ALIGN TECHNOLOGY INC
Form 10-K
March 01, 2006

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, 2005

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:

None

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

Common Stock, $0.0001 par value
Series A Participating Preferred Stock $0.0001 par value

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

As of June 30, 2005, the aggregate market value of the registrant s common stock held by non-affiliates of the registrant was $371,791,641 (based on the closing sale price as reported on the National Association of Securities Dealers Automated Quotation System National Market System). Shares of the registrant s common stock held by each executive officer and director and by each entity or person that, to the registrant s knowledge, owned 5% or more of registrant s outstanding common stock as of June 30, 2005 have been excluded in that such persons may be deemed to be affiliates of the registrant. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

On February 24, 2006, 62,675,855 shares of registrant s common stock were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of registrant s definitive Proxy Statement relating to its 2006 Annual Stockholders Meeting to be filed pursuant to Regulation 14A within 120 days after the registrant s fiscal year end of December 31, 2005 are incorporated by reference into Part III of this Annual Report on Form 10-K.

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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 product development and product enhancements, including the bracket positioning template and the compliance indicator, including the expected impact these new products and product enhancements will have on our market share, our expectations regarding the impact the introduction of Invisalign Express will have on our market share, our intention to invest in capital equipment, including the purchase of additional SLA machines in 2006, our expectations regarding the impact of the decline in our average selling prices on revenue, gross margin and net profits, our expectations regarding increased case shipment volume in 2006, our expectations regarding further expansion into North American and international markets, including Japan, our expectation regarding the anticipated level of our operating expenses in 2006, our expectations regarding relocation of our stereolithography mold fabrication operations to Juarez, Mexico, as well as the timing of such relocation, our expectations regarding the impact of FAS123(R) in 2006, 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 14-A 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 web site 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.

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 are 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, or 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. A third party shelter services provider in Juarez, Mexico 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. Approximately 5% of our revenue is generated by the sale of training and the sale of ancillary products.

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 the treatment plan will consist of as many Aligners as is necessary to achieve the doctor s treatment goals.

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 consisting 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 treatment such as veneers.

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 40 percent, or approximately 800,000 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 throughput.

- *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 substantially 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

Medical devices are classified into one of three classes based on the controls necessary to reasonably assure their safety and effectiveness. Class I or II devices require the manufacturer to submit a pre-market notification to the Food and Drug Administration, or the FDA, requesting permission for commercial distribution, which is known as 510(k) clearance. We obtained our 510(k) clearance in September 1998. Our 510(k) clearance allows us to market Invisalign to treat patients with any type of malocclusion provided that the patient has mature dentition. We currently restrict the use of Invisalign to adults and teens 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. Approximately two million people annually elect treatment by orthodontists in the U.S. These patients represent approximately one percent of the population of people with malocclusion. Of these, we estimate 40 percent, or more than 800,000 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 consisting 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, 2005, approximately 380,000 patients worldwide have started treatment using Invisalign. Internationally, we operate in the geographic regions of Europe, Asia-Pacific, Japan and Latin America. In 2005, international sales accounted for 12% of our net revenues.

In each of fiscal 2005, 2004 and 2003, no single customer accounted for 10% or more of our total 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.

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 selected orthodontic and dental undergraduate curriculums. In 2006, we intend to continue the integration of Invisalign into the programs of additional universities and post-graduate institutions.

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 the second quarter of 2005, we launched a new consumer marketing campaign designed to raise the profile of Invisalign and drive more consumers to our most experienced dental professionals. As of December 31, 2005, we had trained approximately 35,800 dental professionals worldwide on the use and benefits of Invisalign.

Improving the collaboration and referral relationships between orthodontists and GPs. We have two customer channels: the orthodontist and the general practitioner dentist, or GP. Although we have historically generated a majority of our revenues from orthodontists, 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. We believe that improved collaboration is beneficial to the orthodontist and the GP and will accelerate growth in Invisalign cases and consequently increase our revenues. 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 that the percentage of revenue generated by GPs will increase, largely due to the fact that there are significantly more GPs than orthodontists. We believe the expected increase in the number of cases treated by GPs will result in an increase in the overall market for Invisalign as patients that would not have otherwise sought orthodontic treatment are introduced to Invisalign by GPs. Information regarding risks related to our expectation that orthodontists and GPs will collaborate may be found in Part I, Item 1A of this 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. Currently we are in early testing of a bracket positioning template (or BPT). The BPT product, which is intended to be used in conjunction with our digital treatment plan, will, if successfully launched, allow dental professionals to place traditional brackets on teeth with minimal effort, thereby increasing their efficiency and reducing patient chair time. New product features and enhancements include the compliance indicator, Aligner branding and next generation aligner material. The compliance indicator will help the dental professional and the patient understand if the patient has worn their Aligner for enough time to effectively move their teeth. Aligner branding is intended to distinguish and grow the Invisalign brand, differentiating us from our competitors. Next generation Aligner material will more consistently deliver force to the teeth over a longer period of time, improving efficacy of treatment. We believe continuing to introduce new products and product features as well as enhancing the user experience will keep us at the forefront of the market.

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 Report on Form 10-K under the heading Risk Factors. See also Part I, Item 3 of this 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 production times and unit costs.

Manufacturing

We produce highly customized, precise, medical quality products in volume. To do so, 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 becomes unable for any reason to supply us with their respective products, we would experience a manufacturing disruption while we qualify and obtain an alternate source.

As of December 31, 2005, we employed a manufacturing staff in the U.S. and Costa Rica of approximately 573 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 the second quarter of 2005, in an effort to optimize operations, improve efficiency and reduce operating costs, we announced our intention to relocate our streolithography (SLA) mold fabrication operations from our Santa Clara, California facility and outsource this process to a third party shelter services provider based in Juarez, Mexico. We expect this relocation to be complete by the second quarter of 2006. We also outsource the fabrication and packaging of Aligners to this same third party shelter services provider. 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.

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 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 currently fabricated at our Santa Clara, California manufacturing facility using stereolithography that we have adapted for use in orthodontic applications. As noted above, we intend to relocate our SLA mold fabrication operations from

our Santa Clara, California facility and outsource this process to a third party shelter services provider based in Juarez, Mexico. We expect this relocation to be complete by the second quarter of 2006.

Manufacture of Aligners and shipment to the dental professional. From these molds, our third party shelter services provider in Juarez, Mexico 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.

Throughput Management

Because we manufacture each case on a build-to-order basis, we do not build inventories. As a result, we must conservatively build manufacturing throughput for anticipated demand. To increase throughput, we must improve the efficiency and increase the scale of our manufacturing processes.

In order to increase the efficiency of our manufacturing processes, we focus our efforts on software development and the improvement of rate-limiting processes, or bottlenecks. We continue to upgrade our proprietary, three-dimensional treatment-planning software to enhance computer analysis of treatment data and to reduce time spent on manual and judgmental tasks for each case, thereby increasing the efficiency of our technicians in Costa Rica. We are also continuing the development of automated systems for the fabrication and packaging of Aligners manufactured in Juarez, Mexico. In order to scale our manufacturing capacity, we expect that we will continue to invest in capital equipment including the purchase of additional SLA machines during 2006.

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 ISO 13485:1996, recognized standards 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.

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 in our test markets, 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. 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, 2005, we had trained approximately 35,800 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 7,900 orthodontists and approximately 18,200 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 the second quarter of 2005, we launched a new consumer marketing campaign and advertising strategy involving television, radio, print media and consumer website. This marketing program is designed to raise the profile of Invisalign and drive more consumers to our most experienced dental professionals.

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 $18.6 million for fiscal 2005, $15.8 million for fiscal 2004 and $13.1 million for fiscal 2003.

In an effort to demonstrate Invisalign s broad treatment capabilities, a series of 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. Our product development team is testing enhanced materials and a number of complementary products, such as the bracket positioning template that when used in conjunction with our digital treatment plan, will, if successfully launched, guide doctors in proper bracket placement in traditional wires and brackets therapy and the compliance indicator, which will help doctors and patients understand if the patients have worn their Aligners for enough time to effectively move their teeth.

Intellectual Property

We believe our intellectual property position represents a substantial business advantage. As of December 31, 2005, we had 62 issued U.S. patents, 97 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 1A of this 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 wholly owned subsidiary of Sybron Dental Specialties. See Part I, Item 3 Legal Proceedings for a summary of our litigation with Ormco and the permanent injunction issued by the Court to enjoin Ormco from selling the infringing Red, White & Blue. In May 2005, OrthoClear, Inc. announced the commercial launch of the OrthoClear system, a product that is intended to compete directly with our Invisalign system. We believe that OrthoClear s product infringes on our intellectual property, including our trade secrets. *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 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. Invisalign has recently been informed by the Food and Drug Administration, or FDA that our Invisalign system has been classified as a Class II medical device, correcting what the FDA described as a prior classification error. 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 voluntarily filed with and subsequently received pre-market clearance from the FDA pursuant to the 510(k) premarket 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 this classification correction, 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 classification.

Our Aligners are manufactured by International Manufacturing Solutions Operaciones, S.R.L. (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.

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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 provided services to our customers. 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, 2005, we had approximately 1,097 employees, approximately 489 of whom were employed in the U.S., 503 in Costa Rica, 60 in Europe, 18 in Russia, 9 in Latin America and 18 in Asia/Pacific and Japan. As of December 31, 2005, of our U.S. employees, approximately 84 were employed in manufacturing and 26 in operations, 97 were employed in various management, administrative and support positions, 90 were marketing and customer support staff, 130 were employed in sales, 25 were employed in engineering and 37 were employed in research and development. Of our Costa Rica employees, 14 were employed in Customer Service and the remaining 489 were employed in manufacturing.

Executive Officers

The following table sets forth certain information regarding our executive officers as of February 28, 2006:

Name	Age	Position
Thomas M. Prescott	50	President and Chief Executive Officer
Eldon M. Bullington	54	Vice President, Finance and Chief Financial Officer
Hossein Arjomand	45	Vice President, Research and Development
Dan S. Ellis	55	Vice President, North American Sales
Roger E. George	40	Vice President, Legal and Corporate Affairs General Counsel and Corporate Secretary
Len M. Hedge	48	Vice President, Operations
Michael J. Henry	43	Vice President, Information Technology and Chief Information Officer
Gil Laks	40	Vice President, International
Darrell Zoromski	41	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.

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 2003. 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.

ITEM 1A. RISK FACTORS

If we fail to sustain our revenue growth 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;
- 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 drive prospective patients to our most experienced dental professionals, in the second quarter of 2005, we launched a consumer marketing campaign 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 its costs.

While we achieved profitability beginning in the fourth quarter of fiscal 2003, we experienced a net loss in the third quarter of 2005. If we are to achieve profitability in future periods, we will need to continue to increase our revenues, while controlling our expenses. 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. However, we cannot be certain that we will be able to sustain or increase such 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 may not be able to sustain our historical growth rates in future periods. 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:

- the development and marketing of directly competitive products by existing and new competitors, such as OrthoClear, Inc.;
- aggressive price competition from competitors, including OrthoClear;
- changes in the timing of product orders;

- 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;

- inaccurate forecasting of revenues, production and other operating costs;

- costs and expenditures in connection with ongoing litigation, in particular the litigation related to OrthoClear;

- changes in product mix due to the introduction of Invisalign Express, a lower-cost alternative for treating less complex cases; and

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

To respond to these and other factors, we may need to make business decisions that could adversely affect our operating results such as modifications to our pricing policy, business structure or operations. Most of our expenses, such as employee compensation and lease payment obligations, are relatively fixed in the short term. Moreover, our expense levels are based, in part, on our expectations regarding future revenue levels. As a result, if our revenues for a particular period fall below our expectations, 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 are currently involved in litigation with several former employees stemming from our efforts to protect our intellectual property. This litigation is costly and could distract our management and cause a decline in our results of operations and stock price.

We seek to diligently protect our intellectual property rights. On February 2, 2005 we filed a complaint against OrthoClear, Inc., OrthoClear Holdings, Inc., Mr. Chishti, one of our founders, and several former employees. Among other things, the complaint alleges 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 complaint also alleges that OrthoClear, Mr. Chishti, and other defendants are 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 our customer relationships and trade secrets. The complaint seeks injunctive relief and monetary damages in an amount to be determined. On July 19, 2005, we filed a multi-claim lawsuit in the United States District Court for the Northern District of California against OrthoClear. The complaint alleges 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. The complaint also alleges violations by OrthoClear of California s Unfair Practices Act (California Business and Professions Code §17200 et seq.). On January 11, 2006, we filed a complaint with the 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 requests the ITC institute an immediate investigation and ultimately issue an exclusionary order, enforced by U.S. Customs and Border Protection, excluding OrthoClear aligners from importation into the United States. The ITC Complaint also requests the ITC issue two cease and desist orders specifically preventing OrthoClear from importing infringing aligners and from selling in the United States imported OrthoClear aligners. The ITC has determined to institute a formal investigation. In addition, on January 11, 2006, we filed a federal court patent infringement action in the Western District of Wisconsin (Madison). This federal action seeks monetary damages and an injunction to augment the exclusionary relief available from the ITC.

Although each of these lawsuits is in the early stages, litigating claims of this type, 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 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. However, in the Ormco litigation, there is no assurance that the court s decision will not be overturned on appeal. 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 Form 10-K for a summary of our material pending legal proceedings.

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, a subsidiary of Sybron Dental Specialties, and an aligner product manufactured by OrthoClear, Inc. 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. In May 2005, OrthoClear announced the launch of the OrthoClear system, a product that is intended to compete directly with our Invisalign system. Although we intend to vigorously defend our intellectual property rights and prevent OrthoClear from continuing to market any product that infringes on our intellectual property, if OrthoClear is successful in gaining broad market acceptance of its product, our business could be adversely affected. *See Part I Item 3 of this Report on Form 10-K for a more complete summary of the OrthoClear litigation.* Increased competition from OrthoClear and other competitors has 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 directed 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 to more effectively manage our operations.

Throughout 2006 we intend to add additional functionality into our business enterprise systems, 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. In addition, we currently do not have adequate resiliency in our information technology systems. 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. Further, in the fourth quarter of 2005 we began transitioning to a new information technology outsourcing provider. We terminated this relationship in the first quarter of 2006 and are currently transitioning back to our original information technology outsourcing provider. Delays in transition and failure to migrate smoothly through this transition could cause business disruptions.

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, sales and operating results.

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.

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 or if the average selling price of our product declines, 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 of Invisalign 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 the future, unanticipated poor clinical performance of Invisalign could result in significant adverse publicity and, consequently, reduced acceptance by dental professionals. In addition, increased competition from direct competitors could cause us to lose market share and reduce dental professionals efforts and commitment to expand their Invisalign practice. If 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.

In addition, 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 orthodontist 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 orthodontist 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 the second half of 2005, we reduced the list price of full Invisalign cases and 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 has declined. We expect each of these programs, and other similar programs that we may introduce in the future, to adversely affect our revenue, gross margin and net profits.

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 low-cost Aligner system to be used for less complex cases. We are in early testing of a bracket positioning template and other new products. There can be no assurance that we will be able to successfully develop, sell and achieve market acceptance of these and other new products and applications and enhanced versions of our existing product. The extent of, and rate at which, market acceptance and penetration are achieved by future products is a function of many variables, which include, among other things, 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.

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. A third party shelter services provider in Juarez, Mexico fabricates Aligners and ships the completed products to our customers. We are currently in the process of relocating our SLA mold fabrication operations from our Santa Clara, California facility to this same third party provider. We expect this relocation to be complete by the second quarter of 2006. As a result of this relocation, our reliance on our international manufacturing operations will continue to increase. Our costs associated with these operations are denominated in Costa Rican colons, Mexican pesos and U.S. dollars. Our increasing reliance on

international operations exposes us to risks and uncertainties that may affect our business or results of operation, including:

- difficulties in hiring and retaining employees generally, as well as difficulties in hiring and retaining employees with the necessary skills to perform the more technical aspects of our operations;
- difficulties in managing international operations, including our relationship with IMS, our third party shelter services provider;
- 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. In addition to the risks set forth above, if we do not successfully coordinate the relocation and consolidation of our SLA mold fabrication operations, we may be unable to produce sufficient volume of molds to meet customer demand, which would harm our 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.

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, 2005, we had 62 issued U.S. patents, 97 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, 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 re-examination of a number of our patents. The USPTO has granted the request to reexamine U.S. Patent Nos. 5,975,893, 6,398,548, 6,309,215, 6,705,863, 6,217,325. As of the date of this Report on Form 10-K, the USPTO issued initial Office Actions with regard to U.S. Patent Nos. 6,217,325 (the 325 patent), 6,309,215 (the 215 patent) and 5,975,893 (the 893 patent). While the pending re-examinations are in a preliminary stage and we are still evaluating all issues, we believe that the 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 proceedings. However, there can be no assurance that we will prevail, and the re-examination proceedings could cause some or all of these patent claims to have a narrower scope of coverage or even to be invalidated, which would have an adverse affect on us. *See Part I Item 3 of this 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 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.

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.

See Part I Item 3 of this Form 10-K for a summary of our material pending legal proceedings.

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 a third party shelter services provider located in Juarez, Mexico to fabricate Aligners and to ship the completed product to customers. In addition, by the second quarter of fiscal 2006, we expect to complete the relocation of our SLA mold fabrication process to the same third party shelter services provider in Juarez, Mexico. As a result, if this third party 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 the third party shelter services provider 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 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 approximately 1,097 employees as of December 31, 2005. 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, rapid 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 this level of 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 market and internationally. As of December 31, 2005 our sales organization consisted of 130 people of which 106 were direct sales representatives and 24 were sales administration and management. 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. In the first half of 2005, approximately 17 orthodontic sales representatives, representing approximately 50% of our orthodontic sales force, left Align and joined OrthoClear. Although we have replaced the majority of these individuals with new sales representatives, to adequately train and successfully deploy new representatives into effected regions and to reestablish strong customer relationships takes time. If we are unable to replace our direct sales force personnel 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 premarket approval of new products, new intended uses, or modifications to existing products;
- withdrawing clearance or premarket 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 our third party shelter services provider have not yet been subject to an FDA inspection, and we cannot assure you we or our third party shelter services provider will successfully pass such an inspection in the future. Our failure or the failure of our third party shelter services provider to take satisfactory

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corrective action in response to an adverse inspection or the failure to comply with applicable manufacturing regulations could result in enforcement action, and we may be required to find alternative manufacturers, which could be a long and costly process.

Before we can sell a new medical device in the U.S., or market a new use of or claim for an existing product we must obtain FDA clearance or approval, unless an exemption applies. Obtaining regulatory clearances or approvals can be a lengthy and time-consuming process. Even though the devices we market have obtained the necessary clearances from the FDA, we may be unable to maintain such clearances in the future. Furthermore, we may be unable to obtain the necessary clearances for new devices that we intend to market in the future. Our inability to maintain or obtain regulatory clearances or approvals could materially harm our business.

If the security of our customer and patient information is compromised, patient care could suffer, and we could be liable for related damages, and our reputation could be impaired.

We retain confidential customer and patient information in our processing centers. Therefore, it is critical that our facilities and infrastructure remain secure and that our facilities and infrastructure are perceived by the marketplace and our customers to be secure. Despite the implementation of security measures, our infrastructure may be vulnerable to physical break-ins, computer viruses, programming errors, attacks by third parties or similar disruptive problems. If we fail to meet our clients expectations regarding the security of healthcare information, we could be liable for damages and our reputation could be impaired. In addition, patient care could suffer, and we could be liable if our systems fail to deliver correct information in a timely manner. Our insurance may not protect us from this risk.

If compliance with healthcare regulations becomes costly and difficult for our customers or for us, we may not be able to grow our business.

Participants in the healthcare industry are subject to extensive and frequently changing regulations under numerous laws administered by governmental entities at the federal, state and local levels, some of which are, and others of which may be, applicable to our business. Furthermore, our healthcare provider customers are also subject to a wide variety of laws and regulations that could affect the nature and scope of their relationships with us.

The healthcare market itself is highly regulated and subject to changing political, economic and regulatory influences. Regulations implemented pursuant to the Health Insurance Portability and Accountability Act (HIPAA), including regulations affecting the security and privacy of patient healthcare information held by healthcare providers and their business associates may require us to make significant and unplanned enhancements of software applications or services, result in delays or cancellations of orders, or result in the revocation of endorsement of our products and services by healthcare participants. The effect of HIPAA and newly enforced regulations on our business is difficult to predict, and there can be no assurance that we will adequately address the business risks created by HIPAA and its implementation or that we will be able to take advantage of any resulting business opportunities.

Extensive and changing government regulation of the healthcare industry may be expensive to comply with and exposes us to the risk of substantial government penalties.

In addition to medical device laws and regulations, numerous state and federal healthcare-related laws regulate our business, covering areas such as:

- storage, transmission and disclosure of medical information and healthcare records;

- prohibitions against the offer, payment or receipt of remuneration to induce referrals to entities providing healthcare services or goods or to induce the order, purchase or recommendation of our products; and

- the marketing and advertising of our products.

Complying with these laws and regulations could be expensive and time-consuming, and could increase our operating costs or reduce or eliminate certain of our sales and marketing activities or our revenues.

We face risks related to our international sales, including the need to obtain necessary foreign regulatory clearance or approvals.

We currently sell our products in Europe, Canada, the United Kingdom, Mexico, Brazil, Australia and Hong Kong, and may expand into other countries from time to time. Recently, we announced our intention to launch sales of Invisalign in Japan. 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 2004 and fiscal 2005, 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, such as expensing of stock options, 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 (SFAS 123R) which we will adopt effective in the first quarter of fiscal 2006. As a result, we expect that SFAS 123R will have a significant adverse effect on our reported financial results and may impact the way in which we conduct our business, which may affect our stock price.

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 our 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 manufacturing, customer support, software engineering 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 $70,000. Commencing July 1, 2005 and continuing on the first day of each calendar month thereafter, $10,575 will be deducted from the $1,269,000 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 $56,000. 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 $17,000. The lease for this facility expires in 2014 with an option to terminate with a fee of approximately $220,000 during 2009. We expect this lease will not be renewed beyond 2009.

We operate a facility in Moscow, Russia. The facility comprises approximately 6,000 square feet of office space where we conduct certain research and development activities. The monthly rent for the Russian facility is approximately $17,000. The lease for this facility expires in March 2006 and we currently expect that this lease will be renewed.

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 alleges 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 alleges that OrthoClear, Chishti and other defendants are 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 our customer relationships and trade secrets. The State Action seeks injunctive relief and monetary damages in an amount to be determined.

On February 15, 2005, OrthoClear, Chishti, Riepenhausen, Breeland, Tunnell, Kawaja and Wen filed a multi-claim cross-complaint against Align, Thomas Prescott, Roger George, Eldon Bullington, David Thrower, Patricia Wadors, Gil Laks and Kelsey Wirth (collectively, the Align Parties) alleging conspiracy, breach of contract, libel, slander, unjust enrichment, intentional interference with prospective economic advantage, and unfair competition. The cross-complaint seeks injunctive relief and monetary damages in an amount to be determined.

On February 18, 2005, the Court granted our request for and issued a Temporary Restraining Order (TRO) prohibiting OrthoClear and the individual OrthoClear defendants from engaging, assisting, or participating, directly or indirectly, in soliciting, inducing to leave, recruiting, or encouraging any current Align employee or consultant to terminate or alter his or her employment or business relationship with Align or attempting to do the same. The Court also granted our request and issued a TRO prohibiting OrthoClear and the individual OrthoClear defendants from disclosing, using, lecturing upon or publishing any of our proprietary information without our express prior written permission. In addition, in response to a cross-application for TRO filed by certain OrthoClear defendants, the Court enjoined Chishti and the Align Parties from disparaging each other in such a manner as to violate the mutual non-disparagement clause contained in the Separation Agreement between Align and Chishti dated as of March 27, 2002. The Court also enjoined the Align Parties from advising any Align employee or consultant that he or she will be subject to criminal charges or a civil lawsuit if that person elects to change his or her employment status with Align, unless we have good cause to believe criminal conduct has been or will be committed or that a civil cause of action will lie against the employee or consultant. The Court also required the Align Parties to refrain from taking any actions inconsistent with Federal or State securities laws relating to the issuance or redemption of Align stock. On March 1, 2005, the Court signed a Stipulated Preliminary Injunction Order, whereby the Court ordered that the express terms of the TRO remain in place until the earlier of (i) trial, (ii) written agreement of the parties or further Court order setting an earlier termination, or (iii) as to the preliminary injunction regarding non-solicitation or recruiting of Align employees or consultants only, October 27, 2005.

The defendants and the Align Parties filed demurrers to the complaint and the cross-complaint, respectively. On June 6, the Court ruled on demurrers on the complaint filed by OrthoClear and denied OrthoClear s challenges to the core of our complaint Align s claims of Misappropriation of Trade Secrets and Breach of Contract by overruling the OrthoClear demurrers to these causes of action. In addition, the Court granted our request for permission to amend our original complaint to consolidate several duplicative causes of action and to add specific evidence not available to us when the original complaint was filed. OrthoClear did not oppose the demurrer filed by us and amended its original pleading by filing a first supplemental and amended cross-complaint.

On July 6, 2005, OrthoClear filed a demurrer to our first amended complaint. On August 23, 2005, the Court issued an order overruling all of OrthoClear s demurrers. As a result, on September 9, 2005, OrthoClear filed answers to eleven causes of action brought by us. On September 6, 2005, defendant Bao Tran filed answers to our causes of action and also filed a cross-complaint against us. In September 2005, we presented demurrers to OrthoClear s first supplemental and amended cross-complaint. In November 2005, the Court agreed with the Align Parties challenges to 18 of the 19 causes of action. Of the 18 causes of action successfully challenged by Align, the Court ordered that 6 be dismissed entirely. As to the remaining 12 challenged causes of action, OrthoClear is required to either dismiss them or attempt to

state a valid claim against the Align Parties. On December 5, 2005, OrthoClear filed a second amended cross-complaint alleging unfair competition, intentional interference with prospective economic advantage, intentional interference with contract, libel, slander, breach of contract, wrongful withholding of wages, and abuse of process. The second amended cross-complaint eliminates David Thrower as a cross-defendant and attempts to add a new cross-defendant. On December 9, 2005, defendant Bao Tran filed a first amended cross-complaint alleging wrongful termination, intentional interference with contract, wrongful withholding of wages, breach of contract, libel, slander, false light, abuse of process, and unfair competition.

On January 4, 2006, the Align Parties filed a demurrer to OrthoClear s second amended cross-complaint, and a motion to strike the portions of the second amended cross-complaint that refer to the new cross-defendant. On January 12, 2006, the Align Parties filed a demurrer to Bao Tran s first amended cross-complaint and also filed special motions to strike certain causes of action in both OrthoClear s and Bao Tran s cross-complaints. Bao Tran subsequently agreed to dismiss his cause of action for abuse of process, and in response Align has agreed to withdraw its special motion to strike Bao Tran s cross-complaint. The demurrers against OrthoClear s second amended cross-complaint and against Bao Tran s first amended cross-complaint, the motion to strike the portions of Orthoclear s second amended cross-complaint that refer to the new cross-defendant, and the special motion to strike certain causes of action in OrthoClear s second amended cross-complaint was heard on February 27, 2006. The judge has taken the matters presented under submission and no ruling has been issued.

No trial date has been set by the Court in this case.

Federal Lanham Action. On July 19, 2005, we filed a multi-claim lawsuit in the United States District Court for the Northern District of California against OrthoClear (the Federal Lanham Action). The Federal Lanham Action alleges 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. The Federal Lanham Action also alleges violations by OrthoClear of California s Unfair Practices Act (California Business and Professions Code §17200 et seq.).

The Federal Lanham Action seeks monetary damages according to proof at trial and an injunction preventing OrthoClear from further false advertising and unfair competition including any use of our trademarks or any advertising which deceives consumers into incorrectly believing that OrthoClear has a program for training and certifying dentists and orthodontists or that dentists or orthodontists have used OrthoClear to successfully treat patients. We also seek an order requiring OrthoClear to conduct corrective advertising to counteract its misleading advertising. A trial date has been scheduled for October 30, 2006.

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 Complaint alleges that OrthoClear utilizes our trade secrets and infringes 12 of our patents in the production of the OrthoClear aligners at a facility in Lahore, Pakistan. The ITC Complaint requests the ITC institute an immediate investigation and ultimately issue an exclusionary order, enforced by U.S. Customs and Border Protection, excluding OrthoClear aligners from importation into the United States. The ITC Complaint also requests the ITC issue two cease and desist orders specifically preventing OrthoClear from importing infringing aligners and from selling in the United States imported OrthoClear aligners. The ITC has announced that it has instituted a formal investigation.

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. The Patent Infringement Federal Action seeks monetary damages and an injunction to augment the exclusionary relief available from the ITC.

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. The complaint sought unspecified monetary damages and injunctive relief. On February 18, 2003, we answered the complaint and asserted counterclaims seeking a declaration by the Court of invalidity and non-infringement of the asserted patents. In addition, we counterclaimed for infringement of our U.S. Patent No. 6,398,548, seeking unspecified monetary damages and injunctive relief. Ormco filed a reply to our counterclaims on March 10, 2003 and asserted counterclaims against us seeking a declaration by the Court of invalidity and non-infringement of U.S. Patent No. 6,398,548. We amended our counterclaim to add Allesee Orthodontic Appliances, Inc. (AOA), a wholly-owned subsidiary of Ormco, as a counterdefendant in regard to our counterclaim of infringement of U.S. Patent No. 6,398,548. The Court then permitted Ormco to amend its Complaint and permitted us to amend our counterclaim to add an additional patent each. Ormco filed a first amended complaint for infringement of U.S. Patent No. 6,616,444 on October 15, 2003. On October 27, 2003, we filed an answer to Ormco s first amended complaint and a counterclaim for invalidity and non-infringement of U.S. Patent No. 6,616,444 and for infringement of U.S. Patent No. 6,554,611.

In connection with these claims, the Court granted five motions for summary judgment that we filed. First, on May 14, 2004, the Court granted our motion for summary judgment of non-infringement, finding that our Invisalign system does not infringe any of the asserted Ormco patents (5,477,432, 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, upon a motion for reconsideration made by Ormco and AOA, the Court advised 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. As of the date of this Report on Form 10-K, the Permanent Injunction remains in full force and effect.

On February 1, 2006, we entered into a settlement agreement (the Settlement Agreement) with Ormco and AOA. Pursuant to the Settlement Agreement, the issues of past damages, willfulness and attorneys fees for Ormco s and AOA s adjudged infringement of our U.S. patent Nos. 6,398,548 and 6,554,611 (the Align Patents) through the manufacture and sale by Ormco and AOA of its Red, White & Blue appliances has been settled. The Settlement Agreement does not affect (1) Ormco and AOA s currently pending appeal of the permanent injunction preventing Ormco and AOA from selling the infringing Red, White & Blue system; (2) any appeal by Ormco of the decisions and orders of the United States District Court relating to Ormco s patents; or (3) any appeal by us of the orders of the United States District Court relating to our patents.

In accordance with the terms of the Settlement Agreement, Ormco and AOA will pay us $884,000 (the Settlement Amount) to resolve the issues of past damages, willfulness and attorneys fees for the adjudged infringement of the Align Patents through the manufacture and sale of Ormco s and AOA s Red, White & Blue appliances. The Settlement Amount will be paid into escrow pending the completion of the appeals process. 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. Once final judgment was entered, Ormco filed a Notice of Appeal from the final judgment. The time has not yet expired for us to file a cross-appeal on the few issues that were not previously resolved in our favor.

Other matters

During fiscal 2005, 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 re-examination of six of our patents (U.S. Patent Nos. 5,975,893, 6,398,548, 6,309,215, 6,705,863, 6,217,325 and 6,722,880). The USPTO has granted the request to reexamine five of the six patents, specifically, Patent No. 5,975,893, Patent No. 6,398,548, Patent No. 6,309,215, Patent No. 6,705,863 and Patent No. 6,217,325. As of the date of this Report on Form 10-K, the USPTO issued initial Office Actions with regard to US Patent Nos. 6,217,325 (the 325 patent), 6,309,215 (the 215 patent) and 5,975,893 (the 893 patent). In these initial Office Actions, the examiners confirmed the validity of three of the twenty-six claims of the 325 patent and five of the eleven claims of the 215 patent without amendment and preliminarily rejected the remaining claims of the patents. In addition, the examiners preliminarily rejected all the claims in the 893 patent. These non-final initial Office Actions present Align with its first opportunity to respond to the USPTO s review and interpretation of the prior art. We may and intend to submit amendments, affidavits or declarations, or other documents as evidence of patentability in response to its actions on the 325, 215 and 893 patents. The re-examination proceedings on Patent Nos. 6,398,548, 6,705,863 (collectively, the Remaining Patents) are currently pending but no Office Action has been received by us. 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 215, 325 and 893 patent claims) having a narrower scope of coverage or even to being invalidated, which could have an adverse effect on us. 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 our U.S. Patent No. 6,722,880 (the 880 patent). Accordingly, the validity of all twenty-one claims of our 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. As of the date of this Report on Form 10-K, we have not received a response from the USPTO.

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, fraud and negligent misrepresentation by us. 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 of $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 expenses. We intend to vigorously defend ourselves.

Litigating claims of these types, 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 2005.

PART II

ITEM 5. MARKET FOR REGISTRANT S COMMON EQUITY AND RELATED STOCKHOLDER MATTERS.

(a) Price Range of Common Stock

Our common stock is listed on The NASDAQ National 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 National Market:

	High	Low
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
Year Ended December 31, 2004:		
Fourth quarter	$ 16.34	$ 8.97
Third quarter	$ 18.72	$ 13.90
Second quarter	$ 22.80	$ 17.36
First quarter	$ 21.79	$ 16.69

On February 24, 2006, the last reported sale price of our common stock on The NASDAQ National Market was $8.38 per share. As of February 24, 2006 there were approximately 277 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. In addition, in December 2005, we renegotiated our existing revolving line of credit. The new credit facility contains certain restrictive loan covenants, including, 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 .*

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, 2005. 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 52 to 83 and Management s Discussion and Analysis of Financial Condition and Results of Operations beginning on page 40. We have derived the statement of income data for the years ended December 31, 2005, 2004 and 2003 and the balance sheet data as of December 31, 2005 and December 31, 2004 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, 2002 and 2001 and the balance sheet data as of December 31, 2003, 2002 and 2001 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,				
	2005	**2004**	**2003**	**2002**	**2001**
Consolidated Statement of Operations Data:					
Revenues	$207,125	$ 172,830	$ 122,725	$ 69,698	$ 44,808
Gross profit (loss)	$143,341	$ 115,304	$ 71,160	$ 24,707	$ (2,022)
Profit (loss) from operations	2,446	9,765	(19,937)	(72,935)	(100,769)
Other income (expense), net	283	(3)	(101)	116	1,730
Net profit (loss) before provision for income taxes	2,729	9,762	(20,038)	(72,819)	(99,039)
Provision for income taxes	1,316	994	84		10
Net profit (loss)	1,413	8,768	(20,122)	(72,819)	(99,049)
Dividend related to beneficial conversion feature of preferred stock					(11,191)
Net profit (loss)	$ 1,413	$ 8,768	$ (20,122)	$ (72,819)	$ (110,240)
Net profit (loss) per share					
Basic	$ 0.02	$ 0.15	$ (0.35)	$ (1.52)	$ (2.61)
Diluted	$ 0.02	$ 0.14	$ (0.35)	$ (1.52)	$ (2.61)
Shares used in computing net profit (loss) per share:					
Basic	61,644	59,963	57,758	47,878	42,247
Diluted	63,152	64,089	57,758	47,878	42,247

	December 31,				
	2005	**2004**	**2003**	**2002**	**2001**
Consolidated Balance Sheet Data:					
Working capital	$ 62,978	$ 61,886	$ 39,737	$ 41,160	$ 62,172
Total assets	142,110	130,712	102,202	92,856	118,218
Total long-term liabilities	64	25	1,849	3,837	980
Stockholders equity	$ 93,438	$ 85,739	$ 62,976	$ 64,347	$ 97,827

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

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

Overview

Align Technology, founded in April 1997, designs, manufactures and markets Invisalign, a proprietary method for treating malocclusion, or the misalignment of teeth. Invisalign corrects malocclusion using a series of clear, nearly invisible, removable appliances that gently move teeth to a desired final position. Because it does not rely on the use of metal or ceramic brackets and wires, Invisalign significantly reduces the aesthetic and other limitations associated with braces. Invisalign is appropriate for treating adults and teens with mature dentition. We received FDA clearance to market Invisalign in 1998, and we began commercial operations in July 1999.

The Invisalign system is manufactured in phases. The initial step in our manufacturing process is the creation of electronic treatment plans using ClinCheck, an internally developed computer-modeling program. These treatment plans are developed at our operations facility in Costa Rica and are made available to the prescribing dental professional via our proprietary customer interfacing software, VIP. The prescribing orthodontist or general practitioner dentist (GP) then reviews the ClinCheck simulation. ClinCheck allows the orthodontist or GP to simulate treatment in three dimensions by modeling two-week stages of tooth movement. Upon the dental professional s approval of the ClinCheck simulation, we use the data underlying the simulation, in conjunction with stereolithography (SLA) technology, to manufacture Aligner molds. A third party shelter services provider located in Juarez, Mexico uses these molds to fabricate Aligners. Aligners are 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 a dental professional using ClinCheck. After the Aligners are produced, our third party shelter services provider ships the finished products to our customers.

We generate the vast majority of our revenues from the sales of the Invisalign system to orthodontists and GPs in the United States and Canada, our domestic market. For the year ended December 31, 2005, sales of Invisalign in our domestic GP channel and our domestic orthodontist channel represented approximately 43% and 41% of our total revenues, respectively.

A number of factors, the most important of which are set forth below, may affect our success during 2006 and beyond.

- *Increased Pricing Pressure.* In May 2005, OrthoClear, Inc. announced the commercial launch of the OrthoClear System, a product that is intended to compete directly with our Invisalign system. We believe that OrthoClear s product infringes on our intellectual property and we have filed several lawsuits alleging, among other things, OrthoClear s unlawful use of our intellectual property, including our trade secrets. *See Part I, Item 3 Legal Proceedings of this Report on Form 10-K for a more complete summary of the OrthoClear litigation.* In response to OrthoClear s launch and in an effort to simplify our pricing structure, in the fourth quarter of 2005 we announced that all Invisalign cases (other than Invisalign Express) in our domestic market will have a list price of $1,495 per case. Previously, list prices ranged from $1,195 to $1,895 per case depending on the treatment option selected. In addition, in the fourth quarter of 2005, we expanded our volume based discount program to all doctors. We expect each of these programs, and other similar programs that we may launch in 2006, to adversely affect our revenue, gross margin and net profits.

- *Disruption in Sales Coverage and Customer Relationships.* In the first half of 2005, 17 orthodontic sales representatives, representing approximately 50% of our orthodontic sales force, left Align and joined OrthoClear. We have replaced the majority of these individuals with new sales representatives. Case submissions in our orthodontic channel were slightly lower in the last two quarters of 2005 compared to the previous two quarters due in part to the disruption in our sales force and the resulting disruption to many of our key customer relationships. We are committed to train and successfully deploy our new sales team and rebuild these disrupted customer relationships. *See Part I, Item 1A Risk Factors We rely on our direct sales force to sell our products, any failure to maintain our direct sales force could harm our business.*

- *Penetration into our Domestic Market.* Although we have historically generated a majority of our revenues from orthodontists, there exists a significantly greater number of GPs in North America than orthodontists. As the primary provider of dental care, GPs have access to a greater number of patients than orthodontists, and possess a unique opportunity to educate these patients on the benefits of oral care and introduce them to Invisalign. GPs also have the ability to refer appropriate cases to orthodontists and may choose to treat less complex cases themselves. Largely due to the fact that there are significantly more GPs than orthodontists, we expect that an increasingly larger percentage of our revenues will be generated by GPs. In fact, in fiscal 2005, our domestic GP channel generated 43% of our total revenue, while the orthodontist channel represented 41%. We believe that by focusing on increasing utilization rates among our existing GP customers, the overall market for Invisalign will increase, as patients who would not have otherwise sought orthodontic treatment are introduced to Invisalign by their GPs. In addition, by educating dental students and orthodontic residents on the benefits of the Invisalign technique, we believe they will be more likely to use this technology in their future practices and offer Invisalign as a treatment option. In 2005, four dental schools, Harvard University, Columbia University, Temple University and the University of Texas at San Antonio, announced the integration of the Invisalign technique into their curriculums. We expect additional dental schools to integrate the Invisalign technique into their curriculums in the future.

- *Continued Product Leadership*. We are committed to investing in delivering new products, enhancing the user experience and introducing new product features to our existing products. In the second half of 2005, we launched Invisalign Express, a lower-cost Aligner system to be used for less complex cases. Invisalign Express is intended to assist our customers to treat a broader range of patients by providing a lower cost option for less complex orthodontic cases thereby increasing the market for our products. In addition, we are currently in the early testing of a bracket positioning template which, if successfully launched, is intended to be used in conjunction with our digital treatment plan in order to guide doctors in proper bracket placement in traditional wires and bracket treatment. We are also planning to introduce a compliance indicator which will help doctors and patients understand if the patients have worn their Aligners for enough time to effectively move their teeth. By investing in developing these new products and continually enhancing our existing products, we expect to increase market share.

- *Expansion of International Markets.* We will focus our efforts towards increasing adoption of Invisalign by dental professionals in key international markets, including Europe and Japan. We will consider expanding into additional international markets on a case by case basis. In October 2005, we announced the launch of Invisalign in Japan. In fiscal 2005, our international channel represented approximately 12% of our total revenue.

- *Increasing reliance on International Manufacturing Operations.* Our manufacturing efficiency has been and will be an important factor in our future profitability. We use a third party based in Juarez, Mexico, International Manufacturing Solutions Operaciones, S.R.L. (IMS), for the fabrication and packaging of Aligners. We are currently in the process of relocating our SLA mold

fabrication operations from our Santa Clara, California facility to IMS. We expect this relocation to be complete by the second quarter of 2006. As a result of this relocation, our reliance on our international manufacturing operations will continue to increase. Our success will depend in part on the efforts and abilities of management to effectively manage this international operation, including our relationship with IMS. In addition, we currently are and will become increasingly dependant on IMS s ability to hire and retain employees generally, as well as hire and retain employees with the necessary skills to perform the more technical aspects of our operations. If our management and/or IMS fail in any of these respects, we could experience production delays and lost or delayed revenue. In addition, even if we have case submissions in the manufacturing backlog, if IMS is unable for any of these or other reasons to timely ship our product to our customers, our revenue will be delayed which will cause our operating results to fluctuate. *See Part I, Item 1A Risk Factors for risks related to our international operations*.

Results of Operations

Comparison of Years Ended December 31, 2005, 2004 and 2003:

Revenues:

Invisalign product revenues by channel and other revenue, which represented training and sales of ancillary products, for the years ended December 31, 2005, 2004 and 2003, are as follows:

Revenues	Years Ended December 31, 2005 (in millions)	Change	% Change	2004	Change	% Change	2003
Domestic:							
Orthodontic	$ 85.4	$ (0.7)	-1 %	$ 86.1	$ 14.0	19 %	$ 72.1
GP	89.1	27.1	44 %	62.0	30.5	97 %	31.5
International	23.2	6.8	41 %	16.4	4.7	40 %	11.7
Total Invisalign	197.7	33.2	20 %	164.5	49.2	43 %	115.3
Other revenue	9.4	1.1	13 %	8.3	0.9	12 %	7.4
Total Revenue	$ 207.1	$ 34.3	20 %	$ 172.8	$ 50.1	41 %	$ 122.7

Revenue grew by 20% for the year ended December 31, 2005, compared to the year ended December 31, 2004. The growth in revenues resulted primarily from an increase in overall case shipment volume in the domestic GP channel driven by an increase in the number of participating clinicians and the launch of Invisalign Express in the third quarter of 2005. Additionally, international sales improved primarily as a result of increased number of participating clinicians and case utilization by our European practitioners.

For the year ended December 31, 2004, growth in revenues from our domestic orthodontic and general practitioner channels over fiscal 2003 resulted primarily from higher case volumes driven by an increase in the number of participating clinicians and utilization within the general practitioner practices. Higher product sales during fiscal 2004 as compared to fiscal 2003 also benefited from increased promotional advertising campaigns and sales initiatives in effect during fiscal 2004.

For the fiscal year 2006, although we expect our case shipment volume to increase, we anticipate that our revenues will remain consistent with fiscal year 2005. In 2006, we will begin to see the full impact of the lower average selling price resulting from both the pricing initiatives we introduced during the fourth quarter of 2005, and Invisalign Express, which we launched in the third quarter of 2005 and has a lower average selling price than our full Invisalign product.

Cost of revenues:

	Years Ended December 31, 2005	Change	2004	Change	2003
	(in millions)				
Cost of revenues	$ 63.8	$ 6.3	$ 57.5	$ 5.9	$ 51.6
% of Revenues	31 %		33 %		42 %
Gross Profits	$ 143.3	$ 28.0	$ 115.3	$ 44.1	$ 71.2
% of Revenues	69 %		67 %		58 %

Cost of revenues includes the salaries for staff involved in the production process, the cost of materials, packaging, shipping costs, depreciation on the capital equipment used in the production process, training costs and the cost of facilities.

Gross margin improved to 69% of revenues for the fiscal year ended December 31, 2005, compared to 67% of revenues for the year ended December 31, 2004. This improvement in gross margin is primarily the result of cost savings achieved from manufacturing process improvements and increased cost absorption due to higher production volumes partially offset by increased training costs as a result of dental professionals auditing training classes for no charge.

Gross margin for the year ended December 31, 2004 improved to 67% of revenues, compared to 58% of revenues for the year ended December 31, 2003. The higher gross margin for the year ended December 31, 2004 was primarily attributable to improved fixed cost absorption related to increasing volumes, manufacturing process improvements in both our treatment operations facility in Costa Rica and in the aligner fabrication process. Also included in cost of revenues are stock-based compensation expenses of $0.9 million and $2.6 million for the years ended December 31, 2004 and 2003, respectively.

For the fiscal year 2006, we anticipate that our gross margin, including stock based compensation, will decrease slightly, primarily as we begin to see the full impact of the lower average selling price discussed in revenues above.

Sales and marketing:

	Years Ended December 31, 2005	Change	2004	Change	2003
	(in millions)				
Sales and marketing	$ 80.1	$ 24.2	$ 55.9	$ 12.2	$ 43.7
% of Revenues	39 %		32 %		36 %

Sales and marketing expense includes sales force compensation (combined with travel related costs and expenses for professional marketing programs), expenses relating to conducting workshops and market surveys, advertising, and dental professional trade show attendance.

Sales and marketing expense increased by $24.2 million for the year ended December 31, 2005, compared to the year ended December 31, 2004. This increase was primarily related to incremental head-count which resulted in higher payroll costs of $10.3 million, $6.7 million related to increased advertising, media and trade show costs, an additional $4.8 million on outside services and other sales and marketing support costs, and $2.4 million of expenses attributable to retention incentives and guarantees paid to our sales force in response to the solicitation of our sales force by OrthoClear during the first quarter of 2005.

The increase in sales and marketing expense during fiscal 2005 was consistent with our marketing and sales initiatives. We expect 2006 sales and marketing expense, including stock based compensation, to be comparable to 2005, as we continue to develop and expand our domestic and international markets, develop new media programs, enhance our web site and provide clinical education. Sales and marketing

expense increased by $12.2 million for the year ended December 31, 2004 as compared to the year ended December 31, 2003. This increase resulted primarily from an increase in spending of $4.4 million related to incremental headcount in our North American sales and marketing work force, $0.9 million related to North America sales force training, $2.7 million related to our international workforce and outside services, and $5.9 million related to increases in media, advertising costs, marketing promotions and other related expenses. The increase in spending was partially offset by the decrease of $1.5 million in stock-based compensation expense. Sales and marketing expense includes stock-based compensation expenses of $0.7 million and $2.2 million for the years ended December 31, 2004 and 2003, respectively.

General and administrative:

	Years Ended December 31,				
	2005	Change	2004	Change	2003
	(in millions)				
General and administrative	$ 42.2	$ 8.3	$ 33.9	$ (0.4)	$ 34.3
% of Revenues	20 %		20 %		28 %

General and administrative expense includes salaries for administrative personnel, outside consulting services, legal expenses and general corporate expenses.

General and administrative expense increased by $8.3 million for the year ended December 31, 2005, compared to the year ended December 31, 2004. During 2005 we incurred $8.0 million of incremental expense related to the OrthoClear litigation, which resulted from higher external legal and consulting costs and the hiring of additional legal staff.

Compared to year ended December 31, 2003, general and administrative expenses decreased by $0.4 million for the year ended December 31, 2004, primarily due to the decrease in stock-based compensation expense of $4.4 million and legal fees of $2.4 million. The decrease in litigation spending was primarily due to the settlement charge of $2.1 million included in general and administrative expenses for the year ended December 31, 2003 related to the conclusion of the Discus arbitration proceedings. The decreased expenses for the year ended December 31, 2004 as compared to the year ended December 31, 2003 were offset by increases of $4.2 million in payroll expenses and $2.1 million in general corporate expenses.

For the fiscal year 2006, we expect that general and administrative expenses will increase from fiscal 2005. This increase will be primarily attributable to stock based compensation and OrthoClear related expenses.

General and administrative expenses include stock-based compensation expenses of $0.1 million, $2.7 million and $7.1 million for the years ended December 31, 2005, 2004 and 2003, respectively.

Research and development:

	Years Ended December 31,				
	2005	Change	2004	Change	2003
	(in millions)				
Research and development	$ 18.6	$ 2.8	$ 15.8	$ 2.7	$ 13.1
% of Revenues	9 %		9 %		11 %

Research and development expense includes the costs associated with software engineering, the cost of designing, developing and testing our products and conducting clinical and post-marketing trials. We expense our research and development costs as they are incurred.

Research and development expense increased by $2.8 million for the year ended December 31, 2005, compared to the year ended December 31, 2004. The primary reasons for the higher expenses in 2005, compared to 2004, were an increase of $1.3 million in outside services and consulting expenses, $1.1 million of additional payroll related costs due to higher headcount and a $0.4 million increase in training and other research and development expenses.

The $2.7 million increase in research and development expense for the year ended December 31, 2004, over the year ended December 31, 2003, resulted from increased spending of $3.2 million for product improvement initiatives and a $1.1 million severance charge related to the departure of our Vice President, Engineering, partially offset by a $1.6 million decrease in stock-based compensation expense. Research and development expenses included $1.6 million and $3.2 million of stock-based compensation for the years ended December 31, 2004 and 2003, respectively.

For fiscal 2006, we expect a slight increase in research and development spending, including stock based compensation, over 2005 as we continue to invest in research and development efforts to bring new products to market, conduct clinical research and focus on product improvement initiatives.

Interest and other income (expense), net:

	Years Ended December 31,				
	2005	Change	2004	Change	2003
	(in millions)				
Interest and other income (expense), net	$ 0.3	$ 0.3	$	$ 0.1	$ (0.1)

Interest and other income (expense), net, includes interest income earned on cash balances, interest expense on debt, foreign currency translation gains and losses for the dollar against other currencies related to international businesses and other miscellaneous charges.

Interest and other income and expenses for the year ended December 31, 2005, included interest income of $1.9 million, which resulted from higher interest rates and average cash balances during 2005, offset by exchange losses of $1.0 million and $0.6 million of interest expense, bank charges and other expense. For year ended December 31, 2004, interest and other income and expense included interest income of $0.7 million, exchange gains of $0.3 million, offset by interest expense of $0.3 million and $0.7 of other expense and bank charges. For the year ended December 31, 2003, interest income was $0.5 million, exchange gains were $0.4 million, which were reduced by interest expense of $0.4 million and other expenses of $0.4 million.

Income tax provision:

	Years Ended December 31,				
	2005	Change	2004	Change	2003
	(in millions)				
Provision for income taxes	$ (1.3)	$ (0.3)	$ (1.0)	$ (0.9)	$ (0.1)

Our effective tax rate was 48.2%, 10.2% and 0.4% for fiscal 2005, 2004 and 2003, respectively. As of December 31, 2005, we have recorded a full valuation allowance for our existing deferred tax assets due to uncertainties about whether we will be able to utilize these assets before they expire. As a result, our income tax provision is based upon our operating results for each taxable jurisdiction in which we operate and the amount of statutory tax that we incur in each jurisdiction.

At December 31, 2005, we had a net operating loss carryforwards of approximately $193.5 million for federal purposes and $66.9 million for California state tax purposes. If not utilized, these carryforwards will begin to expire beginning in 2017 for federal purposes and 2007 for California purposes. The Internal Revenue Code imposes an annual limitation on the use of a corporation s tax attributes if a corporation

undergoes an ownership change for tax purposes. If an ownership change is determined to have occurred, our ability to use the net operating loss carryforwards would be subject to an annual limitation. However, based on our current estimate of the total net operating losses at December 31, 2005 and our current estimate of the annual limitation had a change of ownership occurred, we do not expect current utilization of our net operating loss carryforwards to result in a limitation prior to utilization. At December 31, 2005, we had research credit carryforwards of approximately $3.9 million for federal purposes and $4.6 million for California state tax purposes. If not utilized, the federal credit carryforwards will begin to expire in 2017. The California state credit can be carried forward indefinitely.

We have not provided additional U.S. income taxes on undistributed earnings from non-U.S. operations as of December 31, 2005 because such earnings are intended to be reinvested indefinitely outside of the United States.

Stock-based compensation:

	Years Ended December 31,				
	2005	Change	2004	Change	2003
	(in millions)				
Stock Based Compensation	$ 0.1	$ (5.8)	$ 5.9	$ (9.1)	$ 15.0

In connection with the grant of stock options to employees and non-employees prior to 2001, we recorded deferred stock-based compensation as a component of stockholders equity. Stock based compensation was fully amortized as of December 31, 2004. For options granted to non-employees, we measure the option s fair value using the Black-Scholes valuation model at each reporting period and recognize stock based compensation as options vest, which is generally four years. This stock-based compensation is amortized as charges to operations over the vesting periods of the options.

Historically, we have accelerated the vesting of options to several employees in connection with severance packages. These accelerations were accounted for as a charge to the consolidated statements of operations. This charge is equal to the intrinsic value of the options which was calculated as a difference between the exercise price of the accelerated options and the fair value of the common stock on the date of the acceleration.

For the year ended December 31, 2005, we recorded $0.1 million resulting from accelerated vesting of options in connection with severance packages.

For the year ended December 31, 2004, deferred stock-based compensation expenses included $5.1 million of amortization of deferred compensation expenses, $0.4 million of expense relating to options granted to non-employees, and $0.4 million of expenses resulting from accelerated vesting of options in connection with severance packages.

For fiscal the year ended December 31, 2003 we recorded $12.8 million of amortization of deferred compensation expense, $1.3 million of expenses relating to options granted to non-employees and $0.9 million of expenses resulting from accelerated vesting of options in connection with severance packages.

Option Acceleration.

On October 6, 2005, the Compensation Committee of our Board of Directors approved acceleration of the vesting for all unvested stock options with exercise prices greater than $7.10. Options held by non-employee directors are excluded from the vesting acceleration. As a result of the acceleration, approximately 3.8 million options or 35% of the total outstanding options became immediately exercisable as of October 6, 2005. Of the aggregate number of options subject to the acceleration, approximately 1.2 million options or 32% of the total accelerated options were held by our executive officers. Because the exercise price of all options subject to acceleration was greater than the fair market value of our underlying

common stock on the date of acceleration, we did not record any compensation expense, in accordance with generally accepted accounting principles.

The primary purpose of the acceleration was to eliminate future compensation expense we would otherwise recognize in our statement of operations with respect to these accelerated options upon the adoption of FAS 123(R). FAS 123(R) is effective for us beginning in the first quarter of 2006, and will require that compensation expense associated with stock options be recognized in the statement of operations, rather than as a footnote disclosure in our consolidated financial statements.

Recent Accounting Pronouncements

In November 2004, the Financial Accounting Standards Board (FASB) issued SFAS No. 151, Inventory Costs an amendment of ARB No. 43 (SFAS 151), which is the result of its efforts to converge U.S. accounting standards for inventories with International Accounting Standards. SFAS No. 151 requires idle facility expenses, freight, handling costs and wasted material (spoilage) costs to be recognized as current period charges. It also requires that allocation of fixed production overheads to the cost of conversion be based on the normal capacity of the production facilities. SFAS No. 151 will be effective for inventory costs incurred during fiscal years beginning after June 15, 2005. We do not expect this standard to have a material impact on its consolidated financial position, results of operations or cash flows.

In December 2004, the FASB issued SFAS No. 123 (revised 2004), Share-Based Payment (SFAS 123(R)) which requires the measurement of all employee share-based payments to employees, including grants of employee stock options, using a fair-value-based method and the recording of such expense in our consolidated statements of income. In March 2005, the SEC released Staff Accounting Bulletin No. 107, Share-Based Payment (SAB No. 107) relating to the adoption of SFAS 123(R). Beginning in the first quarter of 2006, Align will adopt SFAS 123(R) under the modified prospective transition method using the Black-Scholes pricing model. Under the new standard, our estimate of compensation expense will require a number of complex and subjective assumptions including our stock price volatility, employee exercise patterns (expected life of the options), future forfeitures and related tax effects. During the first quarter of fiscal 2006, we will begin recording the fair value of our share-based compensation in our financial statements in accordance with Statement of Financial Accounting Standards No. 123(R), Share-Based Payment (Revised 2004). Although the adoption of SFAS 123(R) will have no adverse impact to our balance sheet and cash flows, it will adversely affect our net profit (loss) and earnings (loss) per share. See Notes 1 and 7 to the Notes to Consolidated Financial Statements.

In October 2005, the FASB issued Financial Statement of Position (FSP) FAS 123(R)-2, Practical Accommodation to the Application of Grant Date as Defined in FAS 123(R) (FSP 123(R)-2). FSP 123(R)-2 provides guidance on the application of grant date as defined in SFAS No.123(R). In accordance with this standard a grant date of an award exists if a) the award is unilateral grant and b) the key terms and conditions of the award are expected to be communicated to an individual recipient within a relatively short time period from the date of approval. We will adopt this standard when we adopt FAS 123(R) beginning in the first quarter of 2006, and we do not expect it will have a material impact on our consolidated financial position, results of operations or cash flows.

In November 2005, the FASB issued FSP FAS 123(R)-3, Transition Election Related to Accounting for Tax Effects of Share-Based Payment Awards (FSP 123(R)-3). FSP 123(R)-3 provides an elective alternative method that establishes a computational component to arrive at the beginning balance of the accumulated paid-in capital pool related to employee compensation and simplified method to determine the subsequent impact the accumulated paid-in capital pool employee awards that are fully vested and outstanding upon the adoption of SFAS No. 123(R). We are currently evaluating this transition method.

In May 2005, the FASB issued SFAS No. 154, Accounting Changes and Error Corrections (SFAS No. 154). SFAS No. 154 is a replacement of Accounting Principles Board Opinion No. 20 and SFAS No. 3. SFAS No. 154 provides guidance on the accounting for and reporting of accounting changes and error corrections. It establishes retrospective application as the required method for reporting a change in accounting principle. SFAS No. 154 provides guidance for determining whether retrospective application of a change in accounting principle is impracticable and for reporting a change when retrospective application is impracticable. SFAS No. 154 also addresses the reporting of a correction of an error by restating previously issued financial statements. SFAS No 154 is effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005. We do not believe that it will have a material impact on our consolidated financial position, results of operations or cash flows.

In November 2005, the FASB issued FSP FAS 115-1 and FAS 124-1, The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments (FSP 115-1 and 124-1), which clarifies when an investment is considered impaired, whether the impairment is other-than-temporary, and the measurement of an impairment loss. It also includes accounting considerations subsequent to the recognition of the other-than-temporary impairment and requires certain disclosures about unrealized losses that have not been recognized as other-than-temporary impairments. FSP 115-1 and 124-1 are effective for all reporting periods beginning after December 15, 2005. At December 31, 2005, we have no unrealized investment losses that had not been recognized as other-than-temporary impairments in our available-for-sale securities. We do not anticipate that the implementation of these statements will have a significant impact on our financial position, results of operations or cash flows.

Liquidity and Capital Resources

We fund our operations from the proceeds of the sale of our common stock and from cash generated from sales of our product. Our cash and cash equivalents balance improved for the year ended December 31, 2005, to $74.2 million from $69.7 million for the year ended December 31, 2004. Restricted cash was $0.2 million and $0.3 million for the years ended December 31, 2005 and 2004, respectively. We had an accumulated deficit of $290.4 million as of December 31, 2005.

We generated cash of $16.1 million and $24.6 million from our operating activities during the years ended December 31, 2005 and 2004, respectively. Net cash provided by operating activities for the year ended December 31, 2005, resulted primarily from operating profits adjusted for non cash items and increases in accrued liabilities partially offset by reductions in accounts payable. For the year ended December 31, 2004, net cash was provided by operating activities primarily from operating profits adjusted for non cash items and increases in accrued liabilities and deferred revenue, which was partially offset by increases in accounts receivable.

We used $15.3 million of cash for our investing activities for the year ended December 31, 2005. This included $13.8 million of cash used to purchase capital assets, and $0.9 million of net cash used to purchase General Orthodontics, LLC. For the year ended December 31, 2004, we used $6.0 million of our cash in investing activities, primarily to purchase property and equipment for capacity expansion and manufacturing improvements, including approximately $3.2 million for the implementation of the new version of our enterprise resource planning system and new software for our manufacturing execution system. Partially offsetting these purchases were proceeds from the sale of equipment and maturities of marketable securities during fiscal 2004.

Net cash provided by financing activities was $3.7 million and $6.1 million for the years ended December 31, 2005 and 2004, respectively. For the year ended December 31, 2005, and 2004, net cash provided by financing activities consisted of proceeds from the issuance of common stock, primarily from exercises of employee stock options, partially offset by payments on debt obligations related to the equipment-based term loan and capital lease obligations.

In December 2002, we obtained a $5.0 million equipment-based term loan under our revolving line of credit. This loan accrued interest at a rate of 2.25% above prime. During fiscal year 2005, we paid down the outstanding balance of $1.7 million with interest, drawn under this facility.

In December 2005, we renegotiated and amended our existing revolving line of credit. The amended credit agreement increases the available borrowings under the revolving line of credit from $15 million to $20 million. Included in the new revolving line of credit is a letter of credit facility of up to $5 million, a foreign exchange facility of up to $5 million and an equipment facility of up to $10 million. We may elect interest rates on our borrowing calculated by reference to bank s prime rate less one-half of one percent or LIBOR plus two percent. The new credit facility matures on December 16, 2007, at which time all outstanding borrowings must be repaid. The new credit facility contains certain restrictive loan covenants, including, among others, financial covenants requiring a minimum quick ratio and minimum tangible net worth, and covenants limiting our ability to dispose of assets, make acquisitions, be acquired, incur indebtedness, grant liens, make investments, pay dividends and repurchase stock. As of December 31, 2005, there was no outstanding borrowing under these credit facilities.

Contractual Obligations / Off Balance Sheet Arrangements

The impact that our contractual obligations as of December 31, 2005 are expected to have on our liquidity and cash flow in future periods is as follows (in thousands):

	Payments Due by Period				
	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
Operating lease obligations(1)	$ 9,064	$ 3,010	$ 4,417	$ 1,637	$
Equipment purchase agreement(2)	3,424	3,424			
Computer support services	387	387			
Total	$ 12,875	$ 6,821	$ 4,417	$ 1,637	$

(1) Includes an early termination fee of approximately $220,000 on our facility in Amsterdam, The Netherlands. The lease expires in 2014 with an option to cancel in 2009.

(2) Equipment for manufacturing operations in Mexico.

We have no significant contractual obligations not fully recorded on our consolidated balance sheets or fully disclosed in the notes to our consolidated financial statements. We have no off-balance sheet arrangements as defined in the rules and regulations promulgated under the Securities Act.

As discussed under Part I Item 3 Legal Proceedings , we are currently involved in litigation with various parties. Each of these proceedings is in its early stages and it is not yet possible to determine its ultimate outcome. At this time we cannot estimate the impact this litigation may have on our future cash requirements.

We expect that our expense levels for 2006, including stock based compensation, will increase from 2005, depending on our level of business activity. We expect that any increases will be focused on continuing efforts to automate our manufacturing processes, capacity expansion requirements, the size of our sales force and dental professional training staff, continued international sales and marketing efforts, legal expenses including $10.0 million to $12.0 million related to OrthoClear litigation, and research and

development expenses as we develop new products and improvements to our existing product. In addition, we may use cash to fund acquisitions of complementary businesses or technologies. Our capital requirements depend on market acceptance of our products and our ability to market, sell and support our products on a worldwide basis.

Our 2005 Incentive Plan allows for the issuance of restricted stock units (RSUs), among other things. We have recently granted RSUs, together with stock options, to certain of our employees. RSUs do not generate cash, as a result, by granting RSUs we will likely generate less cash from the proceeds of the sale of our common stock.

We believe that our current cash and cash equivalents will be sufficient to fund our operations for at least the next 12 months. If we are unable to generate adequate operating cash flows, we may need to seek additional sources of capital through equity or debt financing, collaborative or other arrangements with other companies, bank financing and other sources in order to realize our objectives and to continue our operations. There can be no assurance that we will be able to obtain additional debt or equity financing on terms acceptable to us, or at all. If adequate funds are not available, we could be required to delay implementing our business strategy and reduce our expenditures in general. Accordingly, the failure to obtain sufficient funds on acceptable terms when needed could have a material adverse effect on our business, results of operations and financial condition.

Critical Accounting Policies

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

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

Revenue Recognition

We enter into arrangements to sell products, services, and other arrangements (multiple element arrangements) that include combinations of products. Revenue from product sales, net of discounts and rebates, is recognized provided that persuasive evidence of an arrangement exists, delivery has occurred, the price is fixed or determinable, and collectibility is reasonably assured. Service revenues are recorded when completed. Other multiple element arrangements require delivery of products in the future. We use objective evidence of fair value to allocate revenue to the elements and recognize revenue when the criteria for revenue recognition have been met for each element. Revenue is deferred on the undelivered element based on a historical usage rate and recognized when delivery occurs. The amount of revenue deferred is affected by the historical breakage factor, and actual results could vary from the estimated outcome, requiring future adjustments to revenue.

Product Warranty

We warrant our products against defects in materials and workmanship until the Invisalign case is completed. We accrue for estimated warranty in costs of goods sold upon the shipment of products. The amount of accrued estimated warranty costs are primarily based on historical experience as to product failures as well as current information on repair costs. Actual warranty costs could differ from the

estimated amounts. We regularly review the accrued balances and update these balances based on historical warranty cost trends. Actual warranty costs incurred have not materially differed from those accrued. If we were to experience higher rates of warranty events, we would be required to accrue additional warranty costs, which would negatively affect our operating results.

Legal contingencies

We are currently involved in certain legal proceedings as discussed in Note 4 to the Notes to Consolidated Financial Statements. Because of uncertainties related to both the potential amount and range of loss from pending litigation, management is unable to make a reasonable estimate of the liability that could result if there is an unfavorable outcome in these legal proceedings. As additional information becomes available, we will assess the potential liability related to this pending litigation and revise our estimates accordingly. Revisions of our estimates of such potential liability could materially impact our results of operations and financial condition.

Deferred Tax Valuation Allowance

We have established a full valuation allowance because we believe the realization of our deferred tax assets is not likely. Deferred tax assets and liabilities are based on temporary differences that result from differing treatments of certain items for tax and accounting purposes. These differences result in deferred tax assets and liabilities, which we show on our balance sheet. We must then assess the likelihood that our deferred tax assets will be realized. To the extent we believe that realization is not likely, we establish a valuation allowance. See Note 6 to the Notes to Consolidated Financial Statements.

While we have considered future taxable income in assessing the need for the full valuation allowance, we would decrease the valuation allowance to take into account deferred tax assets that we could realize. A decrease in the valuation allowance could have a favorable impact, which could be material, on our income tax provision and net income in the period in which we make the decrease.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

Interest Rate Risk

Changes in interest rates could impact our anticipated interest income on our cash equivalents and investments in marketable equity securities. Periodically we invest our excess cash in low risk and short-term available for sale marketable equity securities. These investments are primarily at fixed interest rates. As of December 31, 2005, we had no outstanding investments in available for sale marketable equity securities. Due to the short duration of our cash equivalents and investments in marketable equity securities, an immediate decrease in interest rates of 100 basis points would not have a material adverse impact on the fair value of our investment portfolio. Conversely, a hypothetical decline in interest rates of 100 basis points could have an adverse impact on our future operating results and cash flows of approximately $700 thousand as a result of lower interest income.

We do not have interest bearing liabilities on our books as of December 31, 2005, and are not subject to risks from immediate interest rate increases. An increase in interest rates may affect our future cost of financing. In the past we had used fixed rate long-term financing to minimize our risk on interest rates increases.

Currency Rate Risk

The functional currency of Align and its subsidiaries is the U.S. dollar and, accordingly, gains and losses resulting from the translation of monetary assets and liabilities denominated in Euro, Costa Rican Colon, and other currencies are reflected in the determination of net income or loss. We do not enter into forward exchange contracts to reduce our exposure to foreign exchange translation gains and losses. Included in interest and other expenses for the year ended December 31, 2005, was an exchange loss of $1.0 million. For years 2004 and 2003 we experienced exchange gains of $0.3 million and $0.4 million, respectively, primarily related to Euro denominated balances. An aggregate decline of 10% in foreign currency exchange rates relative to USD may have an adverse effect of approximately $2.0 million on our results of operations and financial position.

ITEM 8. CONSOLIDATED FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

Quarterly Results of Operations

	Three Months Ended							
	2005				**2004**			
	Dec 31	**Sep 30**	**Jun 30**	**Mar 30**	**Dec 31**	**Sep 30**	**Jun 30**	**Mar 30**
	(in thousands, except per share data) (unaudited)							
Revenues	$ 51,164	$ 50,866	$ 53,940	$ 51,155	$ 43,655	$ 45,766	$ 44,204	$ 39,205
Gross profit	34,453	35,891	37,320	35,677	28,694	30,844	29,954	25,812
Operating profit (loss)	663	(1,539)	1,193	2,129	656	3,851	4,341	917
Net profit (loss)	$ 528	(1,516)	538	1,863	$ 1,121	$ 3,318	$ 3,772	$ 557
Net profit (loss) per share,								
Basic	$ 0.01	$ (0.02)	$ 0.01	$ 0.03	$ 0.02	$ 0.06	$ 0.06	$ 0.01
Diluted	0.01	$ (0.02)	$ 0.01	$ 0.03	$ 0.02	$ 0.05	$ 0.06	$ 0.01
Shares used in computing net profit (loss) per share:								
Basic	62,045	61,788	61,484	61,246	60,744	60,319	59,692	59,091
Diluted	63,247	61,788	62,953	63,148	63,560	64,055	64,461	64,559

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF MANAGEMENT ON INTERNAL CONTROL OVER FINANCIAL REPORTING

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

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

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

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

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

Management assessed the effectiveness of Align s internal control over financial reporting as of December 31, 2005. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in *Internal Control-Integrated Framework.* Based on its assessment, management has concluded that, as of December 31, 2005, Align s internal control over financial reporting was effective based on the criteria issued by the COSO in *Internal Control-Integrated Framework.*

Management's assessment of the effectiveness of Align s internal control over financial reporting as of December 31, 2005 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report which immediately follows this report.

/s/ THOMAS M. PRESCOTT
Thomas M. Prescott
President and Chief Executive Officer
March 1, 2006
/s/ ELDON M. BULLINGTON
Eldon M. Bullington
Vice President, Finance and Chief Financial Officer
March 1, 2006

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have completed integrated audits of Align Technology, Inc. s 2005 and 2004 consolidated financial statements and of its internal control over financial reporting as of December 31, 2005 and an audit of its 2003 consolidated financial statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Our opinions, based on our audits, are presented below.

Consolidated financial statements and financial statement schedule

In our opinion, the consolidated financial statements listed in the index appearing under Item 15(a)(i) present fairly, in all material respects, the financial position of Align Technology, Inc. and its subsidiaries at December 31, 2005 and 2004, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2005 in conformity with accounting principles generally accepted in the United States of America. In addition, in our opinion, the financial statement schedule listed in the index appearing under Item 15(a)(ii) presents fairly, in all material respects, the information set forth therein when read in conjunction with the related consolidated financial statements. These financial statements and financial statement schedule are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements and financial statement schedule based on our audits. We conducted our audits of these statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit of financial statements includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

Internal control over financial reporting

Also, in our opinion, management s assessment, included in Report of Management on Internal Control Over Financial Reporting appearing immediately above this report, that the Company maintained effective internal control over financial reporting as of December 31, 2005 based on criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), is fairly stated, in all material respects, based on those criteria. Furthermore, in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2005, based on criteria established in *Internal Control Integrated Framework* issued by the COSO. The Company s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express opinions on management s assessment and on the effectiveness of the Company s internal control over financial reporting based on our audit. We conducted our audit of internal control over financial reporting in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. An audit of internal control over financial reporting includes obtaining an understanding of internal control over financial reporting, evaluating management s assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we consider necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinions.

A company s internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for

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

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

/s/ PricewaterhouseCoopers LLP

San Jose, California

March 1, 2006

ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except per share data)

	Years Ended December 31,		
	2005	**2004**	**2003**
Revenues:			
Invisalign	$ 197,749	$ 164,536	$ 115,278
Ancillary products and other services	9,376	8,294	7,447
Total revenues	207,125	172,830	122,725
Cost of revenues:			
Invisalign	52,654	49,019	43,990
Ancillary products and other services	11,130	8,507	7,575
Total cost of revenues	63,784	57,526	51,565
Gross profit	143,341	115,304	71,160
Operating expenses:			
Sales and marketing	80,068	55,932	43,689
General and administrative	42,242	33,851	34,296
Research and development	18,585	15,756	13,112
Total operating expenses	140,895	105,539	91,097
Profit (loss) from operations	2,446	9,765	(19,937)
Interest income	1,918	713	531
Interest expense	(110)	(271)	(364)
Other expense	(1,525)	(445)	(268)
Net profit (loss) before provision for income taxes	2,729	9,762	(20,038)
Provision for income taxes	1,316	994	84
Net profit (loss)	$ 1,413	$ 8,768	$ (20,122)
Net profit (loss) per share:			
Basic	$ 0.02	$ 0.15	$ (0.35)
Diluted	$ 0.02	$ 0.14	$ (0.35)
Shares used in computing net profit (loss) per share:			
Basic	61,644	59,963	57,758
Diluted	63,152	64,089	57,758

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

ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
(in thousands, except per share data)

	December 31, 2005	2004
ASSETS		
Current assets:		
Cash and cash equivalents	$ 74,219	$ 69,659
Restricted cash	150	303
Accounts receivable, net of allowance for doubtful accounts of $1,626 and $1,493 at December 31, 2005 and 2004, respectively	29,305	28,809
Inventories, net	2,930	2,852
Prepaid expenses and other current assets	4,982	5,211
Total current assets	111,586	106,834
Property and equipment, net	26,427	21,702
Goodwill	478	
Intangible assets, net	719	
Other assets	2,900	2,176
Total assets	$ 142,110	$ 130,712
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	2,489	3,361
Accrued liabilities	29,372	23,481
Deferred revenue	16,747	16,257
Current portion of equipment-based term loan		1,667
Capital lease obligations		182
Total current liabilities	48,608	44,948
Other long term liabilities	64	25
Total liabilities	48,672	44,973
Commitments and contingencies (Note 3 and 4)		
Stockholders equity:		
Preferred stock, $0.0001 par value; Authorized: 5,000 shares at December 31, 2005 and 2004; Issued and Outstanding: no shares at December 31, 2005 and 2004		
Common stock, $0.0001 par value, Authorized: 200,000 shares at December 31, 2005 and 2004; Issued: 62,120 and 60,916 shares at December 31, 2005 and 2004, respectively; Outstanding: 62,080 and 60,876 shares at December 31, 2005 and 2004, respectively	6	6
Additional paid-in capital	383,836	377,559
Accumulated other comprehensive income (loss)	7	(2)
Accumulated deficit	(290,411)	(291,824)
Total stockholders equity	93,438	85,739
Total liabilities and stockholders equity	$ 142,110	$ 130,712

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

ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY (DEFICIT)
For the years ended December 31, 2005, 2004 and 2003
(in thousands)

	Common Stock Shares	Amount	Additional Paid-In Capital	Deferred Stock-Based Compensation	Notes Receivable from Stockholders	Accumulated Other Comprehensive Income(Loss)	Accumulated Deficit	Total
Balances at December 31, 2002	57,700	$ 6	$ 364,691	$ (19,005)	$ (892)	$ 17	$ (280,470)	$ 64,347
Net loss							(20,122)	(20,122)
Net change in unrealized loss from available-for-sale securities						(15)		(15)
Comprehensive loss								(20,137)
Issuance of common stock relating to employee stock purchase plan								