ALIGN TECHNOLOGY INC
Form 10-K
March 12, 2007

# SECURITIES AND EXCHANGE COMMISSION

**Washington, D.C. 20549**

# FORM 10-K

**(Mark One)**

**x** **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
**For the fiscal year ended December 31, 2006**
**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 Prefered 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 o No x

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 x

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act.

Large accelerated filer o Accelerated filer x Non-accelerated filer 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 x

The aggregate market value of the registrant s common stock held by non-affiliates of the registrant was $387,981,710 as of June 30, 2006 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 affiliates have been excluded. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

On March 6, 2007, 65,837,621 shares of registrant s common stock were outstanding.

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of registrant s definitive Proxy Statement relating to its 2007 Annual Stockholders Meeting to be filed pursuant to Regulation 14A within 120 days after the registrant s fiscal year end of December 31, 2006 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, 2006**

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*In addition to historical information, this annual report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. These statements include, among other things, statements concerning our expectations regarding the anticipated benefit of increased collaboration between orthodontists and general practitioner dentists and the impact this collaboration will have on sales of Invisalign and on our revenue, our expectation that the percentage of revenue generated by general practitioner dentists will represent an increasingly larger percentage of our revenue, our intention to continue the integration of Invisalign into the curriculums of additional universities, our expectation regarding the benefits of new products, product features, and software enhancements, including ClinAdvisor, and the expected impact these new products and product enhancements will have on our market share, our expectations regarding product mix and Invisalign Express, our anticipated cost of the Patients First Program, our expectations regarding our average selling prices and gross margins in 2007, our expectations regarding the benefit of increased consumer marketing programs, our expectations regarding increased case shipment volume in 2007, our expectations regarding further expansion into North American and international markets, including Japan, our expectation regarding the anticipated level of our operating expenses in 2007, 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 Part II, 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 braces. Invisalign is appropriate for treating adults and teens with mature dentition. Align Technology received FDA clearance to market Invisalign in 1998.

Under the Corporate Information/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, the misalignment of teeth, is one of the most prevalent clinical dental conditions, affecting over 200 million individuals, or approximately 75% of the U.S. population. Approximately two 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 conventional orthodontic treatments, only a relatively small proportion of people with malocclusion seek traditional treatment.

*Traditional Orthodontic Treatment*

In the U.S., dental professionals treat malocclusion primarily with metal archwires 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 archwire 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 $4,800; generally only a portion of the fees 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. Conventional 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, less than one percent of American 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 conventional 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 (which includes full Invisalign treatment and Invisalign Express discussed below under Our Products ) is a proprietary system for treating malocclusion. The Invisalign treatment process 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 (referred to in this Form 10-K as Aligners ). The complete Invisalign treatment process is described in greater detail under Business The Invisalign Treatment Process .

*ClinCheck.* ClinCheck is an internally developed computer modeling program that allows dental professionals to diagnose and plan treatments for their patients. We use a dental impression and a treatment form submitted by a dental professional to develop a customized, three-dimensional treatment plan that simulates appropriate tooth movement in a series of two-week increments. 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.

Upon review of the ClinCheck simulation, the dental professional may immediately approve the projected treatment, or may provide us with feedback for modification. We reflect any requested adjustments in a modified simulation. Upon the dental professional s approval of the ClinCheck simulation, we use the data underlying the simulation, in conjunction with stereolithography technology, to manufacture Aligner molds. 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.

*Aligners.* 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. This process is repeated until the final

Aligners are used and treatment is complete. Upon completion of the treatment, the dental professional may, at his or her discretion, have the patient use an Invisalign retainer or go directly to a conventional retainer.

**Our Products**

The vast majority of our revenue is generated from the sale of full Invisalign treatment and Invisalign Express treatment.

*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. In fiscal 2006, approximately 81% of our net revenue was 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, and as a pre-cursor to restorative or cosmetic treatments such as veneers. In fiscal 2006, approximately 13% of our net revenue was generated by the sale of Invisalign Express.

*Ancillary and Other.* The remaining 6% of our net revenue is generated by training fees and sales of ancillary products.

**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 conventional 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 within two days. 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 two million people annually elect treatment by orthodontists in the U.S. These patients represent approximately 1 percent of the population of people with malocclusion. Of these, we estimate approximately 45 percent, or approximately 900,000 patients have mature dentition with mild to moderate malocclusion and are therefore potential candidates for Invisalign. We believe that Invisalign will allow dental professionals to attract patients who would not otherwise seek orthodontic treatment.

- *Decreased dental professional and staff time*. Invisalign eliminates the need for time-intensive processes such as bonding appliances to the patient s teeth, adjusting archwires 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 conventional braces.

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

- *Improved oral hygiene*. Patients can remove Aligners for tasks that are difficult with conventional 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 conventional 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 conventional 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 patient and dental professional.

We believe that these benefits will prove attractive to people who currently do not seek treatment because of the limitations of conventional braces.

**Limitations of Invisalign**

In some instances, the Invisalign system may have certain limitations relative to conventional treatment. Aligners cost more to produce than conventional braces, and we charge dental professionals more than they generally pay for the supplies used in conventional treatment. Depending on the individual pricing policies of each dental professional, the cost of full Invisalign treatment to the patient may be greater than for conventional 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 conventional 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**

We currently market Invisalign to treat patients with mature dentition. Individuals with mature dentition have fully erupted second molars and substantially completed jaw growth, which typically occurs between the ages of 11 and 15 years. We do not treat children whose teeth and jaws are still developing, as the effectiveness of Invisalign relies on our ability to accurately predict the movement of teeth over the course of treatment. Based on our clinical studies to date, we recommend that dental professionals use Invisalign as a complete treatment for a broad range of malocclusions and as a component of treatment for severe malocclusions. We estimate 45 percent of the people who annually elect treatment by orthodontists in the U.S., or more than 900,000 patients, have mature dentition and are therefore potential candidates for Invisalign. 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, persons with malocclusion will be more likely to seek treatment. We believe that adults, who are particularly sensitive to the aesthetic limitations of traditional treatment, represent our most immediate and significant market expansion opportunity.

In an effort to more fully penetrate our target market, in August 2005, we launched Invisalign Express, a lower-cost solution for less complex cases. Invisalign Express is a simple, dual arch orthodontic treatment for cases that meet certain predetermined clinical criteria and consist of up to ten Aligners. We expect Invisalign Express will increase the overall market for Invisalign, as patients who would not have otherwise sought orthodontic treatment due to its relatively high cost are introduced to this lower-cost treatment option. We continue to market and sell our traditional full Invisalign treatment option for more complex cases.

As of December 31, 2006, approximately 529,000 patients worldwide have started treatment using Invisalign. Internationally, we operate in the geographic regions of Europe, Asia-Pacific, Japan and Latin America. In 2006, 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.

In each of fiscal 2006, 2005 and 2004, no single customer accounted for 10% or more of our total net revenues.

**Business Strategy**

Our objective is to establish Invisalign as the standard method for treating orthodontic malocclusion through customer responsiveness, product leadership and operational effectiveness. Key elements of our strategy include the following.

*Customer Responsiveness*

*Focus on education and customer support.* In order to build long-term relationships with our customers, we focus on delivering superior training, support and services. Each year, we provide numerous clinical education and training programs, which include certification classes, conference calls, seminars and workshops. 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 awareness for starting and finishing Invisalign cases. We also maintain an online clinical education center which is intended to augment our training workshops, conference calls and seminars by enabling Invisalign-trained doctors to obtain continuing education credits and access a full range of case studies and best practices. As of December 31, 2006, we had trained approximately 40,800 dental professionals worldwide on the use and benefits of Invisalign.

*Educate future orthodontists and general practitioners.* 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.

*Stimulate demand for Invisalign treatment.* 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 orthodontic treatment annually. In 2007, we expect to increase the overall 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 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 market for our products.

*Penetration into our domestic market.* We have two customer channels: the orthodontist and the general practitioner dentist, or GP. As specialists, orthodontists are a critical part of our business, and we expect that orthodontists will continue to treat the majority of complex cases and continue to drive research for expanding Invisalign applications. However, there exists a significantly greater number of GPs in North America than orthodontists. As the primary care dental provider, GPs have access to a greater number of patients than orthodontists, and possess a unique opportunity to educate these patients and introduce them to Invisalign. GPs also have the ability to refer appropriate cases to orthodontists and, in certain instances, may choose to treat less complex cases themselves. We are committed to improving the collaboration and referral relationships between orthodontists and GPs. We continue to support study clubs, which pair experienced orthodontists with less experienced GPs. These orthodontists act as mentors to the GPs and lend them support and guidance in their Invisalign practice. Through these study clubs, GPs are introduced to an experienced Invisalign practitioner and are able to refer appropriate cases to these orthodontists. In 2007, we expect that revenue generated by GPs will represent an increasingly larger percentage of our revenue, largely due to the fact that there are significantly more GPs than orthodontists. We believe that by focusing on increasing utilization rates among our existing GP customers, the overall market for Invisalign will increase, as patients that would not have otherwise sought orthodontic treatment are introduced to Invisalign by their GPs. Information regarding risks related to our expectation that orthodontists and GPs will collaborate may be found in Part I, Item 1A of this Annual Report on Form 10-K under the heading Risk Factors.

*Product Leadership*

*New products and enhancements to products.* Our strategy for ensuring product leadership focuses on delivering new products and product features as well as enhancing the user experience. In 2005 we launched Invisalign Express, a lower-cost solution for less complex cases, allowing the dental professional to treat a broader range of patients. In the second half of 2006, we began a phased rollout of ClinAdvisor, a new suite of software tools designed to make Invisalign case selection and submission processes more efficient for doctors. During 2007, we expect to extend the product features and functionality of ClinAdvisor to an increasing number of practices. In addition, we plan to introduce a further series of software enhancements that will evolve Invisalign into distinct suites of software tools for the orthodontist and GP. Software enhancements for the orthodontist are intended to provide a more robust set of tools for greater predictability, wider applicability and more flexibility in the use of the Invisalign system. Software enhancements targeting the GP will focus on ease of diagnosis, guidance through the case set-up process and self-help tools designed to simplify treatment of cases of mild to moderate malocclusion. We continue to focus research and development efforts on next generation Aligner material and a compliance indicator,

which efforts we expect to extend at least through 2008. Next generation Aligner material is intended to consistently deliver force to the teeth over a longer period of time. The compliance indicator is intended to help the dental professional and the patient understand if the patient has worn their Aligner for enough time to effectively move their teeth. 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.

*Extend and defend technology leadership.* Invisalign represents a significant technological advancement in orthodontics. Our issued U.S. patents broadly cover the Invisalign system, including digital modeling and manipulation of scanned patient data, treatment planning, and fabrication of dental appliances, among others. 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. Nonetheless, 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 countries where the Invisalign system is distributed do not protect our intellectual property rights to the same extent as U.S. laws. Information regarding risks associated with failure to protect our proprietary technology and our intellectual property rights may be found in Part I, Item 1A of this Annual Report on Form 10-K under the heading Risk Factors. *See also Part I, Item 3 of this Annual Report on Form 10-K under the heading Legal Proceedings.*

*Operational Effectiveness*

*Expand and enhance manufacturing capability*. Our manufacturing operations are designed to produce large numbers of custom Aligners at a high level of quality. To improve cost efficiency, we conduct labor intensive processes in relatively low-wage countries. 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. Our proprietary software underlies our manufacturing process. By continually developing this software and other manufacturing processes, we plan to increase the level of production automation. Increased automation will enhance production capacity and reduce both unit costs and production times.

**The Invisalign Treatment Process**

The Invisalign treatment process comprises the following five stages:

*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 Invisalign as it depicts the three-dimensional geometry of the patient s teeth and hence forms the basis for our computer models. 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 Invisalign, 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 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 Costa Rica.

*Preparation of computer-simulated treatment and viewing of treatment using ClinCheck.* In Costa Rica we transform this initial digital model into a customized, three-dimensional treatment plan that simulates appropriate tooth movement in a series of two-week increments. This simulation is then reviewed for adherence to prescribed clinical, treatment and quality standards. Upon passing review, the simulation is then made available to the prescribing dental professional via Virtual Invisalign Practice (VIP), our proprietary customer interfacing software, which is available on our websites located at *www.invisalign.com* and *www.aligntech.com*. The dental professional then reviews the ClinCheck simulation and determines whether to ask us to make adjustments. 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 review ClinCheck, allowing the patient to see the projected course of treatment. The dental professional then approves the proposed treatment and, in doing so, engages us for the manufacture of corresponding Aligners.

*Construction of molds corresponding to each step of treatment.* We use the approved ClinCheck simulation 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. These molds are fabricated by IMS, a third party shelter services provider based in Juarez, Mexico.

*Manufacture of Aligners and shipment to the dental professional.* From these molds, IMS fabricates Aligners by pressure-forming polymeric sheets over each mold. The Aligners are then trimmed, polished, cleaned and packaged. Following final inspection, the Aligners are shipped directly to the prescribing dental professional. We ship all of the Aligners in a single batch. 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.

**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, computed tomography, known as 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, 2006, our manufacturing and operations staff in the U.S. and Costa Rica consisted of 672 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. In anticipation of increased capacity demands primarily resulting from the Patients First Program, we hired approximately 100 new dental technicians in Costa Rica in the fourth quarter of 2006. *For a more complete discussion of the Patients First Program, please see Part I, Item 7 of this Annual Report on Form 10-K under the heading Management s Discussion and Analysis Overview* . In the second quarter of 2006, in an effort to optimize operations, improve efficiency and reduce operating costs, we relocated our streolithography (SLA) mold fabrication operations from our Santa Clara, California facility to IMS, a third party shelter services provider based in Juarez, Mexico. We

also use IMS for the fabrication and packaging of Aligners. Information regarding risks associated with our manufacturing process and foreign operations may be found in Part I, 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. During the first half of 2007, as a result of the increase in demand for Invisalign case volume primarily due to of the Patients First Program (discussed in Part I, Item 7 Managements Discussion and Analysis Overview ), we will monitor our capacity in Costa Rica to ensure a sufficient number of technicians have been hired. 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. Align has 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 100% of the product at various points in 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 the 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.

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. 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.

**Sales and Marketing**

We market Invisalign by communicating Invisalign s benefits directly to dental professionals through our training, certification programs and direct mail campaigns and to consumers with 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 are training 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 general practitioner dentists in our domestic market. As of December 31, 2006 our North America sales organization consisted of 130 people of which 109 were direct sales representatives and 21 were sales administration and management. Internationally, we have approximately 40 people engaged in sales and sales support as December 31, 2006. We provide training, certification, marketing and clinical support to orthodontists and general practitioner dentists in the U.S. and Canada, which we consider our domestic market, and internationally.

As of December 31, 2006, we had trained approximately 40,800 dental professionals worldwide to use Invisalign. Of those trained dental professionals, approximately 73% are dental professionals in our domestic market (United States and Canada). Within our domestic market, we have trained approximately 8,000 orthodontists and approximately 22,000 active general practitioner dentists.

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 training, sales representatives follow up with the dental professional to ensure that their staff is prepared to handle Invisalign cases. Such follow up 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.

*Consumer Marketing*

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

- an orthodontist;
- a general practice dentist;
- 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 2007, we expect to increase the overall marketing spend 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. Our research and development expenses were $18.5 million for fiscal 2006, $18.6 million for fiscal 2005 and $15.8 million for fiscal 2004.

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. We have recently started a phased roll out of ClinAdvisor, a new suite of software tools, designed to make Invisalign case selection and submission processes more efficient and predictable for our doctors. In addition, we plan to introduce a further series of software enhancements that will evolve Invisalign into distinct suites of software tools for the orthodontist and GP. Software enhancements for the orthodontist are intended to provide a more robust set of tools for greater predictability, wider applicability and more flexibility in the use of the Invisalign system. Software enhancements targeting the GP will focus on ease of diagnosis, guidance through the case set-up process and self-help tools designed to simplify treatment of cases of mild to moderate malocclusion. We continue to focus research and development efforts on next generation Aligner material and a compliance indicator, which efforts we expect to extend at least through 2008.

**Intellectual Property**

We believe our intellectual property position represents a substantial business advantage. As of December 31, 2006, we had 85 issued U.S. patents, 120 pending U.S. patent applications, and numerous foreign issued patents, as well as pending foreign patent applications. *See Part I, 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 failure to protect our proprietary technology and our intellectual property rights may be found in Part I, Item IA of this Annual Report on Form 10-K under the heading Risk Factors.

**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 product called Red, White & Blue manufactured and distributed by Ormco Orthodontics, a division of Sybron Dental Specialties. In May 2006, Danaher Corporation purchased Sybron Dental Specialties. *See Part I, Item 3 Legal Proceedings for a summary of our litigation with Ormco.* In May 2005, OrthoClear, Inc. announced the commercial launch of the OrthoClear system, a product that was intended to compete directly with our Invisalign system. On October 13, 2006, we entered into a formal agreement with OrthoClear, Inc., OrthoClear Holdings, Inc., and OrthoClear Pakistan Pvt. Ltd. ( OrthoClear ), together with certain

individuals associated with OrthoClear to end all pending litigation between the parties. In addition, OrthoClear agreed, among other things, to stop accepting new patient cases for treatment, consent to the entry of an exclusion order by the ITC prohibiting the importation of OrthoClear aligners into the United States, 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. *See Part I, Item 3 Legal Proceedings for a summary of our litigation with OrthoClear.* In the future, we may face further competition from other 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 Part I, Item IA 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.* In 2006, we were informed by the Food and Drug Administration, or FDA, that our Invisalign system had been reclassified as a Class II medical device. The Invisalign system was previously regulated as a Class I medical device and was exempted from requiring 510(k) pre-market notification prior to commercialization. In 1998, however, we had voluntarily filed with and subsequently 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. Therefore, we currently possess the necessary 510(k) clearance from the FDA to continue to market our product under the Class II classification. Prior to the reclassification, our product development, manufacturing processes, packaging, labeling, handling, storage and distribution activities were subject to extensive oversight by the FDA. We believe our Invisalign system is in compliance in all material respects with applicable quality system regulations, record keeping and reporting requirements in the production and distribution of the Invisalign system. We do not anticipate any significant difficulty or material cost increases in complying with applicable performance standards as a result of the incremental regulatory requirements resulting from the Class II reclassification.

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, 2006, we had 1,253 employees, including 672 in manufacturing and operations, 309 in sales and marketing, 115 in research and development and 157 in general and administrative functions. We had 487 employees in the U.S., 620 employees in Costa Rica, 116 employees in Europe and 30 employees in other international regions.

**Executive Officers of the Registrant**

The following table sets forth certain information regarding our executive officers as of March 12, 2007:

| Name | Age | Position |
|---|---|---|
| Thomas M. Prescott | 51 | President and Chief Executive Officer |
| Eldon M. Bullington | 55 | Vice President, Finance and Chief Financial Officer |
| Hossein Arjomand | 46 | Vice President, Research and Development |
| Sonia Clark | 42 | Vice President, Human Resources |
| Dan S. Ellis | 55 | Vice President, North American Sales |
| Roger E. George | 41 | Vice President, Legal and Corporate Affairs<br>General Counsel and Corporate Secretary |
| Len M. Hedge | 49 | Vice President, Operations |
| Michael J. Henry | 44 | Vice President, Information Technology and Chief Information Officer |
| Gil Laks | 41 | Vice President, International |
| Darrell Zoromski | 42 | 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 27, 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.

*Eldon M. Bullington* has served as our Vice President of Finance and Chief Financial Officer since October 2002. Mr. Bullington was previously Vice President, Finance and Chief Financial Officer of Verplex Systems, Inc, an electronic design automation company, from January 2002 until October 2002. Prior to that, Mr. Bullington spent two years as the Vice President and Chief Financial Officer at Cardiac Pathways, Inc., until it was acquired by Boston Scientific in August 2001. Prior to Cardiac Pathways, Mr. Bullington was Vice President and Chief Financial Officer at Saraide, Inc. from September 1998 to March 1999. He also served in executive financial management roles at Verifone, Inc. and Radius, Inc.

*Hossein Arjomand* has served as our Vice President, Research & Development since November 2005. Prior to joining Align as our Senior Director, Research & Development in October 2005, Mr. Arjomand served as Senior Director for the Wireless Networking Division of Symbol Technologies, a provider of mobility products and solutions, from April 2002 to October 2005. Prior to Symbol Technologies, Mr. Arjomand held senior R&D and product engineering positions at Agilent Technologies, from March 1999 to March 2002. Mr. Arjomand also served for more than ten years in various positions in research and development at Hewlett Packard.

*Sonia Clark* has served as 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. Mr. Ellis spent from June 1999 to May 2004, 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 Vice President, Operations since March 2002, and served as our Vice President of Manufacturing from January 1999 to March 2002. 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.

*Michael J. Henry* has served as our Vice President, Information Technology and Chief Information Officer since December 2005. Prior to joining Align, Mr. Henry was Vice President, Global IT & Information Security for IHS Inc., a Colorado-based information services provider, from February 2004. From January 2001 to January 2004, Mr. Henry was at Applied Materials, most recently as Senior Director of Global Architecture and Information Security. From April 1997 to December 2000, Mr. Henry served in various positions at Silicon Graphics, most recently as Director of Enterprise Information Security and Infrastructure. Earlier in his career Mr. Henry held technical positions at Tab Products, the University of California at Berkeley, and Alza Corporation.

*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.

*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.

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**ITEM 1A. RISK FACTORS**

**If we fail to grow our revenue while controlling our expenses, the market price of our common stock may decline.**

You should consider our business and prospects in light of the risks, expenses and difficulties encountered by a company in an early stage of operations. Consistent with a company in an early stage of operations, we continue to incur significant operating expenses to:

- develop new software and increase the automation of our manufacturing processes;
- execute our consumer marketing campaign and dental professional marketing efforts;
- increase the capacity of our business enterprise systems and manufacturing operations;
- execute clinical research and education plans;
- develop technological improvements to our products and new product development;
- continue our international sales and marketing efforts;
- protect our intellectual property, including trade secrets; and
- undertake quality assurance and improvement initiatives.

For instance, in an effort to raise the profile of Invisalign and match prospective patients with our most experienced dental professionals, we have in the past utilized consumer marketing campaigns involving television, radio and print media. Marketing programs of this nature are expensive and may have limited success, if any, and may not result in revenue generation commensurate with their costs.

In addition, in an attempt to help minimize treatment disruptions for former OrthoClear patients and their doctors, we committed to make Invisalign treatment available to existing OrthoClear patients at no charge from Align through our Patients First Program . As a result, we will receive no revenue for any additional cases we start under this program while incurring significant expenses as well as increased demands on our sales and customer service representatives and on our manufacturing processes. We currently anticipate that we will be able to complete the Patients First Program by the end of the second quarter of fiscal 2007. Our success will depend in part on our ability to effectively integrate the OrthoClear patients into our infrastructure with minimal impact on our existing and new doctors. In implementing this program, we experienced higher than anticipated demand from the Patients First Program as well as regular new patients. As a result, many of our customers experienced longer customer service hold times and slight delays in ClinCheck processing times during the fourth quarter of 2006 which we anticipate will continue during the first and second quarters of 2007. Although we believe these delays are temporary in nature, these difficulties could cause us to lose existing customers, face potential customer disputes or limit the number of new customers who purchase our products or services. This could cause a decline in our revenues, gross margins and net profits, and could adversely affect our operating results. *See Part II, Item 7 Management s Discussion and Analysis of Financial Condition and Results of Operations Overview .*

While we achieved profitability beginning in the fourth quarter of fiscal 2003 and through the second quarter of fiscal 2005, we experienced a net loss in the third quarter of 2005 as well as each quarter of 2006. If we are to achieve profitability in future periods, we will need to continue to increase our revenues, while controlling our expenses. While we generated positive operating cash flow for the first time in fiscal year 2003 and continued to generate positive operating cash flow in fiscal years 2004 and 2005, 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.

**We have a limited operating history and expect our future financial results to fluctuate which may cause volatility in our stock price.**

We were incorporated in April 1997 and began sales of Invisalign in July 1999. Thus, we have a limited operating history, which makes it difficult to evaluate our future prospects. In addition, we expect our future quarterly and annual operating results to fluctuate as we focus on increasing our commercial sales. These fluctuations could cause our stock price to decline. Some of the factors that could cause our operating results to fluctuate include:

- changes in the timing of receipt of case product orders during a given quarter;
- changes in product mix due to the introduction of Invisalign Express, a lower-cost alternative for treating less complex cases;
- unanticipated delays in production caused by insufficient capacity;
- any disruptions in the manufacturing process, including as a result of unexpected turnover in the labor force or the introduction of new production processes or as a result of 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 ongoing 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. For instance, although we entered into a definitive agreement in October 2006 with OrthoClear whereby, among other things, OrthoClear agreed to discontinue all design, manufacture, marketing and sales of removable dental aligners worldwide, we experienced increased pricing pressure in 2005 and 2006 as a result of the commercial launch of OrthoClear s product. Partly in response to this increased competition, in the fourth quarter of 2005, we changed our pricing structure and reduced our list price for full Invisalign treatment to $1,495 and expanded our volume based discount program to all doctors. These programs were in effect in 2006, and had an adverse impact on our revenues, gross margins and net profit (loss). 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, we may be unable to adjust spending quickly enough to offset any shortfall in revenues. Therefore, our operating results for a given period may be adversely affected. 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 Invisalign for the vast majority of our revenues, and any decline in sales of Invisalign or average selling prices would adversely affect revenue, gross margin and net profits.**

We expect that revenues from the sale of Invisalign 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 and GPs do not collaborate as we expect, 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. 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 Invisalign does not achieve growing acceptance in the orthodontic and GP communities, our operating results will be harmed.

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

Our success depends upon the acceptance of Invisalign by a substantially larger number of dental professionals as well as potential consumers to whom we are now actively marketing. Invisalign represents a significant change from traditional orthodontic treatment, and consumers may be reluctant to accept it or may not find it preferable to conventional 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, reliability, improved treatment, aesthetics, greater comfort and hygiene compared to conventional 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 orthodontists and GPs may choose not to collaborate and referrals between orthodontists and GPs may not increase at the rate that we anticipate or at all.*

Our success depends in part upon improving the collaboration and referral relationships between orthodontists and GP dentists. As specialists, orthodontists are a critical part of our business, and we expect that orthodontists will continue to treat the majority of complex cases and continue to drive research for expanding Invisalign applications. We expect, however, that the percentage of revenues generated by GPs will increase, largely due to the fact that there are significantly more GPs than orthodontists. As the primary provider of dental care, GPs have access to a greater number of patients than orthodontists, possess a unique opportunity to educate these patients and introduce them to

Invisalign, have the ability to refer appropriate cases to orthodontists and, in certain instances, may chose to treat less complex cases themselves. If this collaboration and increase in referrals does not occur or occurs more slowly than we anticipate, our operating results could be harmed.

*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 for our products declined in 2006 compared to 2005 and may further decline in 2007 as a result of greater participation in our volume discount program. Additionally in Europe, we introduced new pricing initiatives in the first quarter of 2006 which resulted in a lower average selling price in 2006. If we are required to introduce any similar programs in the future, our revenue, gross margin and net profits (losses) may be adversely affected.

**We are dependent on our international manufacturing 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. In the first quarter of 2006, we completed the process of relocating our SLA mold fabrication operations from our Santa Clara, California facility to our third party shelter services provider, IMS, located in Juarez, Mexico. IMS also fabricates the Aligners and ships the completed products to our customers. As a result of this relocation, our reliance on our international manufacturing operations will continue to increase. 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, as well as staffing in numbers sufficient to implement the Patients First Program;
- difficulties in managing international operations, including our relationship with IMS, our third party shelter services provider;
- 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;
- fluctuations in currency exchange rates; 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 sufficient number of technicians in advance of such demand, the delivery time of our product 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 forms that form 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 forms 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 limit the number of new customers who purchase our products. This could cause a decline in our revenue 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 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. A 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 a product called Red, White and Blue, which is manufactured and distributed by Ormco Orthodontics, a division of Sybron Dental Specialties. In May 2006, Danaher Corporation purchased Sybron Dental Specialties. Prior to OrthoClear agreeing, pursuant to the terms of an agreement entered into in October 2006, to discontinue all design, manufacture, marketing and sales of removable dental aligners worldwide, our Invisalign system competed

directly with an aligner product manufactured by them. In addition, manufacturers of traditional braces, such as 3M Company, Sybron Dental Specialties and Dentsply International have substantially greater financial resources and manufacturing and marketing experience than we do and may, in the future, attempt to develop an orthodontic system similar to ours. 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 from OrthoClear and other competitors recently resulted in 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 revenue, volume growth, net profit and stock price. For instance, in the fourth quarter of 2005, in order to encourage continued use of our products, we extended our volume based discount program to all of our doctors. In addition, in the second half of 2005, we introduced Invisalign Express, a lower-cost solution for less complex cases as well as a new pricing initiative which had the effect of reducing our average selling price per case. These programs have adversely affected our revenues, gross margin and net profit. 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.

In addition, our data center operations are located in our headquarters in Santa Clara, California. We are in the process of moving our data center operations and changing our data center infrastructure. We expect the move to be completed over the next two years. We may experience technical difficulties in connection with these changes. If we experience a system failure or disruption for any reason, including in connection with changes in our data center location or infrastructure, the performance of our website would be harmed and our service could shut down.

Throughout 2006 we 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 upon 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, 2006, we had 85 issued U.S. patents, 120 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 Part I 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. *See Part I Item 3 of this Annual Report on Form 10-K for a summary of the OrthoClear litigation.* 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 of 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, in October 2006, we entered into an agreement with OrthoClear whereby OrthoClear and Align agreed, among other things, to dismiss all pending lawsuits against each other, including the patent infringement action against OrthoClear filed in the Western District of Wisconsin (Madison). In addition, we are currently involved in a patent infringement lawsuit with Ormco. 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.

In addition, we are currently a party to various other legal proceedings and claims. Management does not believe that the ultimate outcome of these other legal proceedings and claims will have a material adverse effect on our financial position or results of operations. In addition, litigation is subject to inherent uncertainties and unfavorable rulings could occur. An unfavorable ruling could include monetary damages or, in cases where injunctive relief is sought, an injunction prohibiting us from selling our products. Any of these results from our litigation could adversely affect our results of operations and stock price. *See Part I Item 3 of this Annual Report on Form 10-K for a summary of our material pending legal proceedings.*

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

Pursuant to the Sarbanes-Oxley Act of 2002 and the rules and regulations promulgated by the SEC, we are required to furnish in our Form 10-K an Annual Report by our management regarding the effectiveness of our internal control over financial reporting. The report includes, among other things, an assessment of the effectiveness of our internal control over financial reporting as of the end of our fiscal year, including a statement as to whether or not our internal control over financial reporting is effective. This assessment must include disclosure of any material weaknesses in our internal control over financial reporting identified by management. While we currently believe our internal control over financial reporting is effective, the effectiveness of our internal controls to future periods is subject to the risk that our controls may become inadequate because of changes in conditions, and, as a result, the degree of compliance of our internal control over financial reporting with the policies or procedures may deteriorate. If we are unable to assert that our internal control over financial reporting is effective in any future period (or if our auditors are unable to express an 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 would have an adverse effect on our stock price.

**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. In the second half of 2005, we launched Invisalign Express a lower-cost Aligner system used for less complex cases. We recently announced a phased rollout of ClinAdvisor, a new suite of software tools designed to make Invisalign case selection and submission processes more efficient for doctors. In addition, we plan to introduce a further series of software enhancements that will evolve Invisalign into distinct suites of software tools for the orthodontist and GP. 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, price, safety, efficacy, reliability, marketing and sales efforts, the availability of third-party reimbursement of procedures using our new products, the existence of competing products and general economic conditions affecting purchasing patterns. 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, or FDA, and foreign government agencies. Any failure in our ability to successfully develop and introduce new products or enhanced versions of existing products and achieve market acceptance of new products and new applications could have a material adverse effect on our operating results and could cause our revenues to decline.

**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 will 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 purchase 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 1,253 employees as of December 31, 2006. 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 domestic and international markets. As of December 31, 2006 our North America sales organization consisted of 130 people of which 109 were direct sales representatives and 21 were sales administration and management. Internationally, we have approximately 40 people engaged in sales and sales support as December 31, 2006. 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 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.

**Complying with regulations enforced by the Food and Drug Administration (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. We and IMS, our third party shelter services provider have not yet been subject to an FDA inspection, and we cannot assure you we or IMS will successfully pass such an inspection in the future. Our failure or the failure of IMS to take satisfactory corrective action in response to an adverse inspection or the failure to

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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 domestic 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.

**In fiscal 2006 and during the first two months of fiscal 2007, the market price for our common stock was 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.

In particular, the FASB recently enacted SFAS No. 123 (revised 2004), Share-Based Payment ( FAS 123R ) which we adopted effective in the first quarter of fiscal 2006. *See Note 10 Shareholders Equity of the Notes to Consolidated Financial Statements for further information on the impact of FAS 123R on our reported financial results.*

**We have made use of 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.

**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 $59,000. The lease for this facility expires at the end of 2008.

Our European headquarters are located in Amsterdam, The Netherlands. The facility comprises approximately 11,000 square feet of office space. The monthly rent for the Amsterdam facility is approximately $33,000. The lease for this facility expires in 2014 with an option to terminate with a fee of $238,000 during 2009. We expect this lease will not be renewed beyond 2009.

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.

***OrthoClear***

*State Action.* On February 2, 2005, we filed a multi-claim lawsuit in San Francisco County Superior Court against defendants OrthoClear, Inc., OrthoClear Holdings, Inc., Muhammad Ziaullah Chishti, Bao Tran, Peter Riepenhausen, Joe Breeland, Jeff Tunnell, Christopher Kawaja, and Charles Wen (the State Action ). Among other things, the State Action alleged tort, contract, statutory and common law causes of action arising from OrthoClear and the individual defendants alleged plan to unlawfully utilize our intellectual property, confidential information and employees. The State Action also alleged that OrthoClear, Chishti and other defendants were in breach of contractual obligations, statutory law and common law for attempting to intentionally interfere and disrupt our ongoing business operations and improperly gain access to its customer relationships and trade secrets. Subsequent to the initial filing date, there were extensive proceedings in the case as reported in previous Align filings.

*Federal Lanham Action.* On July 19, 2005 and June 19, 2006, we filed a multi-claim lawsuit in the United States District Court for the Northern District of California against OrthoClear (the Federal Lanham Action I and Federal Lanham Action II , respectively). The Federal Lanham Action I and Federal Lanham Action II alleged numerous violations of the Federal Lanham Act (15 U.S.C. §1051 et seq.) by OrthoClear and its officers and employees. These violations include unfair competition, trademark infringement and false advertising, among other things. The Federal Lanham Action I and Federal Lanham Action II also alleged violations by OrthoClear of California s Unfair Practices Act (California Business and Professions Code §17200 et seq.).

*Patent Infringement ITC Complaint.* On January 11, 2006, we filed a formal complaint with the United States International Trade Commission (ITC) against OrthoClear, seeking to halt the importation into the United States of infringing aligners manufactured by OrthoClear in Pakistan in violation of our

patents and other intellectual property rights (the ITC Complaint ). The ITC instituted a formal investigation on February 7, 2006.

*Patent Infringement Federal Action.* On January 11, 2006, we filed a federal court patent infringement action against OrthoClear in the Western District of Wisconsin (Madison) (the Patent Infringement Federal Action ) asserting infringement of our U.S. Patents Nos. 6,685,469; 6,450,807; 6,394,801; 6,398,548; 6,722,880; 6,629,840; 6,669,037; 6,318,994; 6,729,876; 6,602,070; 6,471,511 and 6,227,850.

*OrthoClear Agreement*

On October 13, 2006, Align and OrthoClear, Inc., OrthoClear Holdings, Inc., and OrthoClear Pakistan Pvt. Ltd. ( OrthoClear ), together with certain individuals associated with OrthoClear, executed a formal agreement (the OrthoClear Agreement ) that included the following terms:

- OrthoClear was required to immediately discontinue all design, manufacture, marketing and sales of removable dental aligners worldwide;

- OrthoClear consented to the entry of an exclusion order by the ITC, enforced by the United States Customs Service, which prevents OrthoClear from importing its dental aligner products into the U.S., either directly or through a third party and the ITC subsequently terminated its formal investigation on October 27, 2006;

- The parties agreed to dismiss all pending lawsuits against each other, including the State Action, Federal Lanham Action I, Federal Lanham Action II, and Patent Infringement Federal Action, with prejudice, and each such action has been subsequently dismissed;

- OrthoClear agreed to stop accepting new patient cases for treatment;

- OrthoClear and Muhammad Ziaullah Chishti its CEO, and Charles Wen, its President, transferred and assigned to Align all intellectual property rights with application to the treatment of malocclusion;

- OrthoClear principals Muhammad Ziaullah Chishti, Charles Wen, Peter Riepenhausen, and Christopher Kawaja signed 5-year, global non-compete agreements in the field of removable aligner therapy products and related software market;

- OrthoClear employees Joe Breeland and Jeff Tunnell signed 5-year U.S. non-compete agreements and prohibiting their personal participation in the removable aligner therapy product and related software market;

- We made Invisalign treatment available to OrthoClear patients in the United States, Canada and Hong Kong at no charge from Align. We implemented this program as the Patients First Program. *See Part II, Item 7 Management s Discussion and Analysis of Financial Condition and Results of Operations Overview for discussion of the Patients First Program.*

In accordance with the terms of the OrthoClear Agreement, on October 16, 2006, we made a one-time cash payment of $20.0 million to OrthoClear Holdings, Inc.

***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

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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 (5,477,432, 5,683,243, 6,244,861 and 6,616,644). 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 (5,477,432, 5,683,243, 6,244,861 and 6,616,644). 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 noticed an appeal to the Federal Circuit from the Permanent Injunction.

On February 1, 2006, we entered into a settlement agreement (the Settlement Agreement ) with Ormco and AOA. In accordance with the terms of the Settlement Agreement, Ormco and AOA paid into escrow, pending the completion of the appellate process, $884,000 to resolve the issues of past damages, willfulness and attorneys fees for the adjudged infringement of Align s U.S. Patent Nos. 6,398,548 and 6,554,611 (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 is 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. If, however, the Court issues a final, non-appealable judgment of non-infringement, invalidity or

unenforceability with respect to each asserted claim of the Align Patents, all funds in the escrow account will be returned to Ormco and AOA. The Settlement Agreement does not affect (a) Ormco s appeal of the decisions and orders of the District Court relating to Ormco s patents; or (2) our pending cross-appeal of the orders of the District Court relating to our patents.

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 that order 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. 6,544,611 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 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 order in which the appliances are to be worn and use of the appliances in intervals of 2-20 days.

The 6,544,611 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 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 appeal and the CAFC s ruling. The 6,544,611 patent does not contain claims related to digital data, computer-generated models, or methods of fabrication.

The second appeal is from the final judgment. Once final judgment was entered, Ormco filed a Notice of Appeal from the final judgment and we filed a notice of cross-appeal. Ormco has appealed the ruling of the District Court that 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. Briefing on this appeal and cross-appeal is complete, and oral argument occurred on February 6, 2007.

*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 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 in response to this Final Office Action, which included claims discussed in an interview with the Examiners. We are awaiting further action by the USPTO. |
| 6,398,548 | Yes | No | We filed a preliminary amendment on July 16, 2006. We are awaiting an initial office action. |
| 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. |
| 6,705,863 | Yes | No | We filed a preliminary amendment on May 26, 2006. We are awaiting an initial office action. |
| 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. We are awaiting further action by the USPTO. |

| | | | |
|---|---|---|---|
| 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 Re-examination of the 880 patent was filed by the same San Francisco, California law firm. |
| 6,318,994 | Yes | No | The USPTO has granted the requests for reexamination of the U.S. Patent No. 6,318,994. We are awaiting an initial Office Action. |

**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. We are awaiting further action by the USPTO. |
| 6,685,469 | No | N/A | The USPTO has granted the requests for reexamination of U.S. Patent of U.S. Patent No. 6,685,469. We are awaiting an initial Office Action. |

The re-examination proceedings on Patent Nos. 6,318,994, 6,398,548, 6,685,469 and 6,705,863 (collectively, the Remaining Patents ) are currently pending but we have not received an Office Action. We, however, filed Preliminary Amendments adding additional claims regarding two of the Remaining Patents. While the pending re-examinations are in a preliminary stage, we believe that claims of the patents in re-examination will be determined to be patentable as currently written or as may be amended during the re-examination proceeding. However, there can be no assurance that we will prevail, and re-examination proceedings could result in some or all of the Remaining Patent claims (as well as the 893, 215, 325 and 840 patent claims) having a narrower scope of coverage or even to being invalidated, which could have an adverse effect on us.

*Bay Materials*

On July 25, 2005, Bay Materials, LLC ( Bay ) filed suit against us in the Superior Court of the State of California for the County of San Mateo. The complaint, as amended, asserts, among other things, breach of contract, promissory estoppel and fraud. Bay alleges that we breached the terms of a purchase

order by failing to pay for unshipped goods manufactured by Bay pursuant to such order. Bay further alleges that we promised to purchase from Bay an alternative polyurethane product, and Bay relied on this representation to develop such an alternative product which we determined not to use. The complaint seeks monetary damages exceeding $1.1 million related to breach of contract and research and development costs incurred plus unspecified damages related to lost profit, punitive and exemplary damages, and legal costs.

On March 27, 2006, we filed our answer to Bay s amended complaint, and also filed our cross-complaint against Bay for breach of contract, breach of implied warranty of fitness, intentional misrepresentation, concealment, specific performance, unjust enrichment and unfair business practices. The cross-complaint seeks monetary damages against Bay exceeding $1.0 million. In the fourth quarter of 2006, the parties agreed to settle their dispute and dismiss all claims and cross-claims against each other in exchange for a one time payment by us to Bay in the amount of $750,000.

Litigating claims of the types discussed in Note 5 Legal Proceedings of the Notes to Consolidated Financial Statements and in Part II, Item 3 Legal Proceedings of 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 fiscal 2006.

**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, 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 |
| Year Ended December 31, 2005: | | |
| Fourth quarter | $ 7.59 | $ 6.27 |
| Third quarter | $ 8.34 | $ 5.88 |
| Second quarter | $ 8.80 | $ 5.89 |
| First Quarter | $ 10.72 | $ 5.96 |

On March 6, 2007, the closing price of our common stock on the NASDAQ Global Market was $16.40 per share. As of March 6, 2007 there were approximately 228 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 restriction on our ability to pay dividends. *See Part II, 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. and a peer group that we believe in good faith is an appropriate basis for comparison since it reflects the labor market in which Align competes. The comparison for each of the periods assumes that $100 was invested on January 1, 2002 in our common stock, the stocks included in The NASDAQ Stock Market US Index and the stocks included the peer group index and that all dividends were reinvested.

**COMPARISON OF 5 YEAR CUMULATIVE TOTAL RETURN***
**Among Align Technology, Inc., The NASDAQ Composite Index**
**And A Peer Group**

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$100 invested on 12/31/01 in stock or index including reinvestment of dividends, Fiscal year ending December 31.

The companies that comprise our peer group were chosen using the following principles: companies that are close industry competitors (regardless of size); companies that are similar in size as measured by revenue and headcount; medical devices companies, and companies with similar growth potential and include:

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

**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, 2006. 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 89 and Management s Discussion and Analysis of Financial Condition and Results of Operations beginning on page 42. We have derived the statement of income data for the years ended December 31, 2006, 2005 and 2004 and the balance sheet data as of December 31, 2006 and December 31, 2005 from the consolidated audited financial statements included elsewhere in this Annual Report on Form 10-K. The statement of income data for the years ended December 31, 2003 and 2002 and the balance sheet data as of December 31, 2004, 2003 and 2002 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, | | | | |
|---|---|---|---|---|---|
| | **2006** | **2005** | **2004** | **2003** | **2002** |
| **Consolidated Statement of Operations Data:** | | | | | |
| Net revenues | $ 206,354 | $ 207,125 | $ 172,830 | $ 122,725 | $ 69,698 |
| Gross profit | $ 141,579 | $ 143,341 | $ 115,304 | $ 71,160 | $ 24,707 |
| Profit (loss) from operations(1) | (37,536) | 2,446 | 9,765 | (19,937) | (72,935) |
| Other income (expense), net | 3,401 | 283 | (3) | (101) | 116 |
| Net profit (loss) before provision for income taxes(1) | (34,135) | 2,729 | 9,762 | (20,038) | (72,819) |
| Provision for income taxes | 828 | 1,316 | 994 | 84 | |
| Net profit (loss)(1) | $ (34,963) | $ 1,413 | $ 8,768 | $ (20,122) | $ (72,819) |
| Net profit (loss) per share | | | | | |