.

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.
6,685,469	Yes	Yes	The USPTO has granted the requests for reexamination of U.S. Patent No. 6,685,469. We received on May 14, 2007 an initial Office Action. We filed a response to this Office Action on July 16, 2007. We have received an Action Closing Prosecution dated September 24, 2007.

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 2007.

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, 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
Year Ended December 31, 2006:		
Fourth quarter	$ 15.03	$ 11.31
Third quarter	$ 11.56	$ 5.66
Second quarter	$ 9.52	$ 7.05
First quarter	$ 9.33	$ 6.08

On February 20, 2008, the closing price of our common stock on the NASDAQ Global Market was $13.00 per share. As of February 20, 2008 there were approximately 202 holders of record of our common stock. Because the majority of our shares of outstanding common stock is held by brokers and other institutions on behalf of stockholders, we are unable to estimate the total number of stockholders represented by these record holders.

We have never declared or paid any cash dividends on our common stock. We currently intend to retain any future earnings to fund the development and growth of our business and do not anticipate paying any cash dividends in the foreseeable future. Our credit facility contains certain restrictive loan covenants, including restrictions on our ability to pay dividends. *See Item 7 "Management's Discussion and Analysis of Financial Condition and Results of Operations Liquidity and Capital Resources".*

Performance Graph

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

The following graph compares the cumulative total stockholder return on our common stock with that of the NASDAQ Stock Market US Index, a broad market index published by the National Association of Securities Dealers, Inc., a peer group that we used from January 2005 until July 2007 and a new peer group that we believe in good faith is a more appropriate basis for comparison since it better 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,
A New Peer Group And An Old Peer Group

In 2007, we completed a review of our peer group and determined that 4 of the original peer group companies had been acquired or were otherwise no longer publicly traded and the former peer group in general no longer was the best reflection of the companies for which we compete for executive talent. As a result, we formed a new peer group for 2007 and 2008. This 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 (generally of comparable size);

medical device companies that are similar in size as measured by revenue and growth rates; and

technology companies with similar growth potential and technology development needs for software and enterprise system designers.

The former peer group consisted of 15 companies listed below.

Old Peer Group

American Medical Systems	Silicon Image	Interwoven
Ariba	Sonosite	Magma Design
ArthroCare	Thoratec	Vignette
Digital Insight	Cantel Medical	
Intuitive Surgical	Altiris	
Kyphon	InPhonic	

New Peer Group

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

We believe that the companies included in the new peer group provide a more accurate representative sample of enterprises that compete in sectors related to the market in which we compete for executive talent.

ITEM 6. SELECTED CONSOLIDATED FINANCIAL DATA

The following discussion and analysis of our selected consolidated financial data should be read together with our consolidated financial statements and related notes included elsewhere in this Annual Report on Form 10-K.

The following tables set forth the selected consolidated financial data for each of the years in the five-year period ended December 31, 2007. 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 58 to 90 and "Management's Discussion and Analysis of Financial Condition and Results of Operations" beginning on page 42. We have derived the statement of operations data for the years ended December 31, 2007, 2006 and 2005 and the balance sheet data as of December 31, 2007 and 2006 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, 2004 and 2003 and the balance sheet data as of December 31, 2005, 2004 and 2003 were derived from the consolidated audited financial statements that are not included in this Annual Report on Form 10-K.

SELECTED CONSOLIDATED FINANCIAL DATA

(in thousands, except per share data)

	Years Ended December 31,				
	2007	**2006**	**2005**	**2004**	**2003**
Consolidated Statement of Operations Data:					
Net revenues	$ 284,332	$ 206,354	$ 207,125	$ 172,830	$ 122,725
Gross profit	$ 209,297	$ 141,579	$ 143,341	$ 115,304	$ 71,160
Profit (loss) from operations(1)	33,855	(37,536)	2,446	9,765	(19,937)
Other income (expense), net	3,095	3,401	283	(3)	(101)
Net profit (loss) before provision for income taxes(1)	36,950	(34,135)	2,729	9,762	(20,038)
Provision for income taxes	1,226	828	1,316	994	84
Net profit (loss)(1)	$ 35,724	$ (34,963)	$ 1,413	$ 8,768	$ (20,122)
Net profit (loss) per share					
Basic	$ 0.53	$ (0.55)	$ 0.02	$ 0.15	$ (0.35)
Diluted	$ 0.50	$ (0.55)	$ 0.02	$ 0.14	$ (0.35)
Shares used in computing net profit (loss) per share:					
Basic	67,176	63,246	61,644	59,963	57,758
Diluted	71,444	63,246	63,152	64,089	57,758

	December 31,				
	2007	**2006**	**2005**	**2004**	**2003**
Consolidated Balance Sheet Data:					
Working capital	$ 123,058	$ 40,306	$ 62,978	$ 61,886	$ 39,737
Total assets	222,761	151,558	142,110	130,712	102,202
Total long-term liabilities	148	219	64	25	1,849
Stockholders' equity	$ 161,154	$ 83,556	$ 93,438	$ 85,739	$ 62,976

(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 includes a $1.8 million credit and a $14.3 million charge, respectively, for the Patients First Program and settlement costs. See *Note 2 "Patients First Program and settlement costs" in the Notes to Consolidated Financial Statements* for additional information.

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

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

Overview

Align Technology, Inc., founded in April 1997, designs, manufactures and markets Invisalign, 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 braces. We received the United States Food and Drug Administration ("FDA") clearance to market Invisalign in 1998, and we began commercial operations and sales of full Invisalign treatment in July 1999.

Each Invisalign treatment plan is unique to the individual patient. Our full Invisalign 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 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, minor crowding and spacing or as a pre-cursor to restorative or cosmetic treatment such as veneers.

A number of factors, the most important of which are set forth below, may affect our results during 2008 and beyond.

Product innovation New products and enhancements to existing products. We believe that product performance and innovation is a cornerstone to our future long-term growth by driving and sustaining product adoption and enhancing the user experience and thereby increasing utilization growth. Currently, the Invisalign system is a single system used by both GPs and orthodontists. We are committed to delivering new products and introducing new product features to better meet the needs of our two customers orthodontists and GPs each with distinct and separate needs. Orthodontists want a more robust set of tools for greater predictability, wider applicability and more flexibility in the use of the Invisalign system. On the other hand, typical GPs want greater ease of use, more efficient and simplified diagnostic tools, guidance through the case set-up process, minimal treatment intervention and self-help tools designed to simplify treatment of cases of mild to moderate malocclusion. Based on this knowledge, we announced the anticipated release of two products Invisalign Teen in the latter half of 2008 and Invisalign ClinAssist in the latter half of 2008 or early 2009. Invisalign Teen will include features such as an aligner wear indicator to help gauge patient compliance and specially engineered aligner features to address the natural eruption of key teeth and root control issues common in teen patients. Predominately 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. Invisalign ClinAssist is the first phase of our GP-specific product platform and is being designed as a turnkey, consultative approach to Invisalign treatment for doctors who want a highly efficient treatment process with built-in monitoring tools and progress tracking. 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 demand for Invisalign. The planned roll out of Invisalign ClinAssist and Invisalign Teen 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. We believe enhanced product performance and innovation will continue to drive the adoption and frequency of use (what we call utilization), and increase customer productivity resulting in increased demand for Invisalign and market share expansion.

However, with the anticipated introduction of Invisalign Teen, our Invisalign product family will for the first time include a product designed to meet the specific needs of the non-adult comprehensive, or teen, treatment market. Specifically, those individuals who have shed their "baby" teeth but do not yet have fully-erupted mature dentition. Teen patients make up the majority of most orthodontists' case starts. As a result, launching a teen-specific product will make the Invisalign system more applicable to an orthodontist's patient base, which we believe we are better positioned to increase our penetration into and our share of the non-adult comprehensive, or teen, treatment market.

Increase customer adoption and utilization. By first increasing adoption through the expansion of our customer base and then increasing utilization by offering new products and feature enhancements to meet the needs of orthodontists and GPs, we believe the overall market for Invisalign and our share of that market will increase. Although we expect that over the long-term our utilization rates will gradually improve, we expect that period over period comparisons of our utilization rates will fluctuate. Our quarterly utilization rates for the years ended December 31, 2007 and 2006 are as follows:

Utilization Rates*

*

Utilization rates = # of cases shipped / # of doctors cases were shipped to

Training new orthodontists and general practitioners. Expanding our customer base through training is a key part of our strategy. Through December 31, 2007, we have trained 27,480 GPs and 8,310 orthodontists in the United States and 12,340 doctors internationally. In addition, 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. In 2007, we trained approximately 7,400 GPs and orthodontists worldwide, and expect to train a comparable amount in 2008. Currently, we have incorporated the Invisalign technique into the curriculum of 38 university programs. We expect additional dental schools to integrate the Invisalign technique into their curricula in the future.

Focus on education and customer support. In order to build long-term relationships with our customers and increase utilization, we focus on providing ongoing training, support and services. In early 2008, we announced the introduction of the Aligntech Institute program brand, which consolidates our extensive clinical education programs under a new interactive website that will provide clinical education and practice development training opportunities for our Invisalign trained doctors. These practice development training opportunities will include instructor-led certification 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. By participating in these events, 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. The cornerstone of our clinical education program is *www.aligntechinstitute.com*, which provides information and registration for our training workshops, conference calls and seminars and provides an extensive range of case studies, best practices, testimonials and online coursework to ensure treatment success and improve practice economics. 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.

Stimulate demand for Invisalign treatment Increasing our patient base. 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 vast majority of people with malocclusion who desire treatment do not elect traditional treatment because of 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 Invisalign treatment annually. In 2008, we expect to increase our overall marketing spending in the United States with a focus on programs such as advertising and digital online media, designed to raise the profile of Invisalign and drive more consumers to our most experienced doctors. We also intend to initiate similar consumer marketing efforts, but on a smaller scale, in key European countries. Similar to 2007, we will continue to conduct advertising and consumer marketing activities involving television, radio, print media and our consumer website in 2008. We anticipate that this increased consumer awareness of Invisalign will increase the demand for our product.

Product mix. During 2007, we experienced a decline in the number of Invisalign Express cases compared to the same period of 2006. We believe that this shift in product mix began in the fourth quarter of 2006 after we removed the cancellation fees on full Invisalign cases prior to ClinCheck approval and clarified clinical protocols surrounding what is an appropriate Invisalign Express case. For the years ended December 31, 2007, 2006 and 2005, our Invisalign revenues as a percentage of total net revenues are as follows:

	Years Ended December 31,		
Revenues By Channel	**2007**	**2006**	**2005**
North American Invisalign:			
Full revenues	71.3%	65.7%	80.9%
Express revenues(1)	7.8%	13.1%	3.4%
Total North American Invisalign revenues	79.1%	78.8%	84.3%
International Invisalign revenues	16.4%	15.6%	11.2%
Other revenues	4.5%	5.6%	4.5%
Total net revenues	100.0%	100.0%	100.0%

(1) Invisalign Express was launched in the third quarter of 2005.

We recently launched Vivera retainers and have announced the planned launch of Invisalign Teen and Invisalign ClinAssist. As a result of and depending upon the timing of these new product launches as well as the timing of customer adoption, we expect our mix of products to begin shifting gradually in the latter part of 2008 and into 2009. Key features of these new products, include staged delivery of aligners with Invisalign ClinAssist and three free replacement aligners will be included in Invisalign Teen. 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 price, compared to our current products. Included in the price of full Invisalign treatment, we offer case refinement, which is a finishing tool used to adjust a patient's teeth to the desired final position. Each of Invisalign Teen and Invisalign ClinAssist include the deferral for case refinement. In addition, however, revenue for the three replacement aligners included in Invisalign Teen will be deferred based on their fair market value until the earlier of replacement aligners being used or until the case is completed. Invisalign ClinAssist will be invoiced upon the first staged shipment and revenue will be deferred to the balance sheet and recognized upon shipment of the final staged shipment. The Vivera retainer subscription includes four shipments per year. Our customers will be invoiced upon the first shipment and revenue will be recognized ratably over the one year subscription period. As these new products increase as a percentage of our revenues in the latter part of 2008, deferred revenue on our balance sheet will increase.

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. We will consider expanding to additional countries on a case-by-case basis. We expect our international revenues to continue to increase in absolute dollars and as a percentage of total net revenues in the foreseeable future.

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 electronic treatment plans. These electronic treatment plans form the basis of ClinCheck and are used to manufacture aligner molds. In addition, we use International Manufacturing Solutions Operaciones, S.R.L. ("IMS"), a third party based in Juarez, Mexico, for the fabrication and packaging of aligners. Our success will depend in part on the efforts and abilities of management to effectively manage these international operations, including our relationship with IMS. In addition, we currently are and will continue to be dependent on IMS's and our ability to hire and retain employees generally, as well as hire and retain employees with the necessary skills to perform the more technical aspects of our operations. If our management or IMS fail 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 treatment forms, or if IMS is 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 Item 1A "Risk Factors" for risks related to our international operations.*

Stock-based compensation. Effective January 1, 2006, we adopted Statement of Financial Accounting Standards No. 123 (Revised 2004), "Share-based Payment" ("FAS 123R") using the modified prospective transition method, which requires the measurement and recognition of compensation expense for all share-based payment awards based on estimated fair values over the requisite service period. In accordance with the modified prospective transition method, our financial statements for the prior periods have not been restated to reflect and do not include

the impact of FAS 123R. For the years ended December 31, 2007 and 2006, stock-based compensation expense recognized in accordance with FAS 123R is as follows (in thousands):

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

Results of Operations

Comparison of Years Ended December 31, 2007, 2006 and 2005:

Net revenues:

Invisalign product revenues by channel and other revenues, which represent training and sales of ancillary products for the years ended December 31, 2007, 2006 and 2005, are as follows:

	Years Ended December 31,						
Net revenues	2007	Change	% Change	2006	Change	% Change	2005
				(in millions)			
North America:							
Ortho full	$ 81.1	$ 22.7	39.0%	$ 58.4	$ (24.3)	(29.4)%	$ 82.7
Ortho Express(1)	9.2	(1.0)	(10.2)%	10.2	7.5	278.8%	2.7
Total Ortho revenues	90.3	21.7	31.7%	68.6	(16.8)	(19.6)%	85.4
GP full	121.5	44.3	57.4%	77.2	(7.6)	(9.0)%	84.8
GP Express(1)	13.0	(3.7)	(22.2)%	16.7	12.4	282.1%	4.3
Total GP revenues	134.5	40.6	43.2%	93.9	4.8	5.3%	89.1
Total North American Invisalign	224.8	62.3	38.3%	162.5	(12.0)	(6.9)%	174.5
International Invisalign	46.6	14.5	45.1%	32.1	8.9	38.3%	23.2
Total Invisalign revenues	271.4	76.8	39.5%	194.6	(3.1)	(1.6)%	197.7
Other revenues	12.9	1.1	10.3%	11.8	2.4	25.6%	9.4
Total net revenues	$ 284.3	$ 77.9	37.8%	$ 206.4	$ (0.7)	(0.4)%	$ 207.1

(1) Invisalign Express was launched in the third quarter of 2005.

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Case volume data which represents Invisalign case shipments by channel, for the years ended December 31, 2007, 2006 and 2005 are as follows:

	Years Ended December 31,						
Invisalign Case Volume	**2007**	**Change**	**% Change**	**2006**	**Change**	**% Change**	**2005**
	(in thousands)						
North America:							
Ortho full	60.5	18.7	44.5%	41.8	(5.3)	(11.1)%	47.1
Ortho Express(1)	12.4	(1.3)	(9.2)%	13.7	10.0	268.5%	3.7
Total Ortho volume	72.9	17.4	31.3%	55.5	4.7	9.2%	50.8
GP full	84.0	31.0	58.6%	53.0	(0.1)	(0.1)%	53.1
GP Express(1)	18.0	(4.4)	(19.7)%	22.4	16.5	280.6%	5.9
Total GP volume	102.0	26.6	35.3%	75.4	16.4	27.9%	59.0
Total North American Invisalign	174.9	44.0	33.6%	130.9	21.1	19.2%	109.8
International Invisalign	28.0	8.8	46.1%	19.2	6.0	45.0%	13.2
Total Invisalign case volume	202.9	52.8	35.2%	150.1	27.1	22.0%	123.0

(1) Invisalign Express was launched in the third quarter of 2005.

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 full Invisalign. This product mix shift towards full Invisalign began in the fourth quarter of 2006 after we removed the cancellation fees on full Invisalign cases prior to ClinCheck approval and clarified clinical protocols surrounding what is an appropriate Invisalign Express case. The increase in full Invisalign revenues is partially offset by a lower average selling price, which is due to the increased participation in our volume-based discount programs.

Revenues from our North American orthodontic channel decreased $16.8 million or 19.6% in 2006 compared to 2005 as a result of a decline in full Invisalign revenues of $24.3 million partially offset by a $7.5 million increase in Invisalign Express revenues. The decline in full Invisalign revenues is attributed to lower average selling prices and case volumes. In 2006 the reduced average selling price of the full Invisalign product reflects the full year impact of pricing initiatives introduced in the second half of 2005, including the reduction in the list price of our full Invisalign product and the expansion of our volume based discount program. Additionally, the increase in Invisalign Express revenue resulted from higher case volumes in 2006 compared to 2005, since this product was launched in the third quarter of 2005.

Revenues from our North American GP channel increased $4.8 million or 5.3% in 2006 compared to 2005 primarily due to an increase in Invisalign Express revenues of $12.4 million partially offset by a $7.6 million decline in full Invisalign revenues. The increase in Invisalign Express revenues resulted from higher case volumes in 2006 compared to 2005, since this product was launched in the third quarter of 2005. The reduction in full Invisalign revenues is attributed to lower average selling prices which reflect the full year impact of the pricing initiatives mentioned above.

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 against the U.S. dollar in 2007. These increases were partially offset by a slight decrease in the average selling price due to the increased participation in volume-based discount programs. International revenues increased $8.9 million or 38.3% in 2006 compared to 2005 primarily due to a significant increase in our international Invisalign case volumes partially offset by a lower average selling price as a result of pricing initiatives introduced in the first quarter of 2006.

Other revenues, consisting of training fees and sales of ancillary products, were higher in 2007 compared to 2006 as a result of an increased number of doctors trained year over year. Other revenues increased during 2006 compared to 2005 primarily from an increase in the list price for training.

For 2008, we expect our total net revenues to increase compared to 2007 primarily due to case volume increases in our North American orthodontic and GP channels, as well as in our international markets. We expect our average selling price in 2008 to be comparable to 2007. We recently launched Vivera retainers and have announced the planned launch of Invisalign Teen and Invisalign ClinAssist. As a result of and depending upon the timing of these new product launches as well as the timing of customer adoption, we expect our mix of products to begin shifting gradually in the latter part of 2008 and into 2009. Key features of these new products include staged delivery of aligners with Invisalign ClinAssist and three free replacement aligners with Invisalign Teen. 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 price, compared to our current products.

Cost of revenues and gross margin:

	Years Ended December 31,				
	2007	Change	2006	Change	2005
	(in millions)				
Cost of revenues	$ 75.0	$ 10.2	$ 64.8	$ 1.0	$ 63.8
% of net revenues	26.4%		31.4%		30.8%
Gross profit	$ 209.3	$ 67.7	$ 141.6	$ (1.7)	$ 143.3
Gross margin %	73.6%		68.6%		69.2%

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 2007 compared to 2006 primarily as a result of increased case volume over our relatively fixed cost structure. Our case volume increased 35.2% in 2007 compared to 2006, resulting in decreases in our per unit standard cost. Additionally, cost reductions resulting from improved operating efficiencies also contributed to the increase in 2007 gross margin.

Gross margin decreased in 2006 compared to 2005 primarily due to lower average selling prices attributable to the reduction in the list price of full Invisalign and increased sales of our lower priced Invisalign Express product. This decrease was partially offset by the reductions in product costs driven by increased volumes and manufacturing efficiencies including the relocation of the SLA mold operations to Juarez, Mexico.

We anticipate our gross margin in 2008 to be comparable to 2007.

Sales and marketing:

	Years Ended December 31,				
	2007	Change	2006	Change	2005
	(in millions)				
Sales and marketing	$ 98.2	$ 16.2	$ 82.0	$ 1.9	$ 80.1
% of net revenues	34.5%		39.7%		38.7%

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.

Our sales and marketing expense increased during 2007 compared to 2006 predominately as a result of a $10.3 million increase in media, advertising and product marketing expenses and a $5.1 million increase in personnel-related expenses. The increase in personnel-related expenses primarily resulted from a $3.7 million increase in salaries, benefits and overhead attributable to additional headcount and a $1.4 million increase in stock-based compensation.

Sales and marketing expense increased in 2006 compared to 2005 primarily due to a $2.8 million increase in payroll expense mainly attributable to an increase in headcount, including the replacement of orthodontic sales representatives who left Align in the first half of 2005, and a $2.9 million increase in stock-based compensation expense. These increases were partially offset by a $3.9 million decrease in media, advertising and other marketing expenses due to the initial launch of our consumer marketing campaign in the second quarter of 2005.

For 2008, we expect sales and marketing expense, including stock-based compensation, to be higher than in 2007, as we expanded our North American sales force in late 2007 and anticipate expanding our international sales force in 2008. In addition, we expect to increase marketing spending in the United States and Europe with a focus on consumer advertising, including television, digital online, and print media, and we will incur additional costs in the United States related to bringing new products to market, such as Vivera, Invisalign Teen and Invisalign ClinAssist.

General and administrative:

	Years Ended December 31,				
	2007	Change	2006	Change	2005
	(in millions)				
General and administrative	$ 53.3	$ (11.0)	$ 64.3	$ 22.1	$ 42.2
% of net revenues	18.7%		31.2%		20.4%

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

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. Our 2007 legal expense includes 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 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.

General and administrative expense increased in 2006 compared to 2005 primarily due to a $15.0 million increase in external legal fees primarily related to the OrthoClear litigation, a $3.8 million increase in payroll related expenses primarily resulting from the hiring of additional legal and administrative staff, and a $4.0 million increase in stock-based compensation expense.

For 2008, we expect general and administrative expense, including stock-based compensation, to be higher than 2007 as we continue to build our information technology infrastructure and focus on training and organizational development.

Research and development:

	Years Ended December 31,				
	2007	Change	2006	Change	2005
	(in millions)				
Research and development	$ 25.7	$ 7.2	$ 18.5	$ (0.1)	$ 18.6
% of net revenues	9.0%		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 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.

Research and development expense decreased slightly in 2006 compared to 2005, primarily due to a $1.4 million decrease in temporary services and outside consulting expenses partially offset by a $1.3 million increase in stock-based compensation expense.

For 2008, we expect research and development spending to increase from 2007 as we continue to invest in bringing new products to market, conducting clinical research and focusing on product development and enhancements.

Patients First Program and settlement costs:

	Years Ended December 31,				
	2007	Change	2006	Change	2005
	(in millions)				
Patients First Program	$ (1.8)	$ (10.1)	$ 8.3	$ 8.3	$
Settlement costs		(6.0)	6.0	6.0	
Total Patients First Program and settlement costs	$ (1.8)	$ (16.1)	$ 14.3	$ 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". We received no revenue for the program, and incurred significant expense to complete these cases. In the fourth quarter of 2006, we recorded an $8.3 million charge for the anticipated costs of completing this program in accordance with FASB Statement No. 5, "Accounting for Contingencies" ("FAS 5"). This estimated amount was based on the number of OrthoClear cases registered under the Patients First Program as of December 31, 2006. In accordance with the Patients First Program terms and conditions, those registered cases were required to be received by March 30, 2007. 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 virtually all Patients First Program cases during the first half of 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,				
	2007	Change	2006	Change	2005
	(in millions)				
Interest income	$ 4.2	$ 1.0	$ 3.2	$ 1.3	$ 1.9
Interest expense	(0.3)		(0.3)	(0.2)	(0.1)
Other income (expense), net	(0.8)	(1.3)	0.5	2.0	(1.5)
Total interest and other income(expense), net	$ 3.1	$ (0.3)	$ 3.4	$ 3.1	$ 0.3

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 for the year ended December 31, 2007 increased compared to 2006 primarily due to higher average cash, cash equivalents and marketable securities balances in 2007. The increase in 2006 interest income compared to 2005 was attributable to higher effective interest rates.

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.

Other income (expense), net, increased $2.0 million in 2006 compared to 2005, primarily due to a $2.1 million increase in foreign currency translation gains resulting primarily from the remeasurement of foreign currency denominated assets and liabilities.

Income tax provision:

	Years Ended December 31,				
	2007	Change	2006	Change	2005
	(in millions)				
Provision for income taxes	$ (1.2)	$ (0.4)	$ (0.8)	$ 0.5	$ (1.3)

We recorded an income tax provision of $1.2 million for 2007, $0.8 million for 2006 and $1.3 million for 2005, representing effective tax rates of 3.3%, (2.4)%, and 48.2%, respectively. As of December 31, 2007, we have recorded a full valuation allowance for our existing deferred tax assets due to uncertainties about whether we will be able to utilize these assets before they expire. As a result, 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 exercise 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 tax benefit from deferred tax assets. We have historically experienced operating losses and have significant net operating loss and tax credit carryforwards. We have considered our future taxable income and tax planning strategies in assessing our valuation allowance. Future taxable income is based upon our estimates, and actual results may significantly differ from these estimates. If in the future we determine that we would be able to realize our deferred tax assets in excess of the net amount recorded, we would record an adjustment to the deferred tax asset and valuation allowance,

increasing income in the period such determination was made. Subsequently, we would record a tax provision that approximates the blended statutory tax rate.

At December 31, 2007, we had net operating loss carryforwards of approximately $218.3 million for federal tax purposes and $68.3 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 $7.6 million as of December 31, 2007 and will be accounted for as a credit to additional paid-in capital, if and when realized through a reduction in income taxes 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, 2007 and our current estimate of the annual limitation, we do not expect our net operating loss carryforwards to be limited. At December 31, 2007, we had research credit carryforwards of approximately $4.2 million for federal purposes and $5.3 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, 2007 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, 2007, 2006 and 2005, we had the following cash and cash equivalents, restricted cash and short-term investments:

	Years Ended December 31,		
	2007	2006	2005
	(in thousands)		
Cash and cash equivalents	$ 89,119	$ 55,113	$ 74,219
Restricted cash	21	93	150
Short-term investments	38,771	8,931	
Total	$ 127,911	$ 64,137	$ 74,369

Net cash provided by operating activities for the year ended 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 $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 $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 provided by financing activities was $17.5 million for the year ended December 31, 2007, which 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 2007, we paid $0.4 million of taxes related to RSUs that vested during the period for executive officers.

On March 7, 2007, we renegotiated and amended our existing credit facility with Comerica Bank. The amendment, among other things, reduced financial covenants to require only a quick ratio covenant. Effective January 1, 2008, the amendment automatically increased the available borrowings under the existing revolving line of credit from $20 million to $25 million. The amended credit facility matures on December 31, 2008 at which point all outstanding borrowings on this credit facility must be repaid. During 2007, we repaid $11.5 million of our outstanding borrowings under this credit facility. As of December 31, 2007, we have no outstanding borrowings under this credit facility and we are in compliance with the financial covenant of this credit facility.

Contractual Obligations / Off Balance Sheet Arrangements

The impact that our contractual obligations as of December 31, 2007 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	$ 6,002	$ 2,554	$ 2,587	$ 861	$
Computer support services	1,683	760	923		
Total	$ 7,685	$ 3,314	$ 3,510	$ 861	$

We had no off-balance sheet arrangements as defined in Regulation S-K Item 303(a) (4) as of December 31, 2007.

We expect that our expense levels for 2008 will be higher compared to 2007 due to increases in our level of business activity. We expect to increase sales and marketing spending as we expand our sales force and focus on consumer advertising and the launch of new products. In addition, we expect to incur additional research and development costs as we continue to invest in product development

and enhancements. We also expect increases in our general and administrative expenses as we continue to enhance our information technology infrastructure and business applications. In addition, we may use cash to fund acquisitions of complementary businesses or technologies. Our capital requirements depend on market acceptance of our products and our ability to market, sell and support our products on a worldwide basis.

We believe that our current cash and cash equivalents combined with our existing borrowing capacity will be sufficient to fund our operations for at least the next 12 months. If we are unable to generate adequate operating cash flows, we may need to seek additional sources of capital through equity or debt financing, collaborative or other arrangements with other companies, bank financing and other sources in order to realize our objectives and to continue our operations. There can be no assurance that we will be able to obtain additional debt or equity financing on terms acceptable to us, or at all. If adequate funds are not available, we may need to make business decisions that could adversely affect our operating results such as modifications to our pricing policy, business structure or operations. Accordingly, the failure to obtain sufficient funds on acceptable terms when needed could have a material adverse effect on our business, results of operations and financial condition.

Critical Accounting Policies and Estimates

Management's discussion and analysis of our financial condition and results of operations is based upon our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of financial statements requires our management to make estimates and judgments that affect the reported amounts of assets and liabilities, revenues and expenses and disclosures at the date of the financial statements. We evaluate our estimates on an on-going basis, including those related to revenue recognition, stock-based compensation and income taxes. We use authoritative pronouncements, historical experience and other assumptions as the basis for making estimates. Actual results could differ from those estimates.

We believe the following critical accounting policies and estimates affect our more significant judgments used in the preparation of our consolidated financial statements.

Revenue Recognition

We enter into arrangements to sell products and services that contain multiple elements or multiple deliverables of products in the future. Revenues are recognized when persuasive evidence of an arrangement exists, delivery has occurred or services have been rendered, the price is fixed or determinable, and collectibility is reasonably assured. Revenues are recognized from product sales, net of discounts and rebates. Service revenues are recorded when performance is completed. For revenue arrangements with multiple elements, we use verifiable objective evidence of fair value to allocate revenue to the undelivered elements and recognize the residual revenue for the delivered items upon shipment. Revenues for the undelivered elements are deferred based on a historical utilization rate, or breakage factor, and are recognized when delivery occurs. Actual utilization rates could differ from the historical breakage factor requiring future adjustments to revenue. In addition, changes to the elements in an arrangement and the ability to establish objective and reliable evidence of fair value for those elements could affect the timing of revenue recognition but would not change the total revenue recognized.

Stock-based Compensation Expense

Effective January 1, 2006, we adopted the fair value recognition provisions of Statement of Financial Accounting Standards ("FAS") No. 123 (revised 2004), "Share-Based Payment" ("FAS 123R"), using the modified prospective transition method, and therefore have not restated prior periods' results. Under this method, we recognize stock-based compensation expense for all share-based

payment awards granted after January 1, 2006 and granted prior to but not yet vested as of December 31, 2005, in accordance with FAS 123R. Under the fair value recognition provisions of FAS 123R, we recognize stock-based compensation expense net of an estimated forfeiture rate and recognize compensation cost for only those shares ultimately expected to vest on a straight-line basis over the requisite service period of the award. Prior to FAS 123R adoption, we accounted for share-based payment awards under Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees" ("APB 25") and, accordingly, recognized compensation expense only when we granted options with a discounted exercise price. In conjunction with the adoption of FAS 123R, we changed our method of attributing the value of stock-based compensation expense from the accelerated multiple-option approach to the straight-line single option method.

We estimate the fair value of stock options using a Black-Scholes valuation model, consistent with the provisions of FAS 123R and the SEC issued Staff Accounting Bulletin No. 107 ("SAB 107"). Option-pricing models require the input of highly subjective assumptions, including the option's expected term and stock price volatility. In addition, judgment is also required in estimating the number of stock- based awards that are expected to be forfeited. Forfeitures are estimated based on historical experience at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. The assumptions used in calculating the fair value of share-based payment awards represent management's best estimates, but these estimates involve inherent uncertainties and the application of management's judgment. As a result, if factors change and we use different assumptions, our stock-based compensation expense could be materially different in the future. *See Note 9 "Stockholders' Equity" in the Notes to Consolidated Financial Statements for additional information.*

On October 6, 2005, the Compensation Committee of the Board of Directors approved the acceleration of the vesting for all unvested stock options with exercise prices greater than $7.10. Options held by non-employee directors were excluded from the vesting acceleration. The fair market value of our common stock on the date of acceleration was $6.41 as quoted on the NASDAQ Global Market. As a result of the acceleration, approximately 3.8 million options or 35% of the then total outstanding options became immediately exercisable as of October 6, 2005. The purpose of the acceleration was to eliminate future compensation expense we would otherwise recognize in our statement of operations with respect to these accelerated options upon the adoption of FAS 123R.

Long-lived assets, including finite lived purchased intangible assets

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. Intangible 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. No intangible asset impairment was recorded for the periods presented.

Deferred Tax Valuation Allowance

We have established a full valuation allowance because we believe the realization of our deferred tax assets is not likely. Deferred tax assets and liabilities are based on temporary differences that result from differing treatments of certain items for tax and accounting purposes. These differences result in

deferred tax assets and liabilities. We must then assess the likelihood that our deferred tax assets will be realized. To the extent we believe that realization is not likely, we establish a valuation allowance.

We exercise 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 tax benefit from deferred tax assets. We have historically experienced operating losses and have significant net operating loss and tax credit carryforwards. We have considered our future taxable income and tax planning strategies in assessing our valuation allowance. Future taxable income is based upon our estimates, and actual results may significantly differ from these estimates. If in the future we determine that we would be able to realize our deferred tax assets in excess of the net amount recorded, we would record an adjustment to the deferred tax asset and valuation allowance, increasing income in the period such determination was made.

Recent Accounting Pronouncements

See Note 1 "Summary of Significant Accounting Policies" in the Notes to Consolidated Financial Statements in Item 8 for a full description of recent accounting pronouncements, including the expected dates of adoption and estimated effects on results of operations and financial condition, which is incorporated herein.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

Interest Rate Risk

Changes in interest rates could impact our anticipated interest income on our cash equivalents and investments in marketable securities. Our cash equivalents and investments are in fixed-rate, short-term securities. Fixed-rate securities may have their fair market value adversely impacted due to a rise in interest rates, and as a result, our future investment income may fall short of expectations due to changes in interest rates or we may suffer losses in principal if forced to sell securities which have declined in market value due to changes in interest rates. As of December 31, 2007, we had $38.8 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, 2007 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.

ITEM 8. CONSOLIDATED FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Quarterly Results of Operations

	Three Months Ended							
	2007				2006			
	Dec 31	Sep 30	Jun 30	Mar 31	Dec 31	Sep 30	Jun 30	Mar 31
	(in thousands, except per share data)							
	(unaudited)							
Net revenues	$ 72,517	$ 71,451	$ 76,603	$ 63,761	$ 55,191	$ 49,034	$ 53,221	$ 48,908
Gross profit	53,390	53,319	56,356	46,232	37,994	32,245	36,729	34,611
Profit (loss) from operations(1)	5,012	8,395	13,448	7,000	(18,067)	(10,965)	(3,291)	(5,213)
Net profit (loss)(1)	$ 5,668	$ 9,460	$ 13,618	$ 6,978	$ (17,269)	$ (10,320)	$ (2,610)	$ (4,764)
Net profit (loss) per share:								
Basic	$ 0.08	$ 0.14	$ 0.20	$ 0.11	$ (0.27)	$ (0.16)	$ (0.04)	$ (0.08)
Diluted	$ 0.08	$ 0.13	$ 0.19	$ 0.10	$ (0.27)	$ (0.16)	$ (0.04)	$ (0.08)
Shares used in computing net profit (loss) per share:								
Basic	68,562	67,970	66,696	65,433	64,252	63,230	62,966	62,518
Diluted	71,864	72,230	71,207	69,331	64,252	63,230	62,966	62,518

(1) March 2007 and December 2006 profit (loss) from operations and net profit (loss) includes a $1.8 million credit and a $14.3 million charge, respectively, for the Patients First Program and settlement costs. *See Note 2 "Patients First Program and settlement costs" in the Notes to Consolidated Financial Statements for additional information.*

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Invisalign, Align, ClinCheck, Invisalign ClinAssist, Invisalign Teen and Vivera, amongst others, are trademarks belonging to Align Technology, Inc. and are pending or registered in the United States and other countries.

REPORT OF MANAGEMENT ON INTERNAL CONTROL OVER FINANCIAL REPORTING

Management of Align is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934. Align's internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. Internal control over financial reporting includes those policies and procedures that:

pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company;

provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and

provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. In addition, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions and that the degree of compliance with the policies or procedures may deteriorate.

Management assessed the effectiveness of Align's internal control over financial reporting as of December 31, 2007. In making this assessment, management used the criteria set forth in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

Based on its assessment and those criteria, management has concluded that, as of December 31, 2007, Align's internal control over financial reporting was effective to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles.

The Company's internal control over financial reporting as of December 31, 2007 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report which is included herein, which expresses an unqualified opinion on the effectiveness of the Company's internal control over financial reporting as of December 31, 2007.

/s/ THOMAS M. PRESCOTT

Thomas M. Prescott
President and Chief Executive Officer

February 26, 2008

/s/ KENNETH B. AROLA

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

February 26, 2008

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

In our opinion, the consolidated financial statements listed in the index under item 15(a)(1) present fairly, in all material respects, the financial position of Align Technology, Inc. and its subsidiaries at December 31, 2007 and 2006, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2007 in conformity with accounting principles generally accepted in the United States of America. In addition, in our opinion, the financial statement schedule listed in the accompanying index appearing under item 15(a)(2) presents fairly, in all material respects, the information set forth therein when read in conjunction with the related consolidated financial statements. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2007, based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for these financial statements and financial statement schedule, for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express opinions on these financial statements, on the financial statement schedule, and on the Company's internal control over financial reporting based on our integrated audits. We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

As discussed in Note 9 to the Consolidated Financial Statements, effective January 1, 2006, the Company changed the manner in which it accounts for stock-based compensation.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ PricewaterhouseCoopers LLP
San Jose, CA
February 26, 2008

ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per share data)

	Years Ended December 31,		
	2007	**2006**	**2005**
Net revenues:			
Invisalign	$ 271,350	$ 194,582	$ 197,749
Ancillary products and other services	12,982	11,772	9,376
Total net revenues	284,332	206,354	207,125
Cost of revenues:			
Invisalign	65,490	55,759	54,549
Ancillary products and other services	9,545	9,016	9,235
Total cost of revenues	75,035(1)	64,775(1)	63,784
Gross profit	209,297	141,579	143,341
Operating expenses:			
Sales and marketing	98,231	81,993	80,068
General and administrative	53,280	64,305	42,242
Research and development	25,727	18,474	18,585
Patients First Program and settlement costs	(1,796)	14,343	
Total operating expenses	175,442(1)	179,115(1)	140,895
Profit (loss) from operations	33,855	(37,536)	2,446
Interest income	4,195	3,179	1,918
Interest expense	(342)	(296)	(110)
Other income (expense)	(758)	518	(1,525)
Net profit (loss) before provision for income taxes	36,950	(34,135)	2,729
Provision for income taxes	1,226	828	1,316
Net profit (loss)	$ 35,724	$ (34,963)	$ 1,413
Net profit (loss) per share:			
Basic	$ 0.53	$ (0.55)	$ 0.02
Diluted	$ 0.50	$ (0.55)	$ 0.02
Shares used in computing net profit (loss) per share:			
Basic	67,176	63,246	61,644
Diluted	71,444	63,246	63,152

(1)

Amounts for the years ended December 31, 2007 and 2006 include stock-based compensation expense recognized under FAS 123R for stock options, restricted stock units and employee stock purchases (*See Note 9 "Stockholders' Equity" in the Notes to Consolidated Financial Statements*). The Company recognized $12.2 million total stock-based compensation in 2007 of which $1.0 million was included in cost of revenues and $11.2 million was included in operating expenses. The Company recognized $8.9 million total stock-based compensation in 2006 of which $0.7 million was included in cost of revenues and $8.2 million was included in operating expenses.

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

ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

(in thousands, except per share data)

	December 31,	
	2007	**2006**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 89,119	$ 55,113
Restricted cash	21	93
Marketable securities, short-term	38,771	8,931
Accounts receivable, net of allowance for doubtful accounts of $760 and $844, respectively	44,850	33,635
Inventories, net	2,910	3,090
Prepaid expenses and other current assets	8,846	7,227
Total current assets	184,517	108,089
Property and equipment, net	25,320	26,904
Goodwill	478	478
Intangible assets, net	10,615	13,824
Other assets	1,831	2,263
Total assets	$ 222,761	$ 151,558
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Line of credit	$	$ 11,500
Accounts payable	9,222	5,034
Accrued liabilities	39,875	40,307
Deferred revenues	12,362	10,942
Total current liabilities	61,459	67,783
Other long-term liabilities	148	219
Total liabilities	61,607	68,002
Commitments and contingencies (Notes 6 and 8)		
Stockholders' equity:		
Preferred stock, $0.0001 par value (5,000 shares authorized; none issued)		
Common stock, $0.0001 par value (200,000 shares authorized; 68,682 and 64,899 shares issued, respectively; 68,642 and 64,859 shares outstanding, respectively)	7	6
Additional paid-in capital	450,140	408,921
Accumulated other comprehensive income, net	657	3
Accumulated deficit	(289,650)	(325,374)
Total stockholders' equity	161,154	83,556
Total liabilities and stockholders' equity	$ 222,761	$ 151,558

	December 31,	

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

ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

For the years ended December 31, 2007, 2006 and 2005

(in thousands)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total
	Shares	Amount				
Balances at December 31, 2004	60,876	$ 6	$ 377,559	$ (2)	$ (291,824)	$ 85,739
Net profit					1,413	1,413
Net change in unrealized gain from available-for sale securities				9		9
Comprehensive net income						1,422
Issuance of common stock relating to employee stock purchase plan	374		2,167			2,167
Issuance of common stock upon exercise of stock options	830		3,417			3,417
Tax benefits from exercises of stock options			581			581
Charge for compensation expense on non-employee stock options			45			45
Charge for accelerated vesting of employee stock options			67			67
Balances at December 31, 2005	62,080	$ 6	$ 383,836	$ 7	$ (290,411)	$ 93,438
Net loss					(34,963)	(34,963)
Net change in unrealized loss from available-for sale securities				(4)		(4)
Comprehensive net loss						(34,967)
Issuance of common stock relating to employee stock purchase plan	462		2,583			2,583
Issuance of common stock upon exercise of stock options	2,317		13,592			13,592
Stock-based compensation			8,910			8,910
Balances at December 31, 2006	64,859	$ 6	$ 408,921	$ 3	$ (325,374)	$ 83,556
Net profit					35,724	35,724
Net change in cumulative translation adjustment				703		703
Net change in unrealized loss from available-for sale securities				(49)		(49)
Comprehensive net income						36,378
Issuance of common stock relating to employee stock purchase plan	580		3,434			3,434
Issuance of common stock upon exercise of stock options	3,048	1	25,558			25,559
Issuance of common stock in settlement of restricted stock units, net of shares withheld for employees' taxes	155		(433)			(433)

	Common Stock			Accumulated Other Comprehensive Income (Loss)		
Excess tax benefit from share-based payment arrangements			449			449
Stock-based compensation			12,211			12,211
Balances at December 31, 2007	68,642	$ 7	$ 450,140	$ 657	$ (289,650)	$ 161,154

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

ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

	Years Ended December 31,		
	2007	**2006**	**2005**
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net profit (loss)	$ 35,724	$ (34,963)	$ 1,413
Adjustments to reconcile net profit (loss) to net cash provided by (used in) operating activities:			
Depreciation and amortization	10,176	9,279	10,099
Stock-based compensation	12,211	8,910	112
Amortization of intangibles	3,209	992	352
Provision for doubtful accounts	46	(288)	503
Loss on retirement, disposal and impairment of fixed assets	24	40	92
Excess tax benefit from share-based payment arrangements	(449)		
Changes in assets and liabilities, net of acquisition effect:			
Accounts receivable	(10,703)	(4,042)	(985)
Inventories	186	(160)	(78)
Prepaid expenses and other current assets	(1,480)	(2,245)	229
Accounts payable	2,738	2,997	(1,998)
Accrued and other long-term liabilities	(295)	11,255	6,485
Deferred revenues	1,390	(5,805)	(145)
Net cash provided by (used in) operating activities	52,777	(14,030)	16,079
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchase of property and equipment	(7,429)	(10,028)	(13,801)
Proceeds from sale of property and equipment		366	
Restricted cash	77	57	153
Purchase of marketable securities	(64,686)	(18,416)	(2,217)
Maturities of marketable securities	34,797	9,481	2,226
Payments for acquisition, net of cash acquired			(856)
Purchase of intangible assets		(14,000)	
Other assets	462	(211)	(760)
Net cash used in investing activities	(36,779)	(32,751)	(15,255)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from issuance of common stock	28,993	16,175	5,585
Proceeds from line of credit		15,000	
Payments on line of credit	(11,500)	(3,500)	(1,667)
Payments on capital lease obligations			(182)
Excess tax benefit from share-based payment arrangements	449		
Employees' taxes paid upon the vesting of restricted stock units	(433)		
Net cash provided by financing activities	17,509	27,675	3,736
Effect of foreign exchange rate changes on cash and cash equivalents	499		
Net increase (decrease) in cash and cash equivalents	34,006	(19,106)	4,560
Cash and cash equivalents, beginning of year	55,113	74,219	69,659
Cash and cash equivalents, end of year	$ 89,119	$ 55,113	$ 74,219

	Years Ended December 31,		

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

ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 1. Summary of Significant Accounting Policies

Business Description

Align Technology, Inc. ("Align" or the "Company") was incorporated in April 1997 and is engaged in the development, manufacturing and marketing of Invisalign, used for treating malocclusion, or the misalignment of teeth. Invisalign uses a series of clear plastic aligners to move the patients' teeth in small increments from their original state to a final treated state.

Basis of presentation and preparation

The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries after elimination of intercompany transactions and balances.

Use of estimates and reclassifications

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires the Company's management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. Actual results could differ materially from those estimates. Certain reclassifications have been made to prior period reported amounts to conform to the current year presentation. These reclassifications had no impact on previously reported results of operations or financial position.

Fair value of financial instruments

The carrying amounts of the Company's cash and cash equivalents, accounts receivable, accounts payable and other current liabilities approximate the fair value. The carrying value of marketable securities approximates their fair value as determined by market quotes. Based on borrowing rates currently available to the Company for debt with similar terms, the carrying value of its debt obligations approximates fair value.

Cash equivalents and marketable securities

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

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

ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 1. Summary of Significant Accounting Policies (Continued)

Restricted cash

The Company's restricted cash as of December 31, 2007 and 2006 was $21,000 and $93,000, respectively, and was primarily comprised of a security deposit for a leasing arrangement in Europe.

Foreign currency

The Company accounts for both the translation and remeasurement of balance sheet and income statement items into the U.S. dollar in accordance with Statement of Financial Accounting Standards No. 52, "Foreign Currency Translation" ("FAS 52"). The Company analyzes the functional currency for each of its international subsidiaries on an annual basis, or more often if necessary, to determine if a significant change in facts and circumstances indicate that the primary economic currency has changed.

During the first quarter of 2007, the Company analyzed the various economic factors of its international subsidiaries 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 its 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 to the U.S. dollar was recorded as a separate component of accumulated other comprehensive income, net in the stockholders' equity section of the Consolidated Balance Sheets. This foreign currency translation adjustment reflects the translation of the balance sheet at period end exchange rates, and the income statement at an average exchange rate in effect during the period. As of December 31, 2007, the Company had $0.7 million in accumulated other comprehensive income, net related to the translation of its foreign subsidiaries' financial statements. See *Note 13 "Comprehensive Income (Loss)" in the Notes to Consolidated Financial Statements* for additional disclosures.

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

For the years ended December 31, 2007, 2006 and 2005, the Company included in other income (expense) a loss of $0.1 million, a gain of $1.1 million, and a loss of $1.0 million, respectively.

Certain risks and uncertainties

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

Financial instruments which potentially expose the Company to concentrations of credit risk consist primarily of cash equivalents, marketable securities and accounts receivable. The Company invests excess cash primarily in money market funds of major financial institutions, commercial paper and notes. If the carrying value of the Company's investments exceeds the fair value, and the decline in fair

ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 1. Summary of Significant Accounting Policies (Continued)

value is deemed to be other-than-temporary, the Company will be required to write down the value of its investments, which could materially harm the Company's results of operations and financial condition. Moreover, the performance of certain securities in the Company's investment portfolio correlates with the credit condition of the U.S. financial sector. With the current unstable credit environment, the Company might incur significant realized, unrealized or impairment losses associated with these investments. The Company provides credit to customers in the normal course of business. Collateral is not required for accounts receivable, but ongoing evaluations of customers' credit worthiness are performed. The Company maintains reserves for potential credit losses and such losses have been within management's expectations. No individual customer accounted for 10% or more of the Company's accounts receivable at December 31, 2007 and 2006, or net revenues in 2007, 2006 and 2005.

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

The Company has manufacturing operations located outside the United States of America. The Company currently relies on its manufacturing facilities in Costa Rica to create virtual treatment plans with the assistance of sophisticated software. In addition, the Company relies on a third party shelter services provider in Juarez, Mexico to fabricate aligners and to ship the completed product to the Company's customers. The Company's reliance on international operations exposes it to related risks and uncertainties, including difficulties in staffing and managing international operations; controlling quality of manufacture; political, social and economic instability; interruptions and limitations in telecommunication services; product and material transportation delays or disruption; trade restrictions and changes in tariffs; import and export license requirements and restrictions; fluctuations in foreign currency exchange rates; and potential adverse tax consequences. If any of these risks materialize, the Company's international manufacturing operations, as well as its operating results, may be harmed.

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

Inventories

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

Property and equipment

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

ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 1. Summary of Significant Accounting Policies (Continued)

Development costs for internal use software

Costs relating to internal use software are accounted for in accordance with the provisions of Statement of Position 98-1, Accounting for the Costs of Computer Software Developed or Obtained for Internal Use ("SOP 98-1"). As of December 31, 2007 and 2006 capitalized internal use software at cost was $5.0 million and $4.7 million, respectively. The associated accumulated amortization was $4.4 million and $3.5 million as of December 31, 2007 and 2006, respectively. Capitalized software costs are amortized over the estimated useful lives of three years.

Goodwill

Goodwill represents the excess of the purchase price paid over the fair value of tangible and identifiable intangible net assets acquired in business combinations. Goodwill is reviewed annually in the fourth quarter and whenever events or circumstances occur which indicate that goodwill might be impaired.

Long-lived assets, including finite lived purchased intangible assets

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

The Company performs 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 acquired assets or the strategy for its business, significant negative industry or economic trends, or a significant decline in the Company's 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. No intangible asset impairment was recorded for the periods presented.

Product Warranty

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

Allowance for Doubtful Accounts

The Company maintains an allowance for doubtful accounts for estimated losses resulting from the inability of the Company's customers to make payments. The Company periodically reviews these allowances, including an analysis of the customers' payment history and information regarding the

ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 1. Summary of Significant Accounting Policies (Continued)

customers' creditworthiness. Actual write-offs have not materially differed from the estimated allowance.

Revenue Recognition

Align recognizes revenue in accordance with SEC Staff Accounting Bulletin No. 104 "Revenue Recognition" ("SAB 104"), and Emerging Issues Task Force 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.

Align enters into arrangements that involve multiple product deliveries in the future. Included in the price of a full Invisalign treatment, the Company offers case refinement, which is a finishing tool used to adjust a patient's teeth to the final desired position. Case refinement may be elected by the dental professional in the last stages of orthodontic treatment. The Company uses vendor specific objective evidence of fair value to allocate revenue to the case refinement deliverable and recognizes the residual revenue for full Invisalign upon shipment. Through June 2005, Align deferred the fair value of case refinement for each full Invisalign case shipped. For these full Invisalign cases, case refinement revenue is recognized upon shipment or case expiration, whichever occurs earlier. A full Invisalign case is deemed expired six months after the expected end of treatment. Since the third quarter of fiscal 2005, Align defers the fair value of case refinement upon shipment of full Invisalign based on a breakage factor, which is determined by sufficient historical experience of case refinement utilization. The Company believes 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. The Company has seen no material changes in the breakage factor in the reporting periods presented.

The Company estimates and records a provision for amounts of estimated losses on sales, if any, in the period such sales occur. Provisions for discounts and rebates to customers are provided for in the same period that the related product sales are recorded based upon historical discounts and rebates.

Shipping and Handling Costs

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

Research and development

Research and development costs are expensed as incurred.

Advertising costs

The cost of advertising and media is expensed as incurred. For the years ended December 31, 2007, 2006 and 2005 advertising costs totaled $15.9 million, $9.2 million and $11.3 million, respectively.

ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 1. Summary of Significant Accounting Policies (Continued)

Income taxes

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

On January 1, 2007, the Company adopted the provision of Financial Accounting Standards Board ("FASB") Interpretation No. 48, "Accounting for Uncertain Income Taxes An Interpretation of FASB Statement No. 109" ("FIN 48"). FIN 48 clarifies the accounting for uncertainty in income taxes recognized in an entity's financial statements in accordance with FASB Statement No. 109, "Accounting for Income Taxes" ("FAS 109") and prescribes a recognition threshold and measurement attributes for financial statement disclosure of tax positions taken or expected to be taken on a tax return. Under FIN 48, the impact of an uncertain income tax position on the income tax return must be recognized at the largest amount that is more-likely-than-not to be sustained upon audit by the relevant taxing authority. An uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained. Additionally, FIN 48 provides guidance on de-recognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. The adoption of FIN 48 had no impact on the Company's consolidated financial position, results of operations or cash flows for the year ended December 31, 2007.

Stock-based compensation

Effective January 1, 2006, the Company adopted the fair value recognition provisions of Statement of Financial Accounting Standards ("FAS") No. 123 (revised 2004), "Share-Based Payment" ("FAS 123R"), using the modified prospective transition method, and therefore has not restated prior periods' results. Under this method, the Company recognizes stock-based compensation expense for all share-based payment awards granted after January 1, 2006 and granted prior to but not yet vested as of December 31, 2005, in accordance with FAS 123R. Under the fair value recognition provisions of FAS 123R, stock-based compensation expense is recognized net of an estimated forfeiture rate and only for those shares ultimately expected to vest on a straight-line basis over the requisite service period of the award. Prior to FAS 123R adoption, the Company accounted for share-based payment awards under Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees" ("APB 25"). In conjunction with the adoption of FAS 123R, the Company changed its method of attributing the value of stock-based compensation expense from the accelerated multiple-option method to the straight-line single option method.

The Company estimates the fair value of stock options using a Black-Scholes valuation model, consistent with the provisions of FAS 123R and the SEC issued Staff Accounting Bulletin No. 107 ("SAB 107"). Option-pricing models require 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 were 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

ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 1. Summary of Significant Accounting Policies (Continued)

uncertainties and the application of management's judgment. As a result, if factors change and the Company uses different assumptions, stock-based compensation expense could be materially different in the future. See *Note 9 "Stockholders' Equity" in the Notes to Consolidated Financial Statements* for additional information.

In November 2005, the Financial Accounting Standards Board ("FASB") issued FASB Staff Position No. FAS 123(R)-3, "Transition Election Related to Accounting for Tax Effects of Share-Based Payment Awards" ("FSP 123R-3"). The Company has elected to adopt the alternative transition method provided in FSP 123R-3 that includes simplified methods to establish the beginning balance of the additional paid-in capital pool related to the tax effect of stock-based compensation and to determine the subsequent impact on the additional paid-in capital pool and the Consolidated Statement of Cash Flows for stock-based compensation awards that are outstanding upon the adoption of FAS 123R. See *Note 9 "Stockholders' Equity" of the Notes to Consolidated Financial Statements* for more information.

Comprehensive income (loss)

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

Recent Accounting Pronouncements

In December 2007, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standards No. 141 (revised 2007), "Business Combinations" ("FAS 141R"). FAS 141R establishes principles and requirements for how the acquirer in a business combination recognizes and measures in its financial statements the fair value of identifiable assets acquired, the liabilities assumed and any noncontrolling interest in the acquiree at the acquisition date. FAS 141R determines what information to disclose to enable users of the financial statements to evaluate the nature and financial effects of the business combination. FAS 141R applies prospectively and is effective for fiscal years beginning on or after December 15, 2008. The Company is currently evaluating the potential impact, if any, of the adoption of FAS 141R on its consolidated financial position, results of operations and cash flows.

In December 2007, the FASB issued FAS No.160, ″Noncontrolling Interests in Consolidated Financial Statements" ("FAS 160"), an amendment of Accounting Research Bulletin No. 51, "Consolidated Financial Statements" ("ARB 51"). FAS 160 changes the accounting and reporting for minority interests, which will be recharacterized as noncontrolling interests and classified as a component of equity. This new consolidation method significantly changes the accounting for transactions with minority interest holders. FAS 160 is effective for fiscal years beginning after December 15, 2008. The Company plans to adopt FAS 160 beginning in the first quarter of fiscal 2009. The Company is evaluating the impact the adoption of FAS 160 will have on its consolidated financial position and results of operations.

In February 2007, the FASB issued FAS No. 159, "The Fair Value Option for Financial Assets and Financial Liabilities Including an amendment of FASB Statement No. 115" ("FAS 159"). FAS 159 expands the use of fair value accounting but does not affect existing standards which require assets or liabilities to be carried at fair value. Under FAS 159, a company may elect to use fair value to measure

ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 1. Summary of Significant Accounting Policies (Continued)

accounts and loans receivable, available-for-sale and held-to-maturity securities, equity method investments, accounts payable, guarantees and issued debt. Other eligible items include firm commitments for financial instruments that otherwise would not be recognized at inception and non-cash warranty obligations where a warrantor is permitted to pay a third party to provide the warranty goods or services. If the use of fair value is elected, any upfront costs and fees related to the item must be recognized in earnings and cannot be deferred, e.g., debt issue costs. The fair value election is irrevocable and generally made on an instrument-by-instrument basis, even if a company has similar instruments that it elects not to measure based on fair value. At the adoption date, unrealized gains and losses on existing items for which fair value has been elected are reported as a cumulative adjustment to beginning retained earnings. Subsequent to the adoption of FAS 159, changes in fair value are recognized in earnings. FAS 159 is effective for fiscal years beginning after November 15, 2007 and is required to be adopted by the Company in the first quarter of 2008. The Company does not expect the adoption of FAS 159 to have a material impact on its consolidated financial position, results of operations or cash flows.

In September 2006, the FASB issued FAS No. 157, "Fair Value Measurements" ("FAS 157") which provides guidance for using fair value to measure assets and liabilities. It also responds to investors' requests for expanded information about the extent to which companies measure assets and liabilities at fair value, the information used to measure fair value, and the effect of fair value measurements on earnings. FAS 157 applies whenever other standards require (or permit) assets or liabilities to be measured at fair value, and does not expand the use of fair value in any new circumstances. FAS 157, as originally issued, was effective for fiscal years beginning after November 15, 2007. However, on December 14, 2007, the FASB issued FASB Staff Position FAS157-b, which deferred the effective date of FAS 157 for one year, as it relates to non-financial assets and liabilities. The Company will adopt FAS 157 as it relates to financial assets and liabilities beginning in the first quarter of fiscal 2008 and does not expect the adoption of FAS 157 to have a material impact on its consolidated financial position or results of operations.

Other recent accounting pronouncements issued by the FASB (including its Emerging Issues Task Force), the American Institute of Certified Public Accountants and the SEC did not or are not believed by management to have a material impact on the Company's present or future consolidated financial statements.

Note 2. Patients First Program and settlement costs

On October 13, 2006, the Company entered into a formal agreement with OrthoClear, Inc., OrthoClear Holdings, Inc., and OrthoClear Pakistan Pvt. Ltd. ("OrthoClear"), together with certain individuals associated with OrthoClear (the "OrthoClear Agreement") to end all pending litigation between the parties. In addition, OrthoClear agreed, among other things, to stop accepting new patient cases for treatment, consented to the entry of an exclusion order by the ITC prohibiting the importation of OrthoClear aligners into the United States, to assign and transfer to Align all intellectual property rights with application to the correction of malocclusion and to discontinue all design, manufacture, marketing and sales of removable dental aligners worldwide. In addition, certain OrthoClear principals also signed five year non-compete agreements. The Company evaluated this transaction under the provisions of Emerging Issues Task Force 98-3 "Determining Whether a Non-Monetary Transaction Involves a Receipt of Productive Assets or of a Business" ("EITF 98-3")

ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 2. Patients First Program and settlement costs (Continued)

and concluded that this transaction was not a business acquisition and was accounted for as an asset purchase.

In accordance with the terms of the OrthoClear Agreement, the Company made a $20.0 million one-time cash payment to OrthoClear Holdings, Inc. on October 16, 2006. The Company engaged a third-party firm to assist management in assessing the fair value of the identifiable assets received in conjunction with the OrthoClear Agreement. Using an income valuation approach, it was determined that $14.0 million represented the fair value of the non-compete agreements, which are being amortized over the estimated useful life of 5 years. The intellectual property transferred to Align was determined not to have any alternative future use and therefore had no fair value. 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"), the remaining $6.0 million of the $20.0 million payment was recorded as settlement costs.

As part of the OrthoClear Agreement, 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, the Company committed to make treatment available to these patients at no additional cost under the "Patients First Program". Therefore, Align received no revenue for the program, while incurring significant expense. In the fourth quarter of 2006, the Company recorded an $8.3 million charge for the anticipated costs of completing the Patients First Program in accordance with FASB Statement 5, "Accounting for Contingencies" ("FAS 5"). This amount was based on the number of OrthoClear cases registered under the Patients First Program as of December 31, 2006. In accordance with the Patients First Program terms and conditions, those registered cases were required to be received by March 30, 2007. In the first quarter of 2007, the Company reduced its Patients First Program accrual by $1.8 million to reflect a reduction of the Company's initial estimate to the number of cases actually received by the case submission deadline. During 2007, the Company shipped virtually all Patients First Program cases. The accrued Patients First Program balance as of December 31, 2007 was $1.0 million, and principally consists of estimated future warranty and case refinement costs.

Note 3. Short-term Investments

The Company has the following short-term investments as of December 31, 2007 and 2006 (in thousands):

	December 31, 2007				December 31, 2006			
	Amortized Costs	Gross Unrealized Gains	Gross Unrealized Loss	Fair Value	Amortized Costs	Gross Unrealized Gains	Gross Unrealized Loss	Fair Value
U.S. Government notes and bonds	$ 4,081	$ 6	$	$ 4,087	$ 4,880	$ 2	$	$ 4,882
Corporate bonds	6,983			6,983	2,951			2,951
Commercial paper and asset-backed securities	27,754		(53)	27,701	1,098			1,098
Total	$ 38,818	$ 6	$ (53)	$ 38,771	$ 8,929	$ 2	$	$ 8,931

As of December 31, 2007, all short-term investments have maturity dates of less than one year. For the years ended December 31, 2007 and 2006, realized losses were immaterial.

ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 4. Balance Sheet Components

Inventories consist of the following (in thousands):

	December 31,	
	2007	2006
Raw materials	$ 1,983	$ 2,021
Work in process	631	763
Finished goods	296	306
	$ 2,910	$ 3,090

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

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

	Useful Life (in years)	December 31,	
		2007	2006
Clinical and manufacturing equipment	5	$ 44,230	$ 39,741
Computer hardware	3	10,444	10,404
Computer software	3	8,493	7,719
Furniture and fixtures	5	5,013	4,835
Leasehold improvements	Term of the lease	9,701	9,197
Construction in progress		1,198	1,987
		$ 79,079	$ 73,883
Less: Accumulated depreciation and amortization		(53,759)	(46,979)
		$ 25,320	$ 26,904

As of December 31, 2007, construction in progress consisted primarily of costs for capital equipment expected to be placed in service in the next year. Depreciation and amortization was $10.2 million, $9.3 million, and $10.1 million for the years ended December 31, 2007, 2006 and 2005, respectively.

Accrued liabilities consist of the following (in thousands):

	December 31,	
	2007	2006
Accrued payroll and benefits	$ 22,165	$ 17,768
Accrued Patients First Program costs	996	6,800
Accrued sales rebate	3,724	3,895
Accrued sales and marketing expenses	2,910	2,235
Accrued warranty	2,035	2,094
Other	8,045	7,515

	December 31,	
	$ 39,875	$ 40,307

ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 4. Balance Sheet Components (Continued)

Warranty accrual as of December 31, 2007 and 2006 consists of the following activity (in thousands):

Warranty accrual, December 31, 2005	$ 1,998
Charged to cost of revenues	2,694
Actual warranty expenditures	(2,598)
Warranty accrual, December 31, 2006	$ 2,094
Charged to cost of revenues	2,086
Actual warranty expenditures	(2,145)
Warranty accrual, December 31, 2007	$ 2,035

Note 5. Intangible Assets

The following is a summary of the Company's purchased intangible assets as of December 31, 2007 and 2006 (in thousands):

		December 31, 2007			December 31, 2006		
	Estimated Useful Life (in years)	Gross Carrying Value	Accumulated Amortization	Net Carrying Value	Gross Carrying Value	Accumulated Amortization	Net Carrying Value
Non-compete agreements	5	$ 14,000	$ 3,412	$ 10,588	$ 14,000	$ 612	$ 13,388
Consultant relationships	3	980	980		980	626	354
Patent	5	180	153	27	180	117	63
Other	3	55	55		55	36	19
Total		$ 15,215	$ 4,600	$ 10,615	$ 15,215	$ 1,391	$ 13,824

Non-compete agreements represent the fair value of assets received in conjunction with the OrthoClear Agreement. These intangible assets are being amortized on a straight-line basis over the expected useful life of five years beginning in the fourth quarter of 2006. See *Note 2 "Patients First Program and settlement costs" in the Notes to Consolidated Financial Statements* for additional information.

Consultant relationships and other intangible assets represent the fair value of intangible assets acquired as the result of the acquisition of General Orthodontics, LLC ("GO") in 2005. Upon the integration of GO, Align included GO's consulting services in its clinical education and training programs under the name of Invisalign Consulting Services ("ICS"). During the second quarter of 2007, the Company announced the discontinuation of ICS, and the net carrying values of the consultant relationships and other intangible assets related to ICS were fully amortized.

ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 5. Intangible Assets (Continued)

For the years ended December 31, 2007, 2006 and 2005, total amortization expense for intangible assets was $3.2 million, $1.0 million and $0.4 million, respectively. The total estimated annual future amortization expense for these intangible assets is as follows (in thousands):

Years Ending December 31,	
2008	$ 2,827
2009	2,800
2010	2,800
2011	2,188
Total	$ 10,615

Note 6. Legal Proceedings

Ormco

On January 6, 2003, Ormco Corporation ("Ormco") filed suit against the Company in the United States District Court for the Central District, Orange County Division, asserting infringement of certain patents. Ormco is a division of Sybron Dental Specialties. In May 2006, Danaher Corporation acquired Sybron Dental Specialties. The complaint sought unspecified monetary damages and injunctive relief. On February 18, 2003, the Company answered the complaint and asserted counterclaims seeking a declaration by the Court of invalidity and non-infringement of the asserted patents. In addition, the Company counterclaimed for infringement of one of its patents, seeking unspecified monetary damages and injunctive relief. Ormco filed a reply to its counterclaims on March 10, 2003 and asserted counterclaims against the Company seeking a declaration by the Court of invalidity and non-infringement of the patent. The Company amended its counterclaim to add Allesee Orthodontic Appliances, Inc. ("AOA"), a wholly-owned subsidiary of Ormco, as a counterdefendant in regard to its counterclaim of infringement of the patent.

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. Oral arguments took place on April 3, 2006. Following oral arguments, 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 the Company's 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 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 the Company and that the asserted claims are invalid. Align appealed the ruling of the District Court that certain claims of its 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 the four asserted Ormco patents are invalid and not infringed by Align. The CAFC reversed the District Court's non-infringement rulings on six claims in Ormco's 6,616,444 patent, which will be returned to the District Court for a determination of validity and infringement of those claims. The Court has denied Ormco's petition for rehearing with respect to the portion of the Federal Circuit's opinion that affirmed the District Court's ruling of non-infringement and non-enablement of the 86

ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 6. Legal Proceedings (Continued)

claims. The CAFC has not yet ruled on Ormco's petition. On Align's cross-appeal, the CAFC affirmed the District Court's finding that six claims in the 6,398,548 patent are invalid.

On February 1, 2006, the Company entered into a settlement agreement (the "Settlement Agreement") with Ormco and AOA. In accordance with the terms of the Settlement Agreement, Ormco and AOA were required to pay into escrow, pending the completion of the appeals process, $884,000 to resolve the issues of past damages, willfulness and attorneys' fees for the adjudged infringement of two of the Company's patents (the "Align Patents") through the manufacture and sale of Ormco's and AOA's Red, White & Blue appliances. The Company's receipt of the payments out of escrow was contingent upon the Court, in a final, non-appealable judgment, finding that Ormco or AOA infringes at least one of the claims in the Align Patents. As the CAFC issued a final, non-appealable judgment of invalidity with respect to each asserted claim of the Align Patents, all funds in the escrow account will be returned to Ormco and AOA.

Ormco has filed a petition with the U.S. Supreme Court asking for an extension of time in which to file a petition for review by 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 the 86 claims. The Supreme Court granted Ormco's petition for an extension of time. On February 14, 2008, Ormco filed with the U.S. Supreme Court a petition for review of the Federal Circuit's ruling that 86 of Ormco's patent claims are not infringed and are invalid. The Company will have an opportunity to respond to Ormco's petition.

Class Action

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

On July 3, 2007, the Company filed an answer to the complaint and asserted 17 affirmative defenses. On July 20, 2007, the Company filed a motion for summary judgment on the Third Cause of Action (the only cause of action alleged against Align). On August 24, 2007, Weber filed a motion for class certification. On October 1, 2007, the Company filed an opposition to the motion for class certification and it is currently awaiting rulings from the Court. OrthoClear has filed a motion to dismiss. The initial case management conference and all discovery has been stayed pending the Court's decision on the motion for class certification, OrthoClear's motion to dismiss and the Company's motion for summary judgment.

Litigating claims of these types, whether or not ultimately determined in the Company's favor or settled by the Company, is costly and diverts the efforts and attention of the Company's management and technical personnel from normal business operations. Any of these results from litigation could adversely affect the Company's results of operations. From time to time, the Company has received, and may again receive, letters from third parties drawing the Company's attention to their patent rights. While the Company does not believe that it infringes any such rights that have been brought to the

ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 6. Legal Proceedings (Continued)

Company's attention, there may be other more pertinent proprietary rights of which the Company is presently unaware.

Note 7. Credit Facilities

On March 7, 2007, the Company renegotiated and amended its existing credit facility with Comerica Bank. The amendment, among other things, reduced financial covenants to require only a quick ratio covenant. Effective January 1, 2008, the amendment increased the available borrowings under the existing revolving line of credit from $20 million to $25 million. The amended credit facility matures on December 31, 2008 at which point all outstanding borrowings under this credit facility must be repaid. During 2007, the Company repaid $11.5 million of its outstanding borrowings on this credit facility. As of December 31, 2007, the Company has no outstanding borrowings under this credit facility, and the Company is in compliance with the financial covenant of this credit facility.

Note 8. Commitments and Contingencies

Operating leases

Align rents its facilities and certain equipment and automobiles under non-cancelable operating lease arrangements. Facility leases expire at various dates through 2012 and provide for pre-negotiated fixed rental rates during the terms of the lease.

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

The Company has a facility in San Jose, Costa Rica. The facility comprises approximately 63,000 square feet of manufacturing and office space. The monthly rent for the Costa Rica facility is approximately $71,000. The lease for this facility expires at the end of 2008 with an option to renew for an additional five year term. The Company expects this lease to be renewed beyond 2008.

The Company's European headquarters are located in Amsterdam, The Netherlands. On August 3, 2007, the Company entered into an amendment to the lease agreement. The original lease agreement was amended to expand its Amsterdam facility to approximately 16,000 square feet of office space. This lease will expire in June 2012, with an option to renew for an additional five year term. The Company may also terminate this lease in June 2012 for a fee of $125,000. The monthly rent for the Amsterdam facility is approximately $34,000.

The Company recognizes rent expense on a straight-line basis over the lease period, and has accrued for rent expense incurred but not paid. Total rent expense was $3.4 million, $3.8 million and, $4.3 million for the years ended December 31, 2007, 2006 and 2005, respectively.

ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 8. Commitments and Contingencies (Continued)

Minimum future lease payments for non-cancelable leases as of December 31, 2007, are as follows (in thousands):

Years Ending December 31,	
2008	$ 2,554
2009	1,593
2010	994
2011	533
2012	328
Total	$ 6,002

Note 9. Stockholders' Equity

Preferred Stock Rights Agreement

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

Common Stock

The holders of common stock are entitled to receive dividends whenever funds are legally available and when and if declared by the Board of Directors. The Company has not declared or paid any dividends during 2007.

Employee Stock Purchase Plan

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

ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 9. Stockholders' Equity (Continued)

During the year ended December 31, 2007, 579,676 shares were issued under the Purchase Plan. As of December 31, 2007, the Company had reserved 10,433,456 shares of common stock for future issuance and 8,192,712 shares remain available for future issuance.

As of December 31, 2007, there was $2.0 million of total unamortized compensation costs related to employee stock purchases. These costs are expected to be recognized over a weighted average period of 0.5 years.

Stock Option Plans

In May 2005, stockholder approval was obtained for the 2005 Incentive Plan ("2005 Plan"), which replaced the 2001 Stock Incentive Plan ("2001 Plan"). The 2005 Plan, which expires December 31, 2010, provides for the granting of incentive stock options, non-statutory stock options, restricted stock units, stock appreciation rights, performance units and performance shares. Employees, non-employee directors and consultants are eligible to receive grants under the 2005 Plan. The options are granted for periods not exceeding ten years and generally vest over 4 years with 25% vesting one year from the date of grant and 1/48th each month thereafter. The Plan Administrator may, however, grant options with different vesting schedules. In the first quarter of 2005, the Company granted options under the 2001 Plan (prior to the approval of the 2005 Plan), that vest over 3 years, with 25% vested at the date of grant, and 1/36th each month thereafter. Options are to be granted at an exercise price not less than the fair market value of the underlying shares at the date of grant.

Starting in the first quarter of 2006, the Compensation Committee of the Board of Directors approved the grant of restricted stock units (contracts that give the recipients the right to receive shares as the units vest) to its employees and director(s) in addition to stock options. Each restricted stock unit award generally vests over 4 years with 25% on the one year anniversary of the date of grant and 6.25% vesting quarterly thereafter. Each grant of a restricted stock unit will reduce shares available for grant by 2 shares. In October 2007, the Compensation Committee of the Board of Directors approved to change the vesting for prospective grants of restricted stock units to 25% annually.

The 2005 Plan has 9,983,379 shares of the Company's common stock reserved for issuance, plus up to an aggregate of 5,000,000 shares that have been or will be returned to the 2001 Plan as a result of termination of outstanding options or repurchase of shares granted under the 2001 Plan on or after March 28, 2005. As of December 31, 2007, 2,133,503 shares have been transferred to the 2005 Plan. As of December 31, 2007, 6,258,814 shares remain available for issuance under the 2005 Plan.

Executive Grants

In January 2001, the stockholders approved two option grants to purchase 1,000,000 shares of the Company's common stock at an exercise price of $15.00 per share to each of the Company's then Chief Executive Officer and President. The options were granted outside of the 1997 Equity Incentive Plan and prior to the adoption of the 2001 Plan or the 2005 Plan. The remaining 500,000 shares were cancelled in May 2006. As of December 31, 2007, no options to purchase shares of common stock were outstanding under these grants.

ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 9. Stockholders' Equity (Continued)

Activity for the years ended December 31, 2007, 2006 and 2005 under the stock option plans and the executive grants are set forth below (in thousands, except per share data):

	Options Outstanding	
	Number of Shares	Weighted Average Exercise Price
Balance at December 31, 2004	9,050	$ 10.35
Granted	5,593	7.35
Exercised	(830)	4.04
Cancelled	(1,506)	11.50
Expired	(1,003)	15.00
Balance at December 31, 2005	11,304	$ 8.76
Granted	1,794	8.74
Exercised	(2,317)	5.87
Cancelled or expired	(1,603)	12.37
Balance at December 31, 2006	9,178	$ 8.86
Granted	1,517	18.97
Exercised	(3,048)	8.52
Cancelled or expired	(514)	11.13
Balance at December 31, 2007	7,133	$ 10.99

Information regarding stock options outstanding at December 31, 2007 and 2006 is summarized below (in thousands, except per share data):

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
As of December 31, 2007				
Options outstanding	7,133	$ 10.99	7.0	$ 45,933
Options vested and expected to vest	6,826	$ 10.90	6.9	$ 44,479
Options exercisable	4,485	$ 9.29	5.9	$ 35,047
As of December 31, 2006				
Options outstanding	9,178	$ 8.86	7.5	$ 53,160
Options vested and expected to vest	8,847	$ 8.88	7.4	$ 51,217
Options exercisable	6,436	$ 9.12	6.9	$ 37,139

The aggregate intrinsic value in the table above represents the total pre-tax intrinsic value (the difference between Align's closing stock price on the last trading day in 2007 and 2006 and the exercise price, multiplied by the number of in-the-money options) that would have been received by the option holders had all option holders exercised their options on the last day of each fiscal year. This amount will fluctuate based on the fair market value of Align's stock. The total intrinsic value of stock options exercised for the years ended December 31, 2007 and 2006 was $43.1 million, and $13.2 million, respectively.

ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 9. Stockholders' Equity (Continued)

As of December 31, 2007, there was $17.6 million of total unamortized compensation costs related to stock options and these costs are expected to be recognized over a weighted average period of 2.5 years. For the year ended December 31, 2007, the total recognized tax benefit from exercised options was $0.4 million.

The options outstanding and exercisable by exercise price at December 31, 2007 are as follows:

	Options Outstanding			Options Exercisable	
Range of Exercise Prices	Shares	Weighted Average Remaining Contractual Term (in years)	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
$ 0.05 $ 6.00	910,752	4.2	$ 4.16	864,332	$ 4.07
6.05 6.89	997,239	6.6	6.42	637,437	6.31
6.95 7.35	991,040	7.1	7.26	847,810	7.31
7.40 8.33	622,344	7.0	7.78	547,031	7.73
8.38 8.38	856,409	7.9	8.38	358,211	8.38
8.39 17.77	783,634	7.7	14.06	365,815	12.02
17.88 18.35	914,770	8.8	17.92	64,312	18.35
18.46 19.87	773,810	5.7	18.80	746,835	18.78
$19.93 $28.21	282,915	9.0	24.85	53,565	20.90
	7,132,913	7.0	$ 10.99	4,485,348	$ 9.29

Restricted Stock Units

In 2006, the Company began granting restricted stock units ("RSUs"). The fair value of each unit is based on the Company's closing stock price on the date of grant. A summary of the non-vested shares for the years ended December 31, 2007 and 2006 is as follows (in thousands, except per share amounts):

	Number of Shares	Weighted Average Grant Date Fair Value	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Nonvested as of December 31, 2005		$		
Granted	442	8.69		
Vested and released				
Forfeited	(23)	8.22		
Nonvested as of December 31, 2006	419	$ 8.71	1.5	$ 5,853
Granted	480	19.17		
Vested and released	(178)	9.27		
Forfeited	(70)	13.31		
Nonvested as of December 31, 2007	651	$ 15.78	1.5	$ 10,867

Number of Shares	Weighted Average Grant Date Fair Value	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value

ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 9. Stockholders' Equity (Continued)

The aggregate intrinsic value in the table above represents the total pre-tax intrinsic value (calculated by using Align's closing stock price on the last trading day of 2007 and 2006, multiplied by the number of non-vested RSUs) that would have been received by the unit holders had all RSUs been vested and released on the last day of each fiscal year. This amount will fluctuate based on the fair market value of Align's stock. During 2007, of the 178,000 shares vested and released, approximately 23,000 vested shares were withheld for executive RSU tax payments, resulting in a net issuance of 155,000 shares.

The total intrinsic value of RSUs vested and released during 2007 was $3.4 million. There were no RSUs vested and released during 2006. As of December 31, 2007, there was $8.4 million of total unamortized compensation costs related to RSUs, and these costs are expected to be recognized over a weighted average period of 2.9 years.

Stock-based compensation

Effective January 1, 2006, the Company adopted Statement of Financial Accounting Standards No. 123 (Revised 2004), "Share-based Payment" ("FAS 123R") using the modified prospective transition method, which requires the measurement and recognition of compensation expense for all share-based payment awards based on estimated fair values over the requisite service period. In accordance with the modified prospective transition method, our financial statements for the prior periods have not been restated to reflect and do not include the impact of FAS 123R stock options.

Valuation assumptions

The fair value of stock options granted and the option component of the Purchase Plan shares were estimated at the grant date using the Black-Scholes option pricing model with the following weighted average assumptions:

	Years Ended December 31,		
	2007	2006	2005
Stock options:			
Expected term (in years)	4.5	5.0	4.5
Expected volatility	68.0%	76.2%	85.3%
Risk-free interest rate	4.4%	4.6%	4.1%
Expected dividend			
Weighted average fair value at grant date	$ 10.82	$ 5.67	$ 4.80
Employee stock purchase plan:			
Expected term (in years)	1.2	1.3	1.2
Expected volatility	55.8%	48.2%	62.0%
Risk-free interest rate	4.8%	5.0%	3.8%
Expected dividend			
Weighted average fair value at grant date	$ 9.42	$ 2.69	$ 3.12

The expected term of stock options represents the weighted-average period the stock options are expected to remain outstanding. Upon the adoption of FAS 123R, the Company used a mid-point

ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 9. Stockholders' Equity (Continued)

model to determine the expected term of stock options based on the Company's historical exercise, post-vesting cancellation experience, and the remaining contractual term of its outstanding options.

For the year ended December 31, 2007, the Company used its own historical volatility when determining the expected volatility. In 2006, the Company used a combination of historical volatility and peer group volatility in deriving its expected volatility assumption as allowed under FAS 123R and SAB 107. The Company used its own historical volatility from 2002 to 2006 and a peer group volatility instead of its own historical data for 2001, as the Company had unusually high volatility in its stock price as the result of its Initial Public Offering in 2001. The peer group volatility was derived based on historical volatility of a comparable peer group consisting of companies of similar size and operating in a similar industry.

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

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

Summary of Stock-based Compensation Expense

Stock-based compensation expense recognized in the Consolidated Statements of Operations for the years ended December 31, 2007 and 2006 is based on awards ultimately expected to vest, net of estimated forfeitures. Forfeitures are estimated based on historical experience at the time of grant and may be revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. The stock-based compensation expense related to all of the Company's stock-based awards and employee stock purchases under FAS 123R for the years ended December 31, 2007 and 2006 is as follows:

	For the Years Ended December 31,	
	2007	2006
	(In thousands)	
Cost of revenues	$ 994	$ 700
Sales and marketing	4,225	2,862
General and administrative	5,443	4,054
Research and development	1,549	1,294
Total stock-based compensation	$ 12,211	$ 8,910

Option Acceleration

On October 6, 2005, the Compensation Committee of the Board of Directors approved the acceleration of the vesting for all unvested stock options with exercise prices greater than $7.10. The fair market value of Align's common stock on the date of acceleration was $6.41 as quoted on the NASDAQ National Market. Options held by non-employee directors were excluded from the vesting acceleration. As a result of the acceleration, approximately 3.8 million options or 35% of the then total outstanding options became immediately exercisable as of October 6, 2005. The purpose of the acceleration was to eliminate future compensation expense the Company would have otherwise

ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 9. Stockholders' Equity (Continued)

recognized in its statement of operations with respect to these accelerated options upon the adoption of FAS 123R.

Pro Forma Information Under FAS 123 for 2005

Prior to January 1, 2006, the Company accounted for stock-based employee compensation using the intrinsic value method under Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees" ("APB 25") and related interpretations and complied with the disclosure requirements of FAS 148, "Accounting for Stock-Based Compensation-Transition and Disclosure-an amendment of FASB Statement No. 123." FAS 123R requires the Company to present pro forma information for the comparative period prior to the adoption as if it had accounted for all of its stock options under the fair value method of FAS 123. The following table illustrates the pro forma information regarding the effect on net profit and net profit per share for the year ended December 31, 2005 as if the Company had accounted for the stock-based employee compensation under the fair value method of accounting:

	Year Ended December 31, 2005
	(In thousands, except per share amounts)
Net profit, as reported	$ 1,413
Add: Stock-based employee compensation expense included in reported net profit under APB No. 25, net of related tax effects	70
Deduct: Total stock-based employee compensation determined under the fair value method for all awards, net of related tax effects	(40,342)
Pro forma net loss	$ (38,859)
Basic net profit (loss) per share:	
As reported	$ 0.02
Pro forma	$ (0.63)
Diluted net loss per share:	
As reported	$ (0.02)
Pro forma	$ (0.63)

For the year ended December 31, 2005, the Company incurred $112,000 in total stock-based compensation expense, of which $67,000 resulted from acceleration charges in connection with severance packages, and $45,000 for non-employee options. Align recorded $22,000 to sales and marketing expense and $90,000 to general and administrative expense for stock-based compensation expense incurred during 2005.

Note 10. Employee Benefit Plan

In January 1999, the Company adopted a defined contribution retirement plan under Section 401(k) of the Internal Revenue Code. This plan covers substantially all employees who meet

ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 10. Employee Benefit Plan (Continued)

minimum age and service requirements and allows participants to defer a portion of their annual compensation on a pre-tax basis. Company contributions to the plan may be made at the discretion of the Board of Directors. There have been no contributions by the Company since the inception of the plan.

Note 11. Income Taxes

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

	Years Ended December 31,	
	2007	2006
Deferred tax assets, net:		
Net operating loss carryforwards	$ 73,440	$ 80,008
Research and development credit carryforwards	5,593	8,026
Deferred revenues	444	1,151
Accruals, allowances & other not currently deductible for tax purposes	13,680	12,968
Deferred tax assets	93,157	102,153
Less: Valuation allowance	(93,157)	(102,153)
Net deferred tax assets	$	$

The Company has provided a full valuation allowance at December 31, 2007 because it believes that the net deferred tax assets are unlikely to be realized.

At December 31, 2007, the Company had net operating loss carryforwards of approximately $218.3 million for federal purposes and $68.3 million for California state tax purposes. If not utilized, these carryforwards will begin to expire beginning in 2020 for federal purposes and 2010 for California purposes.

The Company has research credit carryforwards of approximately $4.2 million for federal purposes and $5.3 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.

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

ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 11. Income Taxes (Continued)

The following is a rollforward of the Company's total gross unrecognized tax benefit for 2007 (in thousands):

Balance as of January 1, 2007	$ 3,337
Tax positions related to current year:	
Additions for tax positions related to R&D credits	461
Tax positions related to prior year:	
Reductions for tax positions related to R&D credits	(924)
Other positions	(58)
Balance as of December 31, 2007	$ 2,816

The unrecognized tax benefits of $2.8 million include $0.3 million of uncertain tax positions that would impact the Company's effective tax rate if recognized. The application of FIN 48 would have resulted in a decrease in retained earnings of $2.9 million, except that the decrease was fully offset by the application of a valuation allowance. In accordance with FIN 48, the Company recognizes interest and penalties related to unrecognized tax benefits as a component of income taxes. Interest and penalties are immaterial at the date of adoption and are included in the unrecognized tax benefits.

The Company is subject to taxation in the U.S. and various states and foreign jurisdictions. All of the Company's tax years will be open to examination by the U.S. federal and most state tax authorities due to the Company's net operating loss and overall credit carryforward position. With few exceptions, the Company is no longer subject to examination by foreign tax authorities for years before 2003.

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

	Years Ended December 31,		
	2007	2006	2005
U.S. federal statutory income tax rate	35.00%	35.00%	35.00%
State income taxes, net of federal tax benefit	5.04%	5.15%	5.14%
Deferred tax benefits utilized	(44.53)%	(21.59)%	(236.81)%
Foreign losses not benefited	2.40%	(12.25)%	209.43%
Impact of differences in foreign tax rates	(7.23)%	1.27%	2.05%
Amortization of stock-based compensation	7.89%	(7.67)%	
Non-deductible foreign exchange losses		(0.74)%	16.74%
Non-deductible meals & entertainment charges	1.21%	(1.29)%	14.38%
Other items not individually material	3.54%	(0.31)%	2.31%
	3.32%	(2.43)%	48.24%

ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 11. Income Taxes (Continued)

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

	Years Ended December 31,		
	2007	2006	2005
Federal	$ 276	$ (27)	$ 505
State	309	55	221
Foreign	641	800	590
Total provision for income taxes	$ 1,226	$ 828	$ 1,316

Note 12. Net profit (loss) per share

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

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

	Years Ended December 31,		
	2007	2006	2005
Numerator:			
Net profit (loss)	$ 35,724	$ (34,963)	$ 1,413
Denominator:			
Weighted-average common shares outstanding, basic	67,176	63,246	61,644
Dilutive effect of potential common stock	4,268		1,508
Total shares, diluted	71,444	63,246	63,152
Net profit (loss) per share, basic	$ 0.53	$ (0.55)	$ 0.02
Net profit (loss) per share, diluted	$ 0.50	$ (0.55)	$ 0.02

For the years ended December 31, 2007, 2006 and 2005, stock options and restricted stock units totaling 1.0 million, 6.5 million and 6.6 million, respectively, were excluded from diluted net profit (loss) per share because of their anti-dilutive effect.

ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 13. Comprehensive Income (Loss)

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

	Years Ended December 31,		
	2007	2006	2005
Net profit (loss)	$ 35,724	$ (34,963)	$ 1,413
Foreign currency translation adjustments	703		
Unrealized gain/(loss) on available-for-sale securities	(49)	(4)	9
Comprehensive income (loss)	$ 36,378	$ (34,967)	$ 1,422

Note 14. Supplemental Cash Flow Information

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

	Years Ended December 31,		
	2007	2006	2005
Taxes paid	$ 1,632	$ 992	$ 1,298
Interest paid	$ 415	$ 223	$ 80
Non-cash investing and financing activities:			
Deferred revenue assumed in acquisition	$	$	$ 635
Accrued liabilities assumed in acquisition	$	$	$ 39
Fixed assets acquired with accounts payable or accrued liabilities	$ 1,135	$ 541	$ 1,112

Note 15. Segments and Geographical Information

Segments

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

ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 15. Segments and Geographical Information (Continued)

Geographical Information

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

	For the Years Ended December 31,		
	2007	2006	2005
Net revenues:			
North America	$ 236,758	$ 172,635	$ 182,903
Europe	45,047	28,076	20,750
Other international	2,527	5,643	3,472
Total net revenues	$ 284,332	$ 206,354	$ 207,125

	As of December 31,	
	2007	2006
Long-lived assets:		
North America	$ 35,632	$ 40,744
Europe	1,081	745
Other international	1,531	1,980
Total long-lived assets	$ 38,244	$ 43,469

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

None

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of disclosure controls and procedures.

Under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, we have evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). Based upon that evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that our disclosure controls and procedures are effective as of December 31, 2007 to provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our Chief Executive Officer and our Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure, and that such information is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission rules and forms.

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

See "Report of Management on Internal Control over Financial Reporting" on page 59 of this Annual Report on Form 10-K, which is incorporated herein by reference.

Changes in internal control over financial reporting. There have been no changes in our internal control over financial reporting during the year ended December 31, 2007 that have materially affected or are reasonably likely to material affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

Departure of Directors or Principal Officers; Election of Directors; Appointment of Principal Officers

H. Kent Bowen has informed us that he will not stand for re-election as a director of Align and will retire at our annual meeting of stockholders expected to be held on May 15, 2008. Mr. Bowen has been a director since 2000. The Nominating and Governance Committee is evaluating candidates who would qualify as an independent director under the Nasdaq rules to serve on the Board of Directors in the future.

PART III

Certain information required by Part III is omitted from this Form 10-K because we intend to file a definitive Proxy Statement for our 2008 Annual Meeting of Stockholders (the "Proxy Statement") not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K, and certain information to be included therein is incorporated herein by reference.

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this Item concerning our directors is incorporated by reference to the Proxy Statement under the section captioned "Election of Directors." The information required by this Item concerning our executive officers is set forth in Item 1 "Business" of this Annual Report on Form 10-K. The information required by this item concerning compliance with Section 16(a) of the

Exchange Act is incorporated by reference to the section entitled "Section 16(a) Beneficial Ownership Reporting Compliance" contained in the Proxy Statement.

Code of Ethics

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

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

ITEM 11. EXECUTIVE COMPENSATION

The information required by this Item is incorporated by reference to the Proxy Statement under the sections captioned "Executive Compensation" and "Corporate Governance Director Compensation."

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

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

Equity Compensation Plan Information

The following table provides information as of December 31, 2007 about our common stock that may be issued upon the exercise of options and rights granted to employees, consultants or members of our Board of Directors under all existing equity compensation plans, including the 1997 Equity Incentive Plan, the Employee Stock Purchase Plan, the 2001 Stock Incentive Plan and the 2005 Incentive Plan, each as amended, and certain individual arrangements.

Plan Category	Number of securities to be issued upon exercise of outstanding options and restricted stock units(a)	Weighted average exercise price of outstanding options(b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column(a))
Equity compensation plans approved by security holders	7,784,394(1)(2)	$ 10.99	14,451,526(3)
Equity compensation plans not approved by security holders			
Total	7,784,394	$ 10.99	14,451,526

(1) This number reflects the number of securities to be issued upon exercise of outstanding options and restricted stock units under the 2005 Incentive Plan, the 2001 Stock Incentive Plan and the 1997 Equity Incentive Plan.

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

(3) This number reflects securities available for future issuance under the 2005 Stock Incentive Plan and the Employee Stock Purchase Plan. In January 2001, all outstanding options under the 1997 Equity Incentive Plan were subsumed under the 2001 Stock Incentive Plan. Since that date no options have been granted under the 1997 Equity Incentive Plan. In May 2005, stockholder approval was obtained for the 2005 Incentive Plan and the 2001 Stock Incentive Plan was terminated. Since that date, no further options have been granted under the 2001 Stock Incentive Plan. The 2005 Incentive Plan has 9,983,379 shares of common stock reserved for issuance, plus up to an aggregate of 5,000,000 shares that are or would have been returned to the 2001 Stock Incentive Plan as a result of termination of outstanding options or repurchase of shares granted under the 2001 Stock Incentive Plan after March 28, 2005. As of December 31, 2007, 2,133,503 shares have been transferred to the 2005 Incentive Plan. As of December 31, 2007, the number of shares available for future issuance under the 2005 Incentive Plan was 6,258,814. Any grants of restricted stock units will reduce shares available for grant at a 2:1 ratio. The Employee Stock Purchase Plan provides that the number of shares of our common stock reserved for issuance thereunder will automatically increase on the first trading day of January in each calendar year by an amount equal to three percent (3%) of the total number of shares of common stock outstanding on the last trading day in December of the immediately preceding calendar year, with this annual increase not to exceed 1,500,000 shares. As of December 31, 2007, the total number of shares of our common stock available for future issuance under the Employee Stock Purchase Plan was 8,192,712.

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

The information required by this Item is incorporated by reference to the Proxy Statement under the sections captioned "Certain Relationships and Related Party Transactions" and "Corporate Governance Director Independence."

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by this Item is incorporated by reference to the Proxy Statement under the section captioned "Ratification of Appointment of Independent Registered Public Accountants."

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

1. Consolidated Financial Statements

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

Report of Independent Registered Public Accounting Firm	60
Consolidated Statements of Operations for the years ended December 31, 2007, 2006 and 2005	61
Consolidated Balance Sheets as of December 31, 2007 and 2006	62
Consolidated Statements of Stockholders' Equity for the years ended December 31, 2007, 2006 and 2005	63
Consolidated Statements of Cash Flows for the years ended December 31, 2007, 2006 and 2005	64
Notes to Consolidated Financial Statements	65

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

Schedule II Valuation and Qualifying Accounts and Reserves

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

SCHEDULE II: VALUATION AND QUALIFYING ACCOUNTS AND RESERVES

	Balance at Beginning of Period	Additions (reductions) to Costs and Expenses	Write offs	Reclass from Other Accounts	Balance at End of Period
			(in thousands)		
Allowance for doubtful accounts:					
Year ended December 31, 2005	$ 1,493	$ 457	$ (324)	$	$ 1,626
Year ended December 31, 2006	$ 1,626	$ (332)	$ (450)	$	$ 844
Year ended December 31, 2007	$ 844	$ 46	$ (184)	$ 54	$ 760
Allowance for deferred tax assets:					
Year ended December 31, 2005	$ 88,539	$ 1,449	$	$	$ 89,988
Year ended December 31,2006	$ 89,988	$ 12,165	$	$	$ 102,153
Year ended December 31,2007	$ 102,153	$ (8,996)	$	$	$ 93,157
Allowance for excess and obsolete inventory and abandoned product:					
Year ended December 31, 2005	$ 43	$ 150	$ (15)	$	$ 178
Year ended December 31, 2006	$ 178	$ 10	$	$	$ 188
Year ended December 31, 2007	$ 188	$ 47	$ (19)	$	$ 216

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Exhibit Index

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

10.5	Lease Agreement dated March 4, 2004 by and between James S. Lindsey and registrant for office space located at 831 Martin Avenue, Santa Clara, CA.	Form 10-Q	05/06/2004	10.40
10.6	First Amendment to Lease Agreement dated February 2, 2005 for office space located at 831 Martin Avenue, Santa Clara, CA.	Form 8-K	02/09/2005	10.2
10.7	Shelter Agreement dated December 22, 2005 between registrant and International Manufacturing Solutions Operaciones, S.R.L.	Form 8-K	12/28/2005	10.1
10.8	Amended and Restated Loan and Security Agreement dated December 16, 2005 between registrant and Comerica Bank	Form 8-K	12/19/2005	10.1
10.8A	Amendment to Amended and Restated Loan and Security Agreement dated March 7, 2007 between registrant and Comerica Bank	Form 10-K	03/12/2007	10.8A
10.9	Form of Resale Restriction Agreement with T. Prescott, R. George, L. Hedge and Gil Laks	Form 8-K	10/11/2005	10.1
10.10	Registrant's 2001 Stock Incentive Plan.	Form S-1 as amended (File No. 333-49932)	12/28/2000	10.13
10.11	Form of option agreement under Align's 2001 Stock Incentive Plan	Form 10-Q	11/05/2004	10.13.1
10.12	Registrant's Employee Stock Purchase Plan.	Form S-1 as amended (File No. 333-49932)	12/28/2000	10.14
10.13	Form of Indemnification Agreement by and between registrant and its Board of Directors and its executive officers.	Form S-1 as amended (File No. 333-49932)	01/17/2001	10.15

10.14	Amended and restated 2005 Incentive Plan	Form 10-K	03/12/2007	10.14	
10.14A	Form of restricted stock unit award agreement under registrant's 2005 Incentive Plan (General Form; Officer Form: Director Form)	Form 10-Q	11/05/2007	10.1A, 10.1B, 10.1C	
10.14B	Form of option award agreement under registrant's 2005 Incentive Plan	Form 10-Q	08/04/2005	10.4	
10.14C	Form of restricted stock unit award agreement under registrant's 2005 Incentive Plan with Thomas M. Prescott	Form 10-K	03/12/2007	10.14C	
10.14D	Form of restricted stock unit award agreement amendment under registrant's 2005 Incentive Plan with Thomas M. Prescott	Form 10-K	03/12/2007	10.14D	
10.15	Amended and Restated Employment Agreement dated April 5, 2007 between Thomas M. Prescott and registrant	Form 8-K	04/09/2007	10.4	
10.16	Amended and Restated Employment Agreement dated April 5, 2007 between the registrant and Roger E. George	Form 8-K	04/09/2007	10.2	
10.17	Retirement and General Release Agreement between the registrant and Eldon M. Bullington	Form 8-K (item 5.02 only)	12/18/2007	10.1	
10.18	Form of Employment Agreement entered into by and between registrant and each of Sunny Azadeh, Sonia Clark, Dan Ellis, Darrell Zoromski, and Gil Laks	Form 10-K	03/01/2006	10.20	
10.19	Form of Employment Agreement with Kenneth B. Arola	Form 8-K (item 5.02 only)	12/18/2007	10.2	
10.19A	Form of Employment Agreement with Emory Wright and Len M. Hedge				*

10.20	Lease Agreement dated February 26, 2003 between KPMG FIDES (COSTA RICA) S.A., PARQUE GLOBAL S.A. and registrant.	Form 10-Q	05/13/2003	10.36	
10.21	Lease Agreement between Schootsepoort Onroerendgoed Beheer, for Stichting Philips Pensioenfonds and Align Technology, Inc.	Form 10-Q	08/05/2004	10.41	
10.21A	Amendment to Lease Agreement between Align Technology, B.V. and TT Amsterdam Project Company (formerly Stichting Philips Pensioenfonds)	Form 10-Q	08/03/2007	10.4	
10.22	Summary of 2007 Incentive Awards for Named Executive Officers	Form 8-K	1/17/2008	Item 5.02 only	
10.23	Separation and General Release Agreement dated as of February 6, 2008 between registrant and Hossein Arjomand				*
10.24	Offer letter between the registrant and Afsaneh Azadeh dated September 27, 2007	Form 10-Q	11/05/2007	10.3	
21.1	Subsidiaries of the registrant.				*
23.1	Consent of PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firm.				*
31.1	Certifications of Chief Executive Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2003.				*
31.2	Certifications of Chief Financial Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2003.				*

32	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2003.	*

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

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, on February 26, 2008.

ALIGN TECHNOLOGY, INC.

By: /s/ THOMAS M. PRESCOTT

Thomas M. Prescott
President and Chief Executive Officer

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

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

Signature	Title	Date
/s/ THOMAS M. PRESCOTT Thomas M. Prescott	President and Chief Executive Officer (Principal Executive Officer)	February 26, 2008
/s/ KENNETH B. AROLA Kenneth B. Arola	Chief Financial Officer and Vice President, Finance (Principal Financial Officer and Principal Accounting Officer)	February 26, 2008
/s/ H. KENT BOWEN H. Kent Bowen	Director	February 26, 2008
/s/ DAVID E. COLLINS David E. Collins	Director	February 26, 2008
/s/ JOSEPH LACOB Joseph Lacob	Director	February 26, 2008
/s/ C. RAYMOND LARKIN C. Raymond Larkin	Director	February 26, 2008
/s/ GEORGE J. MORROW George J. Morrow	Director	February 26, 2008
/s/ GREG J. SANTORA Greg J. Santora	Director	February 26, 2008

Signature	Title	Date
/s/ WARREN S. THALER	Director	February 26, 2008
Warren S. Thaler		

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