

ALIGN TECHNOLOGY INC  
Form 10-K  
March 12, 2007

# SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

## FORM 10-K

(Mark One)

☒

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

For the fiscal year ended December 31, 2006

Or

☐

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number: 0-32259

## ALIGN TECHNOLOGY, INC.

(Exact name of registrant as specified in its charter)

**Delaware**

(State or other jurisdiction of  
incorporation or organization)

**94-3267295**

(I.R.S. Employer  
Identification Number)

**881 Martin Avenue**

**Santa Clara, California 95050**

(Address of principal executive offices, including Zip Code)

**(408) 470-1000**

Registrant's telephone number, including area code:

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

Title of each class

Common Stock, \$0.0001 par value  
(Including associated Preferred Stock Purchase Rights)

Name of each exchange on which registered

The NASDAQ Stock Market LLC  
(NASDAQ Global Market)

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

**None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act. Yes ☐ No ☒

## Edgar Filing: ALIGN TECHNOLOGY INC - Form 10-K

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, 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 ☐ Accelerated filer ☒ Non-accelerated filer ☐

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

The aggregate market value of the registrant's common stock held by non-affiliates of the registrant was \$387,981,710 as of June 30, 2006 based on the closing sale price of the registrant's common stock on the NASDAQ Global Market on such date. Shares held by person who may be deemed affiliates have been excluded. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

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

### DOCUMENTS INCORPORATED BY REFERENCE

Portions of registrant's definitive Proxy Statement relating to its 2007 Annual Stockholders' Meeting to be filed pursuant to Regulation 14A within 120 days after the registrant's fiscal year end of December 31, 2006 are incorporated by reference into Part III of this Annual Report on Form 10-K.

---

ALIGN TECHNOLOGY, INC.

FORM 10 K

For the Year Ended December 31, 2006

TABLE OF CONTENTS

	Page
<u>PART I</u>	3
<u>Item 1.</u>	3
	<u>Business</u>
	<u>Executive Officers of the Registrant</u>
<u>Item 1A.</u>	17
<u>Item 1B.</u>	19
<u>Item 2.</u>	32
<u>Item 3.</u>	32
<u>Item 4.</u>	38
<u>PART II</u>	39
<u>Item 5.</u>	39
	<u>Market for Registrant's Common Equity and Related Stockholder Matters and</u>
	<u>Issuer Purchase of Equity Security</u>
<u>Item 6.</u>	41
<u>Item 7.</u>	42
	<u>Selected Consolidated Financial Data</u>
<u>Item 7A.</u>	56
<u>Item 8.</u>	57
<u>Item 9.</u>	90
	<u>Management's Discussion and Analysis of Financial Condition and Results of</u>
	<u>Operations</u>
<u>Item 9A.</u>	90
<u>Item 9B.</u>	90
<u>PART III</u>	92
<u>Item 10.</u>	92
<u>Item 11.</u>	92
<u>Item 12.</u>	92
	<u>Quantitative and Qualitative Disclosures About Market Risk</u>
	<u>Consolidated Financial Statements and Supplementary Data</u>
	<u>Changes In and Disagreements With Accountants on Accounting and</u>
	<u>Financial Disclosure</u>
	<u>Controls and Procedures</u>
	<u>Other Information</u>
<u>Item 13.</u>	93
<u>Item 14.</u>	93
<u>PART IV</u>	94
<u>Item 15.</u>	94
<u>Signatures</u>	100
	<u>Directors, Executive Officers and Corporate Governance</u>
	<u>Executive Compensation</u>
	<u>Security Ownership of Certain Beneficial Owners and Management and</u>
	<u>Related Stockholder Matters</u>
	<u>Certain Relationships and Related Transactions and Director Independence</u>
	<u>Principal Accountant Fees and Services</u>
	<u>Exhibits, Financial Statement Schedule and Reports on Form 8 K</u>

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

*In addition to historical information, this annual report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. These statements include, among other things, statements concerning our expectations regarding the anticipated benefit of increased collaboration between orthodontists and general practitioner dentists and the impact this collaboration will have on sales of Invisalign and on our revenue, our expectation that the percentage of revenue generated by general practitioner dentists will represent an increasingly larger percentage of our revenue, our intention to continue the integration of Invisalign into the curriculums of additional universities, our expectation regarding the benefits of new products, product features, and software enhancements, including ClinAdvisor, and the expected impact these new products and product enhancements will have on our market share, our expectations regarding product mix and Invisalign Express, our anticipated cost of the Patients First Program, our expectations regarding our average selling prices and gross margins in 2007, our expectations regarding the benefit of increased consumer marketing programs, our expectations regarding increased case shipment volume in 2007, our expectations regarding further expansion into North American and international markets, including Japan, our expectation regarding the anticipated level of our operating expenses in 2007, as well as other statements regarding our future operations, financial condition and prospects and business strategies. These statements may contain words such as expects, anticipates, intends, plans, believes, estimates, or other words indicating future results. These forward-looking statements are subject to certain risks and uncertainties that could cause actual results to differ materially from those reflected in the forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in Part II, Item 7 Management's Discussion and Analysis of Financial Condition and Results of Operations, and in particular, the risks discussed below in Item 1A Risk Factors. We undertake no obligation to revise or update these forward-looking statements. Given these risks and uncertainties, readers are cautioned not to place undue reliance on such forward-looking statements.*

## **PART I**

### **ITEM 1. BUSINESS**

#### **Our Company**

Align Technology, Inc. was incorporated in April 1997 under the laws of the state of Delaware. We design, manufacture and market the Invisalign system, a proprietary method for treating malocclusion, or the misalignment of teeth. Invisalign corrects malocclusion using a series of clear, nearly invisible, removable appliances that gently move teeth to a desired final position. Because it does not rely on the use of metal or ceramic brackets and wires, Invisalign significantly reduces the aesthetic and other limitations associated with braces. Invisalign is appropriate for treating adults and teens with mature dentition. Align Technology received FDA clearance to market Invisalign in 1998.

Under the Corporate Information/Investor Relations section of our corporate website which can be accessed at either [www.aligntech.com](http://www.aligntech.com) or [www.invisalign.com](http://www.invisalign.com), we make our Annual Report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, our proxy statement on Schedule 14A for our annual stockholders' meeting and amendments to such reports available as soon as reasonably practicable after they are electronically filed with or furnished to the Securities and Exchange Commission, or SEC. All such filings are available free of charge. The information in, or that can be accessed through, our website is not part of this report.

#### **Industry Background**

##### *Malocclusion*

Malocclusion, the misalignment of teeth, is one of the most prevalent clinical dental conditions, affecting over 200 million individuals, or approximately 75% of the U.S. population. Approximately two million people annually elect treatment by orthodontists in the U.S. While most individuals seek

orthodontic treatment to improve their appearance, malocclusion may also be responsible for dental problems such as tooth decay, tooth loss, gum disease, jaw joint pain and headaches. Because of the compromised aesthetics, discomfort and other drawbacks associated with conventional orthodontic treatments, only a relatively small proportion of people with malocclusion seek traditional treatment.

#### *Traditional Orthodontic Treatment*

In the U.S., dental professionals treat malocclusion primarily with metal archwires and brackets, commonly referred to as braces. Occasionally, dental professionals attempt to improve treatment aesthetics by using ceramic, tooth-colored brackets or bond brackets on the inside, or lingual surfaces, of the patient's teeth. Dental professionals also augment braces with elastics, metal bands, headgear and other ancillary devices.

The average treatment takes approximately 12 to 24 months to complete and requires several hours of direct dental professional involvement, or chair time. To initiate treatment, a dental professional will diagnose a patient's condition and create an appropriate treatment plan. In a subsequent visit, the dental professional will bond brackets to the patient's teeth with cement and attach an archwire to the brackets. Thereafter, by tightening or otherwise adjusting the braces approximately every six weeks, the dental professional is able to exert sufficient force on the patient's teeth to achieve desired tooth movement. Because of the length of time between visits, the dental professional must tighten the braces to a degree sufficient to achieve sustained tooth movement during the interval. In a final visit, the dental professional removes each bracket and residual cement from the patient's teeth. Upon completion of the treatment, the dental professional may, at his or her discretion, have the patient use a retainer.

Fees for traditional orthodontic treatment typically range between U.S. \$3,500 to \$7,000 with a median fee of approximately \$4,800; generally only a portion of the fees is reimbursed by insurance, if covered at all. In addition, dental professionals commonly charge a premium for lingual or ceramic alternatives. Fees are based on the difficulty of the particular case and on the dental professional's estimate of chair time, and are generally negotiated in advance. A treatment that exceeds the dental professional's estimate of chair time generally results in decreased fees per hour of chair time, and reduced profitability for the dental professional.

#### *Limitations of Traditional Orthodontic Treatment*

Although braces are generally effective in correcting a wide range of malocclusions, they are subject to many limitations and disadvantages. Conventional orthodontic treatment is associated with:

- *Unattractive appearance.* Braces call attention to the patient's condition and treatment. In addition, braces trap food, which can further compromise appearance. Braces can also result in permanent discoloration of teeth. Many adults associate braces with adolescence. As a result of these and other limitations, less than one percent of American adults with malocclusion elect traditional orthodontic treatment annually.
- *Oral discomfort.* Braces are sharp and bulky and can abrade and irritate the interior surfaces of the mouth. The tightening or adjustment of braces results in root and gum soreness and discomfort, especially in the few days immediately following an orthodontic visit.
- *Poor oral hygiene.* Braces compromise oral hygiene by making it more difficult to brush and floss. These problems can result in tooth decay and periodontal damage. Additionally, the bonding of brackets to teeth can cause permanent markings on the teeth.
- *Inability to project treatment.* Historically, dental professionals have not had a means to model the movement of teeth over a course of treatment. Accordingly, dental professionals must rely on intuition and judgment to plan and project treatment. As a result, they cannot be precise about the

direction or distance of expected tooth movement between patient visits. This lack of predictability may result in unwanted tooth movements and can limit the dental professional's ability to estimate the duration of treatment. Because most orthodontic treatment is performed on a fixed price basis, extended treatment duration reduces profitability for the dental professional.

- *Physical demands on dental professional.* The manipulation of wires and brackets requires sustained manual dexterity and visual acuity, and may place other physical burdens on the dental professional.
- *Root resorption.* The sustained high levels of force associated with conventional treatment can result in root resorption, which is a shortening of tooth roots. This shortening can have substantial adverse periodontal consequences for the patient.
- *Emergencies.* At times, braces need to be repaired or replaced on an emergency basis. Such emergencies cause significant inconvenience to both the patient and the dental professional.

Due to the poor aesthetics, discomfort and other limitations of braces, relatively few people with malocclusion elect traditional orthodontic treatment. Accordingly, we believe there is a large unmet need for an orthodontic system that addresses these patient concerns. We also believe there is an unmet need among dental professionals for a treatment system that increases the predictability and efficiency of treatment and enhances practice profitability.

#### **The Align Solution**

Invisalign (which includes full Invisalign treatment and Invisalign Express discussed below under **Our Products**) is a proprietary system for treating malocclusion. The Invisalign treatment process is comprised of several phases, the principal steps of which are: the creation of electronic treatment plans using ClinCheck and the manufacturing of Invisalign aligners (referred to in this Form 10-K as **Aligners**). The complete Invisalign treatment process is described in greater detail under **Business The Invisalign Treatment Process**.

*ClinCheck.* ClinCheck is an internally developed computer modeling program that allows dental professionals to diagnose and plan treatments for their patients. We use a dental impression and a treatment form submitted by a dental professional to develop a customized, three-dimensional treatment plan that simulates appropriate tooth movement in a series of two-week increments. ClinCheck allows the dental professional to view this three-dimensional simulation with a high degree of magnification and from any angle. Accordingly, ClinCheck enables the dental professional to project tooth movement with a level of accuracy not previously possible.

Upon review of the ClinCheck simulation, the dental professional may immediately approve the projected treatment, or may provide us with feedback for modification. We reflect any requested adjustments in a modified simulation. Upon the dental professional's approval of the ClinCheck simulation, we use the data underlying the simulation, in conjunction with stereolithography technology, to manufacture Aligner molds. International Manufacturing Solutions Operaciones, S.R.L., or IMS, a third party shelter services provider in Juarez, Mexico, manufactures the molds and then uses these molds to fabricate the patient's Aligners.

*Aligners.* Aligners are custom-manufactured, thin, clear plastic, removable dental appliances that are manufactured in a series to correspond to each two-week stage of the ClinCheck simulation. Aligners are customized to perform the treatment prescribed for an individual patient by dental professionals using ClinCheck. Each Aligner covers a patient's teeth and is nearly invisible when worn. Aligners are commonly worn in pairs, over the upper and lower dental arches. Aligners are generally worn for consecutive two-week periods which correspond to the approved ClinCheck treatment simulation. After two weeks of use, the patient replaces them with the next pair in the series. This process is repeated until the final



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

## **Our Products**

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

*Full Invisalign Treatment.* Commercial sales of full Invisalign treatment commenced in the U.S. in July 1999. Our traditional, full Invisalign treatment option is intended to be used as a complete treatment for a broad range of malocclusions. Each treatment plan is unique to the individual patient and will consist of as many Aligners as indicated by ClinCheck in order to achieve the doctor's treatment goals. In fiscal 2006, approximately 81% of our net revenue was generated by the sale of full Invisalign treatment.

*Invisalign Express.* In the third quarter of 2005, we launched Invisalign Express, a lower-cost solution for less complex orthodontic cases. Invisalign Express is a dual arch orthodontic treatment for cases that meet certain predetermined clinical criteria and consist of up to ten Aligners. Invisalign Express is intended to help a broader range of patients elect orthodontic treatment by providing a lower-cost option for adult relapse cases, for minor crowding and spacing, and as a pre-cursor to restorative or cosmetic treatments such as veneers. In fiscal 2006, approximately 13% of our net revenue was generated by the sale of Invisalign Express.

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

## **Benefits of Invisalign**

We believe that Invisalign provides benefits to dental professionals and patients that have the potential to establish Invisalign as the preferred alternative to conventional braces.

### *Benefits to the dental professional*

- *Ability to visualize treatment and likely outcomes.* ClinCheck enables dental professionals to preview a course of treatment and the likely outcome of treatment in an interactive three-dimensional computer model. ClinCheck allows dental professionals to analyze multiple treatment alternatives before selecting the course of action they feel is most appropriate for the patient.
- *Begin using Invisalign with minimal additional training.* The biomechanical principles that underlie treatment with the Invisalign system are consistent with those of traditional orthodontics. Dental professionals can complete our initial training within two days. We provide additional clinical support following the initial training and encourage dental professionals to attend continuing education classes, seminars and workshops.
- *Expanded patient base.* We believe that Invisalign has the potential to transform the practice of orthodontics. Currently, approximately two million people annually elect treatment by orthodontists in the U.S. These patients represent approximately 1 percent of the population of people with malocclusion. Of these, we estimate approximately 45 percent, or approximately 900,000 patients have mature dentition with mild to moderate malocclusion and are therefore potential candidates for Invisalign. We believe that Invisalign will allow dental professionals to attract patients who would not otherwise seek orthodontic treatment.



- *Decreased dental professional and staff time.* Invisalign eliminates the need for time-intensive processes such as bonding appliances to the patient's teeth, adjusting archwires during the course of treatment and removing the appliances at the conclusion of treatment. As such, use of Invisalign reduces dental professional and staff chair time and can increase practice capacity.
- *Practice productivity.* We believe that as dental professionals move to a higher volume of Invisalign patients, they will be able to better leverage their existing resources, including office space and staff time, resulting in an increase in daily patient appointments and practice productivity.

#### *Benefits to the Patient*

- *Excellent aesthetics.* Aligners are nearly invisible when worn, significantly reducing the aesthetic concerns associated with conventional braces.
- *Comfort.* By replacing the six-week adjustment cycle of traditional braces with two-week stages, Aligners move teeth more gently than conventional braces. Also, Aligners are thin, smooth and low in profile. As a result, Aligners are more comfortable and less abrasive than conventional braces.
- *Improved oral hygiene.* Patients can remove Aligners for tasks that are difficult with conventional braces, such as eating, brushing and flossing. We believe this feature has the potential to reduce tooth decay and periodontal damage during treatment, which may result from conventional braces.
- *Potentially reduced overall treatment time.* Aligners control force by distributing it broadly over the exposed surfaces of the teeth. In addition, the ClinCheck simulation from which Aligners are produced is designed to reduce unintended and unnecessary tooth movements. Together, these factors may reduce overall treatment time relative to conventional braces.
- *Potentially reduced root resorption.* We believe that controlling force and shortening treatment time has the potential to reduce the incidence of root resorption, which is the breakdown or destruction of root structure.
- *Reduced incidence of emergencies.* Typically, a lost or broken Aligner is simply replaced with the next Aligner in the treatment series, minimizing inconvenience to both patient and dental professional.

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

#### **Limitations of Invisalign**

In some instances, the Invisalign system may have certain limitations relative to conventional treatment. Aligners cost more to produce than conventional braces, and we charge dental professionals more than they generally pay for the supplies used in conventional treatment. Depending on the individual pricing policies of each dental professional, the cost of full Invisalign treatment to the patient may be greater than for conventional braces. Dental professionals must also incorporate our manufacturing cycle times into their overall treatment plan. Once a dental professional submits a case to us, there is generally a turn-around time of a month or more before the corresponding Aligners are delivered. Aligners may not be appropriate for all cases, such as severe malocclusion, which may require Aligners to be used in combination with conventional braces for optimal results. In addition, because Aligners are removable, treatment using Invisalign depends on patients wearing their Aligners as recommended. Some patients may experience a temporary period of adjustment to wearing Aligners that may mildly affect speech. In some instances, patients have experienced scratched or irritated gums, cheeks and lips and in some rare instances allergic reactions have occurred. We believe that these limitations are generally outweighed by the many benefits of Invisalign to both patients and dental professionals.



## **Our Target Market and Patient Base**

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

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

As of December 31, 2006, approximately 529,000 patients worldwide have started treatment using Invisalign. Internationally, we operate in the geographic regions of Europe, Asia-Pacific, Japan and Latin America. In 2006, international sales accounted for 16% of our net revenues. A geographic breakdown of our net revenues is summarized in Note 15 Segments and Geographic Information in the Notes to our Consolidated Financial Statements.

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

## **Business Strategy**

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

### *Customer Responsiveness*

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

*Educate future orthodontists and general practitioners.* By educating dental students and orthodontic residents on the benefits of the Invisalign technique, we believe they will be more likely to use this technology in their future practices and offer Invisalign as a treatment option. Currently, we have incorporated the Invisalign technique into the curriculum of 38 university programs. We expect additional dental schools to integrate the Invisalign technique into their curricula in the future.

*Stimulate demand for Invisalign treatment.* Our market research indicates that the vast majority of people with malocclusion who desire treatment do not elect traditional treatment because of its many limitations, such as compromised aesthetics and oral discomfort. By communicating the benefits of Invisalign to both dental professionals and consumers, we intend to increase the number of patients who seek orthodontic treatment annually. In 2007, we expect to increase the overall marketing spending in the United States with a focus on programs designed to raise the profile of Invisalign and drive more consumers to our most experienced doctors. We also intend to initiate similar consumer marketing efforts, but on a smaller scale, in key European countries. We believe that this increased consumer awareness of Invisalign will increase the market for our products.

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

#### *Product Leadership*

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



which efforts we expect to extend at least through 2008. Next generation Aligner material is intended to consistently deliver force to the teeth over a longer period of time. The compliance indicator is intended to help the dental professional and the patient understand if the patient has worn their Aligner for enough time to effectively move their teeth. We believe continuing to introduce new products and product features as well as enhancing the user experience will keep us at the forefront of the market and increase demand for Invisalign.

*Extend and defend technology leadership.* Invisalign represents a significant technological advancement in orthodontics. Our issued U.S. patents broadly cover the Invisalign system, including digital modeling and manipulation of scanned patient data, treatment planning, and fabrication of dental appliances, among others. We continue to pursue further intellectual property protection through U.S. and foreign patent applications and non-disclosure agreements. We also seek to protect our software, documentation and other written materials under trade secret and copyright laws. Nonetheless, our intellectual property rights may not be successfully asserted in the future or may be invalidated, circumvented or challenged. In addition, the laws of various countries where the Invisalign system is distributed do not protect our intellectual property rights to the same extent as U.S. laws. Information regarding risks associated with failure to protect our proprietary technology and our intellectual property rights may be found in Part I, Item 1A of this Annual Report on Form 10-K under the heading *Risk Factors*. *See also Part I, Item 3 of this Annual Report on Form 10-K under the heading Legal Proceedings.*

#### *Operational Effectiveness*

*Expand and enhance manufacturing capability.* Our manufacturing operations are designed to produce large numbers of custom Aligners at a high level of quality. To improve cost efficiency, we conduct labor intensive processes in relatively low-wage countries. We believe that our existing facilities are adequate to meet current requirements and that additional or substitute space will be available as needed to accommodate any expansion of operations. Our proprietary software underlies our manufacturing process. By continually developing this software and other manufacturing processes, we plan to increase the level of production automation. Increased automation will enhance production capacity and reduce both unit costs and production times.

#### **The Invisalign Treatment Process**

The Invisalign treatment process comprises the following five stages:

*Orthodontic diagnosis and transmission of treatment data to us.* In an initial patient visit, the dental professional determines whether Invisalign is an appropriate treatment. The dental professional then prepares a treatment data package which consists of a polyvinyl-siloxane, or PVS, impression of the relevant dental arches, x-rays of the patient's dentition, photographs of the patient, a bite impression depicting the relationship between the patient's upper and lower dental arches and an Invisalign treatment planning form, or prescription. The impression is a critical component of Invisalign as it depicts the three-dimensional geometry of the patient's teeth and hence forms the basis for our computer models. An impression requires the patient to bite into a viscous material. This material hardens, capturing the shape of the patient's teeth. The prescription is also a critical component of Invisalign, describing the desired positions and movement of the patient's teeth. The dental professional sends the treatment data to our Santa Clara, California facility.

*Preparation of three-dimensional computer models of the patient's initial malocclusion.* Upon receipt, we use the treatment data to construct digital models of the patient's dentition. Using CT scanning, we scan the PVS impression to develop a digital, three-dimensional computer model of the patient's current dentition. We then transmit this initial computer model together with the dental professional's prescription and supplemental materials electronically to our facilities in Costa Rica.



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

*Construction of molds corresponding to each step of treatment.* We use the approved ClinCheck simulation to construct a series of molds of the patient's teeth. Each mold is a replica of the patient's teeth at each two-week stage of the simulated course of treatment. These molds are fabricated by IMS, a third party shelter services provider based in Juarez, Mexico.

*Manufacture of Aligners and shipment to the dental professional.* From these molds, IMS fabricates Aligners by pressure-forming polymeric sheets over each mold. The Aligners are then trimmed, polished, cleaned and packaged. Following final inspection, the Aligners are shipped directly to the prescribing dental professional. We ship all of the Aligners in a single batch. In certain cases, dental professionals may use Invisalign in conjunction with tooth-colored attachments bonded to the patient's teeth. These attachments are used to increase the force applied to a tooth or teeth in circumstances where the Aligners alone may have difficulty in effecting the desired movement. In certain cases, we provide an aligner-like template to the dental professionals to aid the placement of bonding attachments to the patient's teeth. Also, in cases where interproximal reduction, or IPR, is requested by the dental professional, we provide an IPR treatment form, quantifying the amount of space to be created through enamel reduction, location, and timing of IPR.

## **Manufacturing**

To produce our highly customized, highly precise, medical quality products in volume, we have developed a number of proprietary processes and technologies. These technologies include complex software solutions, computed tomography, known as CT scanning, stereolithography and automated Aligner fabrication.

We rely on two vendors who are each the sole source of the polymer and resin used in our manufacturing process. In the event that either of these vendors become unable for any reason to supply us with their respective products, we would experience a manufacturing disruption while we qualify and obtain an alternate source.

As of December 31, 2006, our manufacturing and operations staff in the U.S. and Costa Rica consisted of 672 people. Manufacturing is coordinated in Santa Clara, California. Digital dental modeling is processed in our 63,000 square foot facility in San Jose, Costa Rica. The operations team in Costa Rica creates ClinCheck treatments using simulation software. In anticipation of increased capacity demands primarily resulting from the Patients First Program, we hired approximately 100 new dental technicians in Costa Rica in the fourth quarter of 2006. *For a more complete discussion of the Patients First Program, please see Part I, Item 7 of this Annual Report on Form 10-K under the heading Management's Discussion and Analysis Overview.* In the second quarter of 2006, in an effort to optimize operations, improve efficiency and reduce operating costs, we relocated our stereolithography (SLA) mold fabrication operations from our Santa Clara, California facility to IMS, a third party shelter services provider based in Juarez, Mexico. We



also use IMS for the fabrication and packaging of Aligners. Information regarding risks associated with our manufacturing process and foreign operations may be found in Part I, Item 1A of this Annual Report on Form 10-K under the heading Risk Factors.

### Throughput Management

Because we manufacture each case on a build-to-order basis, we must conservatively build manufacturing capacity for anticipated demand. To increase throughput, we must improve the efficiency and increase the scale of our manufacturing processes.

In order to increase the efficiency of our manufacturing processes, we focus our efforts on software development and the improvement of rate-limiting processes, or bottlenecks. We continue to upgrade our proprietary, three-dimensional treatment-planning software to enhance computer analysis of treatment data and to reduce time spent on manual and judgmental tasks for each case, thereby increasing the efficiency of our technicians in Costa Rica. During the first half of 2007, as a result of the increase in demand for Invisalign case volume primarily due to of the Patients First Program (discussed in Part I, Item 7 Management's Discussion and Analysis Overview), we will monitor our capacity in Costa Rica to ensure a sufficient number of technicians have been hired. We are also continuing the development of automated systems for the fabrication and packaging of Aligners manufactured in Juarez, Mexico. In order to scale our manufacturing capacity, we expect that we will continue to invest in capital equipment.

### Quality Assurance

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

Since we custom manufacture Aligners on a build-to-order basis, we do not offer refunds on our products. Because each ClinCheck and each Aligner is unique, we inspect 100% of the product at various points in the manufacturing process, to ensure that the product meets our customers expectations. Aligners are subject to the Invisalign product warranty, which covers defects in materials and workmanship. Our materials and workmanship warranty is in force until the Invisalign case is completed. In the event the Aligners fall within the scope of the Invisalign product warranty, we will replace the Aligners at our expense. Our warranty is contingent upon proper use of the Aligners for the purposes for which they are intended. If a patient chooses not to wear the Aligners, and as a result, requests additional Invisalign treatment, the dental professional pays the additional expense of the replacement Aligners.

The Invisalign product warranty does not provide any assurances regarding the outcome of treatment using Invisalign. Actual treatment results may deviate significantly from the approved ClinCheck treatment plan. Deviations not covered under warranty have typically been the result of unpredictable biological factors, such as variations in bone density or tooth topography and abnormal jaw growth. Warranty treatment requires that the dental professional submit new impressions of the patient's dentition to us. We use the impressions to create a new ClinCheck treatment plan for the dental professional to approve, from which a successive series of Aligners will be produced that will allow the patient to finish treatment.

## Sales and Marketing

We market Invisalign by communicating Invisalign's benefits directly to dental professionals through our training, certification programs and direct mail campaigns and to consumers with a nationwide advertising campaign. Based on our experience with advertising and commercial sales, we believe that making consumers aware of Invisalign as a new treatment alternative generates significant demand for Invisalign. In order to serve anticipated demand, we are training a broad base of dental professionals.

### *Professional Marketing*

Our sales and support staff has been engaged in marketing Invisalign to orthodontists since July 1999. In 2001, we began marketing Invisalign to general practitioner dentists in our domestic market. As of December 31, 2006 our North America sales organization consisted of 130 people of which 109 were direct sales representatives and 21 were sales administration and management. Internationally, we have approximately 40 people engaged in sales and sales support as December 31, 2006. We provide training, certification, marketing and clinical support to orthodontists and general practitioner dentists in the U.S. and Canada, which we consider our domestic market, and internationally.

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

Invisalign relies on the same orthodontic principles that apply to traditional treatment. Our sales and orthodontic teams conduct training primarily in a workshop format. The key topics covered in training include Invisalign applicability, instructions on filling out the Invisalign treatment form, clinical tips and techniques, guidance on pricing and instructions on interacting with our ClinCheck software and the many other features of our website.

After training, sales representatives follow up with the dental professional to ensure that their staff is prepared to handle Invisalign cases. Such follow up may include assisting the dental professional in taking dental impressions, establishing an Internet connection and familiarizing them with our website. Sales representatives may also provide practice-building assistance, including helping the dental professional to market Invisalign to prospective patients through direct mail or other forms of media. Many dental professionals have commenced promotional activity in their local region with our assistance.

### *Consumer Marketing*

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

- an orthodontist;
- a general practice dentist;
- consumer marketing and advertising;
- our website, which can be accessed at either [www.invisalign.com](http://www.invisalign.com) or [www.aligntech.com](http://www.aligntech.com);
- direct-to-consumer mail advertising and public relations efforts; and
- other Invisalign patients.

In 2007, we expect to increase the overall marketing spend in the United States with a focus on programs designed to raise the profile of Invisalign and drive more consumers to our most experienced doctors. We believe that this increased consumer awareness of Invisalign will increase demand for our product.

## Research and Development

Our research and development effort is focused on extending the range of dental applicability of Invisalign, enhancing the software used in the manufacturing process and enhancing our Invisalign system product lines. Our research and development expenses were \$18.5 million for fiscal 2006, \$18.6 million for fiscal 2005 and \$15.8 million for fiscal 2004.

In an effort to demonstrate Invisalign's broad treatment capabilities, various clinical case studies and articles have been published that highlight the applicability of Invisalign to malocclusion cases, including those of severe complexity. We are also undertaking post-marketing studies and making additional technological improvements to the product and manufacturing process. We have recently started a phased roll out of ClinAdvisor, a new suite of software tools, designed to make Invisalign case selection and submission processes more efficient and predictable for our doctors. In addition, we plan to introduce a further series of software enhancements that will evolve Invisalign into distinct suites of software tools for the orthodontist and GP. Software enhancements for the orthodontist are intended to provide a more robust set of tools for greater predictability, wider applicability and more flexibility in the use of the Invisalign system. Software enhancements targeting the GP will focus on ease of diagnosis, guidance through the case set-up process and self-help tools designed to simplify treatment of cases of mild to moderate malocclusion. We continue to focus research and development efforts on next generation Aligner material and a compliance indicator, which efforts we expect to extend at least through 2008.

## Intellectual Property

We believe our intellectual property position represents a substantial business advantage. As of December 31, 2006, we had 85 issued U.S. patents, 120 pending U.S. patent applications, and numerous foreign issued patents, as well as pending foreign patent applications. *See Part I, Item 3 Legal Proceedings for a discussion on Reexamination Proceedings pending with the United States Patent and Trademark Office.*

We continue to pursue further intellectual property protection through U.S. and foreign patent applications and non-disclosure agreements. We also seek to protect our software, documentation and other written materials under trade secret and copyright laws. We cannot be certain that patents will be issued as a result of any patent application or that patents that have been issued to us or that may be issued in the future will be found to be valid and enforceable and sufficient to protect our technology or products. Our intellectual property rights may not be successfully asserted in the future or may be invalidated, circumvented or challenged. In addition, the laws of various foreign countries where Invisalign is distributed do not protect our intellectual property rights to the same extent as U.S. laws. Our inability to protect our proprietary information could harm our business. Information regarding risks associated with failure to protect our proprietary technology and our intellectual property rights may be found in Part I, Item 1A of this Annual Report on Form 10-K under the heading "Risk Factors."

## Competition

We compete for the attention of dental professionals with manufacturers of traditional orthodontic appliances (or wires and brackets), which include 3M Company, Sybron Dental Specialties and Dentsply International, Inc. We also compete directly with established companies that manufacture and distribute products that are similar in use to Invisalign, including the product called Red, White & Blue manufactured and distributed byOrmco Orthodontics, a division of Sybron Dental Specialties. In May 2006, Danaher Corporation purchased Sybron Dental Specialties. *See Part I, Item 3 Legal Proceedings for a summary of our litigation with Ormco.* In May 2005, OrthoClear, Inc. announced the commercial launch of the OrthoClear system, a product that was intended to compete directly with our Invisalign system. On October 13, 2006, we entered into a formal agreement with OrthoClear, Inc., OrthoClear Holdings, Inc., and OrthoClear Pakistan Pvt. Ltd. ( "OrthoClear"), together with certain

individuals associated with OrthoClear to end all pending litigation between the parties. In addition, OrthoClear agreed, among other things, to stop accepting new patient cases for treatment, consent to the entry of an exclusion order by the ITC prohibiting the importation of OrthoClear aligners into the United States, assign and transfer to Align all intellectual property rights with application to the correction of malocclusion and to discontinue all design, manufacture, marketing and sales of removable dental aligners worldwide. *See Part I, Item 3 Legal Proceedings for a summary of our litigation with OrthoClear.* In the future, we may face further competition from other early stage and more mature companies who enter our target markets to manufacture and distribute products that are similar in use to Invisalign. Information regarding risks associated with increased competition may be found in Part I, Item 1A of this Annual Report on Form 10-K under the heading Risk Factors.

We believe that in addition to price, the principal competitive factors in the market for orthodontic appliances include the following:

- aesthetic appeal of the treatment method;
- effectiveness of treatment;
- customer support;
- comfort associated with the treatment method;
- oral hygiene;
- ease of use; and
- dental professionals chair time.

We believe that Invisalign compares favorably with our competitors products with respect to each of these factors.

#### **Government Regulation**

*FDA's Quality System Regulation for Medical Devices.* In 2006, we were informed by the Food and Drug Administration, or FDA, that our Invisalign system had been reclassified as a Class II medical device. The Invisalign system was previously regulated as a Class I medical device and was exempted from requiring 510(k) pre-market notification prior to commercialization. In 1998, however, we had voluntarily filed with and subsequently received pre-market clearance from the FDA pursuant to the 510(k) pre-market notification procedure, allowing us to market the product in the U.S. Therefore, we currently possess the necessary 510(k) clearance from the FDA to continue to market our product under the Class II classification. Prior to the reclassification, our product development, manufacturing processes, packaging, labeling, handling, storage and distribution activities were subject to extensive oversight by the FDA. We believe our Invisalign system is in compliance in all material respects with applicable quality system regulations, record keeping and reporting requirements in the production and distribution of the Invisalign system. We do not anticipate any significant difficulty or material cost increases in complying with applicable performance standards as a result of the incremental regulatory requirements resulting from the Class II reclassification.

Our Aligners are manufactured by IMS, a third party shelter services provider based in Juarez, Mexico. IMS is registered with the FDA as a medical device manufacturer and is certified to ISO 9001:2000 requirements. We have also ensured that our quality system procedures and processes have been implemented at IMS to comply with the FDA's Quality Systems standards. IMS has dedicated an area in its facilities and trained personnel in the manufacture and distribution of Invisalign. We and IMS are subject to routine inspections by the FDA and state agencies to determine compliance with Quality System requirements. We are registered with the State of California as a medical device manufacturer.

If the FDA determines that we or IMS failed to comply with the applicable FDA regulations, it can institute a wide variety of enforcement actions against us, ranging from a public Warning Letter to more severe sanctions, including but not limited to financial penalties, withdrawal of our right to market our products and criminal prosecution.

*Health Canada's Medical Device Regulations.* In Canada, we are required to comply with Health Canada's Medical Device Regulations. Our products are registered with Health Canada. We believe we are in compliance with their regulations and have been granted clearance to market our products in Canada.

*European Union's MDD Requirements & ISO 13485.* In Europe, Invisalign is regulated as a custom device and as such, we follow the requirements of the Medical Device Directives. We are ISO 13485 certified, which facilitates commercialization of Invisalign outside the United States and especially in Europe.

*Health Insurance Portability and Accountability Act of 1996.* Under the Health Insurance Portability and Accountability Act of 1996, or HIPAA, Congress mandated a package of interlocking administrative simplification rules to establish standards and requirements for electronic transmission of certain health information. Confidentiality of patient records and the circumstances under which these records may be released are subject to substantial regulations under the HIPAA Standards for Privacy of Individually Identifiable Health Information, referred to as the Privacy Standard, and other state laws and regulations. The Privacy Standard governs both the disclosure and the use of confidential patient medical information. Although compliance is principally the responsibility of the hospital, physician or other healthcare provider, we are required to maintain the confidentiality of patient information when providing technical services and when handling patient information and records. We have designed our product and service offerings to be consistent with the requirements of the Privacy and Security standards under HIPAA and applicable corresponding state laws and regulations. Maintaining systems that are consistent with these laws and regulations is costly and could require complex changes in the way we do business or provide services to our patients. Additionally, our success may be dependent on the success of healthcare participants in dealing with HIPAA requirements.

*Other Federal and State Laws.* As a participant in the health care industry we are subject to extensive and frequently changing regulation under many other laws administered by governmental entities at the federal, state and local levels, some of which are, and others of which may be, applicable to our business. Furthermore, our health care service provider customers are also subject to a wide variety of laws and regulations that could affect the nature and scope of their relationships with us. Laws regulating medical device manufacturers and health care providers cover a broad array of subjects. For example, the confidentiality of patient medical information and the circumstances under which such information may be used by us, released for inclusion in our databases, or released by us to third parties, are subject to substantial regulation by state governments. These state laws and regulations govern both the disclosure and the use of confidential patient medical information and are evolving rapidly. In addition, provisions under the federal anti-kickback statute prohibit, among other things, paying or offering to pay any remuneration in exchange for the referral of patients to a person participating in, or for the order, purchase or recommendation of items or services that are subject to reimbursement by, Medicare, Medicaid and other similar federal or state health care programs. Most states have also enacted illegal remuneration laws that are similar to the federal laws. These laws are applicable to our financial relationships with, and any marketing or other promotional activities involving, our dental professional customers. Finally, various states regulate the operation of an advertising and referral service for dentists, and may require registration of such services with a state agency as well as compliance with various requirements and restrictions on how they conduct business and structure their relationships with participating dentists. Violations of any of these laws or regulations could subject us to a variety of civil and criminal sanctions.

## Employees

As of December 31, 2006, we had 1,253 employees, including 672 in manufacturing and operations, 309 in sales and marketing, 115 in research and development and 157 in general and administrative functions. We had 487 employees in the U.S., 620 employees in Costa Rica, 116 employees in Europe and 30 employees in other international regions.

## Executive Officers of the Registrant

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

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

*Thomas M. Prescott* has served as our President and Chief Executive Officer and as a member of our Board of Directors since March 27, 2002. Prior to joining us, Mr. Prescott was President and Chief Executive Officer of Cardiac Pathways, Inc., a publicly-traded medical device company, from May 1999 until its acquisition by Boston Scientific in August 2001. Mr. Prescott then worked as a consultant for Boston Scientific Corporation until January 2002. Prior to working at Cardiac Pathways, Mr. Prescott held various sales, general management and executive roles at Nellcor Puritan Bennett, Inc. from April 1994 to May 1999. Mr. Prescott serves as a director of Interventional Rhythm Management, Inc., a privately held company.

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

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



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

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

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

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

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

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

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





## ITEM 1A. RISK FACTORS

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

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

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

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

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

*Management's Discussion and Analysis of Financial Condition and Results of Operations Overview.*

While we achieved profitability beginning in the fourth quarter of fiscal 2003 and through the second quarter of fiscal 2005, we experienced a net loss in the third quarter of 2005 as well as each quarter of 2006. If we are to achieve profitability in future periods, we will need to continue to increase our revenues, while controlling our expenses. While we generated positive operating cash flow for the first time in fiscal year 2003 and continued to generate positive operating cash flow in fiscal years 2004 and 2005, we experienced negative cash flow in 2006. We cannot be certain that we will be able to achieve positive cash flow from operations, from period to period, in the future. Because our business is evolving, it is difficult to predict our future operating results or levels of growth, and we have in the past not been and may in the future not be able to sustain our historical growth rates. If we do not increase profitability or revenue growth or

otherwise meet the expectations of securities analysts or investors, the market price of our common stock will likely decline.

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

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

- changes in the timing of receipt of case product orders during a given quarter;
- changes in product mix due to the introduction of Invisalign Express, a lower-cost alternative for treating less complex cases;
- unanticipated delays in production caused by insufficient capacity;
- any disruptions in the manufacturing process, including as a result of unexpected turnover in the labor force or the introduction of new production processes or as a result of natural or other disasters beyond our control;
- the development and marketing of directly competitive products by existing and new competitors;
- aggressive price competition from competitors;
- costs and expenditures in connection with ongoing litigation;
- inaccurate forecasting of revenues, production and other operating costs; and
- investments in research and development to develop new products and enhancements to Invisalign.

To respond to these and other factors, we may need to make business decisions that could adversely affect our operating results such as modifications to our pricing policy, business structure or operations. For instance, although we entered into a definitive agreement in October 2006 with OrthoClear whereby, among other things, OrthoClear agreed to discontinue all design, manufacture, marketing and sales of removable dental aligners worldwide, we experienced increased pricing pressure in 2005 and 2006 as a result of the commercial launch of OrthoClear's product. Partly in response to this increased competition, in the fourth quarter of 2005, we changed our pricing structure and reduced our list price for full Invisalign treatment to \$1,495 and expanded our volume based discount program to all doctors. These programs were in effect in 2006, and had an adverse impact on our revenues, gross margins and net profit (loss). Most of our expenses, such as employee compensation and lease payment obligations, are relatively fixed in the short term. Moreover, our expense levels are based, in part, on our expectations regarding future revenue levels. As a result, if our revenues for a particular period fall below our expectations, we may be unable to adjust spending quickly enough to offset any shortfall in revenues. Therefore, our operating results for a given period may be adversely affected. Due to these and other factors, we believe that quarter-to-quarter comparisons of our operating results may not be meaningful. You should not rely on our results for any one quarter as an indication of our future performance.

**We depend on the sale of Invisalign for the vast majority of our revenues, and any decline in sales of Invisalign or average selling prices would adversely affect revenue, gross margin and net profits.**

We expect that revenues from the sale of Invisalign will continue to account for the vast majority of our total revenues for the foreseeable future. Continued and widespread market acceptance of Invisalign by orthodontists, GPs and consumers is critical to our future success. If orthodontists and GPs experience a

reduction in consumer demand for orthodontic services, if consumers prove unwilling to adopt Invisalign as rapidly as we anticipate or in the volume that we anticipate, if orthodontists and GPs do not collaborate as we expect, if orthodontists or GPs choose to use a competitive product rather than Invisalign or if the average selling price of our product declines as it has in the past, our operating results would be harmed. Factors that could cause Invisalign not to achieve market acceptance at the rate at which we expect, as well as the risk related to declining average selling prices are described more fully below.

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

Our success depends upon increasing acceptance and frequency of use of the Invisalign system by dental professionals. Invisalign requires orthodontists, GPs and their staff to undergo special training and learn to interact with patients in new ways. In addition, because Invisalign has only been in clinical testing since July 1997 and commercially available only since July 1999, orthodontists and GPs may be reluctant to adopt it until more historical clinical results are available. Also, increasing adoption and cumulative use by orthodontists and GPs will depend on factors such as the capability, safety, efficacy, ease of use, price, quality and reliability of our products, our ability to provide effective sales support, training and service and the availability of competing products, technologies and alternative treatments. In addition, unanticipated poor clinical performance of Invisalign could result in significant adverse publicity and, consequently, reduced acceptance by dental professionals. Also increased competition from direct competitors could cause us to lose market share and reduce dental professionals' efforts and commitment to expand their Invisalign practice. If Invisalign does not achieve growing acceptance in the orthodontic and GP communities, our operating results will be harmed.

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

Our success depends upon the acceptance of Invisalign by a substantially larger number of dental professionals as well as potential consumers to whom we are now actively marketing. Invisalign represents a significant change from traditional orthodontic treatment, and consumers may be reluctant to accept it or may not find it preferable to conventional treatment. In addition, consumers may not comply with recommended treatment guidelines for Invisalign, which could compromise the effectiveness of their treatment. We have generally received positive feedback from both orthodontists, GPs and consumers regarding Invisalign as both an alternative to braces and as a clinical method for treatment of malocclusion, but a number of dental professionals believe that Invisalign is appropriate for only a limited percentage of their patients. Market acceptance will depend in part upon the recommendations of dental professionals, as well as other factors including effectiveness, safety, reliability, improved treatment, aesthetics, greater comfort and hygiene compared to conventional orthodontic products and price for Invisalign compared to competing products. Furthermore, consumers may not respond to our direct marketing campaigns or we may be unsuccessful in reaching our target audience. Adoption by consumers may also be affected by general macroeconomic conditions in North America and internationally, which fluctuate and could be affected by unstable global economic, political or other conditions.

*The orthodontists and GPs may choose not to collaborate and referrals between orthodontists and GPs may not increase at the rate that we anticipate or at all.*

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

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

*Declines in average selling prices of our products.*

In response to challenges in our business, including increased competition, in November 2005, we reduced the list price of full Invisalign cases and in the third quarter of 2005 we introduced Invisalign Express, a lower-cost solution for less complex cases. In addition, in the fourth quarter of 2005, we expanded our volume based discount program to all doctors. As a result of these programs, the blended average selling price for our products declined in 2006 compared to 2005 and may further decline in 2007 as a result of greater participation in our volume discount program. Additionally in Europe, we introduced new pricing initiatives in the first quarter of 2006 which resulted in a lower average selling price in 2006. If we are required to introduce any similar programs in the future, our revenue, gross margin and net profits (losses) may be adversely affected.

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

Currently, two of our key production steps are performed in operations located outside of the U.S. At our facility in Costa Rica, technicians use a sophisticated, internally developed computer-modeling program to prepare electronic treatment plans, which are transmitted electronically back to the U.S. These electronic files form the basis of ClinCheck and are used to manufacture Aligner molds. In the first quarter of 2006, we completed the process of relocating our SLA mold fabrication operations from our Santa Clara, California facility to our third party shelter services provider, IMS, located in Juarez, Mexico. IMS also fabricates the Aligners and ships the completed products to our customers. As a result of this relocation, our reliance on our international manufacturing operations will continue to increase. Our increasing reliance on international operations exposes us to risks and uncertainties that may affect our business or results of operation, including:

- difficulties in hiring and retaining employees generally, as well as difficulties in hiring and retaining employees with the necessary skills to perform the more technical aspects of our operations, as well as staffing in numbers sufficient to implement the Patients First Program;
- difficulties in managing international operations, including our relationship with IMS, our third party shelter services provider;
- import and export license requirements and restrictions;
- controlling production volume and quality of the manufacturing process;
- political, social and economic instability;
- acts of terrorism and acts of war;
- interruptions and limitations in telecommunication services;
- product or material transportation delays or disruption;
- burdens of complying with a wide variety of local country and regional laws;
- trade restrictions and changes in tariffs;
- fluctuations in currency exchange rates; and
- potential adverse tax consequences.



If any of these risks materialize in the future, we could experience production delays and lost or delayed revenue.

**A key step in our manufacturing process relies on sophisticated computer technology that requires new technicians to undergo a relatively long training process. If we are unable to accurately predict our volume growth, and fail to hire sufficient number of technicians in advance of such demand, the delivery time of our product could be delayed which could adversely affect our results of operations.**

Training technicians to use our sophisticated computer modeling program that produces the electronic treatment forms that form the basis of ClinCheck takes approximately 90 to 120 days. As a result, if we are unable to accurately predict our volume growth, we may not have a sufficient number of trained technicians to timely create ClinCheck treatment forms within the timeframe our customers expect. Any delay in ClinCheck processing time could delay the ultimate delivery of finished Aligners to our customers. Such a delay could cause us to lose existing customers or limit the number of new customers who purchase our products. This could cause a decline in our revenue and net profits and could adversely affect our results of operations.

**Our headquarters, ClinCheck setup and other manufacturing processes are all principally located in regions that are subject to earthquakes and other natural disasters.**

Our digital dental modeling is processed in our facility located in San Jose, Costa Rica. The operations team in Costa Rica creates ClinCheck treatment plans using sophisticated computer software. In addition, our Aligner molds and finished Aligners are fabricated by IMS, our third party shelter services provider located in Juarez, Mexico. Both Costa Rica and Mexico are earthquake zones and may be subject to other natural disasters. If there is a major earthquake or any other natural disaster in a region where one of these facilities is located, our ability to create ClinCheck treatment plans or manufacture and ship our Aligners could be compromised which could result in our customers experiencing a significant delay in receiving their completed Aligners. In addition, our headquarters facility is located in the San Francisco Bay area. A earthquake or other natural disaster in this region could result in a disruption in our operations. Any such business interruption could materially and adversely affect our business, financial condition and results of operations.

**We currently rely on third parties to provide key inputs to our manufacturing process, and if our access to these inputs is diminished, our business may be harmed.**

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

**We experience competition from manufacturers of traditional braces and expect aggressive competition from these and other companies that may introduce new technologies in the future.**

Currently, our Invisalign product competes directly against a product called Red, White and Blue, which is manufactured and distributed by Ormco Orthodontics, a division of Sybron Dental Specialties. In May 2006, Danaher Corporation purchased Sybron Dental Specialties. Prior to OrthoClear agreeing, pursuant to the terms of an agreement entered into in October 2006, to discontinue all design, manufacture, marketing and sales of removable dental aligners worldwide, our Invisalign system competed

directly with an aligner product manufactured by them. In addition, manufacturers of traditional braces, such as 3M Company, Sybron Dental Specialties and Dentsply International have substantially greater financial resources and manufacturing and marketing experience than we do and may, in the future, attempt to develop an orthodontic system similar to ours. Large consumer product companies may also enter the orthodontic supply market. Furthermore, we may face competition in the future from new companies that may introduce new technologies. We may be unable to compete with these competitors and one or more of these competitors may render our technology obsolete or economically unattractive. If we are unable to compete effectively with existing products or respond effectively to any products developed by new or existing competitors, our business could be harmed. Increased competition from OrthoClear and other competitors recently resulted in and may in the future result in volume discounting and price reductions, reduced gross margins, reduced profitability and loss of market share, any of which could have a material adverse effect on our revenue, volume growth, net profit and stock price. For instance, in the fourth quarter of 2005, in order to encourage continued use of our products, we extended our volume based discount program to all of our doctors. In addition, in the second half of 2005, we introduced Invisalign Express, a lower-cost solution for less complex cases as well as a new pricing initiative which had the effect of reducing our average selling price per case. These programs have adversely affected our revenues, gross margin and net profit. We cannot assure you that we will be able to compete successfully against our current or future competitors or that competitive pressures will not have a material adverse effect on our business, results of operations and financial condition.

**Our information technology systems are critical to our business. System integration and implementation issues and system security risks could disrupt our operations, which could have a material adverse impact on our business and operating results.**

We rely on the efficient and uninterrupted operation of complex information technology systems. All information technology systems are vulnerable to damage or interruption from a variety of sources. As our business has grown in size and complexity, the growth has placed, and will continue to place, significant demands on our information technology systems. To effectively manage this growth, we will need to continually upgrade and enhance our information systems. In addition, experienced computer programmers and hackers may be able to penetrate our network security and misappropriate our confidential information or that of third parties, create system disruptions or cause shutdowns. Furthermore, sophisticated hardware and operating system software and applications that we either internally produce or procure from third parties may contain defects in design and manufacture, including bugs and other problems that can unexpectedly interfere with the operation of the system. The costs to eliminate or alleviate security problems, viruses and bugs could be significant, and the efforts to address these problems could result in interruptions that may have a material adverse impact on our operations, revenues and operating results.

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

Throughout 2006 we focused on adding additional functionality into our business enterprise systems and intend to continue this effort for the foreseeable future, which will more efficiently integrate these systems with our other system applications, such as customer facing and manufacturing tools. System upgrades and enhancements require significant expenditures and allocation of valuable employee resources. Delays in integration or disruptions to our business from implementation of these new or upgraded systems could have a material adverse impact on our financial condition and operating results.



Furthermore, we continuously upgrade our customer facing software applications, specifically ClinCheck and VIP. Software applications frequently contain errors or defects, especially when they are first introduced or when new versions are released. The discovery of a defect or error in a new upgraded version or the failure of our primary information systems may result in the following consequences, among others: loss of revenue or delay in market acceptance, damage to our reputation or increased service costs, any of which could have a material adverse effect upon our business, financial condition or results of operations.

**Our success depends in part on our proprietary technology, and if we are unable to successfully enforce our intellectual property rights, our competitive position may be harmed. Litigating claims of this type is costly and could distract our management and cause a decline in our results of operations and stock price.**

Our success will depend in part on our ability to maintain existing intellectual property and to obtain and maintain further intellectual property protection for our products, both in the U.S. and in other countries. Our inability to do so could harm our competitive position. As of December 31, 2006, we had 85 issued U.S. patents, 120 pending U.S. patent applications, and numerous foreign issued patents, as well as pending foreign patent applications.

We intend to rely on our portfolio of issued and pending patent applications in the U.S. and in other countries to protect a large part of our intellectual property and our competitive position. However, our currently pending or future patent filings may not result in the issuance of patents. Additionally, any patents issued to us may be challenged, invalidated, held unenforceable, circumvented, or may not be sufficiently broad to prevent third parties from producing competing products similar in design to our products. During fiscal 2005 and 2006, requests were filed with the United States Patent and Trademark Office ( USPTO ) by a San Francisco, California law firm, acting on behalf of an unnamed party and in some instances acting on behalf of OrthoClear, requesting re-examination of a number of our patents. *See Part I Item 3 of this Annual Report on Form 10-K for a summary of the USPTO proceedings.* In addition, any protection afforded by foreign patents may be more limited than that provided under U.S. patents and intellectual property laws. We also rely on protection of our copyrights, trade secrets, know-how and proprietary information. We generally enter into confidentiality agreements with our employees, consultants and our collaborative partners upon commencement of a relationship with us. However, these agreements may not provide meaningful protection against the unauthorized use or disclosure of our trade secrets or other confidential information, and adequate remedies may not exist if unauthorized use or disclosure were to occur. *See Part I Item 3 of this Annual Report on Form 10-K for a summary of the OrthoClear litigation.* Our inability to maintain the proprietary nature of our technology through patents, copyrights or trade secrets would impair our competitive advantages and could have a material adverse effect on our operating results, financial condition and future growth prospects. In particular, a failure of our proprietary rights might allow competitors to copy our technology, which could adversely affect our pricing and market share.

In addition, in an effort to protect our intellectual property we have in the past been and may in the future be involved in litigation. For example, in October 2006, we entered into an agreement with OrthoClear whereby OrthoClear and Align agreed, among other things, to dismiss all pending lawsuits against each other, including the patent infringement action against OrthoClear filed in the Western District of Wisconsin (Madison). In addition, we are currently involved in a patent infringement lawsuit with Ormco. The potential effects on our business operations resulting from similar litigation that we may participate in the future, whether or not ultimately determined in our favor or settled by us, are costly and divert the efforts and attention of our management and technical personnel from normal business operations. Any of these results from our litigation could adversely affect our results of operations and stock price.

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

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

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

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

Our future success may depend on our ability to develop, obtain regulatory approval or clearance of, manufacture and market new products. In the second half of 2005, we launched Invisalign Express a lower-cost Aligner system used for less complex cases. We recently announced a phased rollout of ClinAdvisor, a new suite of software tools designed to make Invisalign case selection and submission processes more efficient for doctors. In addition, we plan to introduce a further series of software enhancements that will evolve Invisalign into distinct suites of software tools for the orthodontist and GP. There can be no assurance that we will be able to successfully develop, sell and achieve market acceptance of these and other new products and applications and enhanced versions of our existing product. The extent of, and rate at which, market acceptance and penetration are achieved by future products is a function of many variables, which include, among other things, price, safety, efficacy, reliability, marketing and sales efforts, the availability of third-party reimbursement of procedures using our new products, the existence of competing products and general economic conditions affecting purchasing patterns. Our ability to market and sell new products may also be subject to government regulation, including approval or clearance by the United States Food and Drug Administration, or FDA, and foreign government agencies. Any failure in our ability to successfully develop and introduce new products or enhanced versions of existing products and achieve market acceptance of new products and new applications could have a material adverse effect on our operating results and could cause our revenues to decline.

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

We are highly dependent on the key employees in our clinical engineering, technology development, sales and marketing personnel and management teams. The loss of the services of those individuals may significantly delay or prevent the achievement of our product development and other business objectives and could harm our business. Our future success will also depend on our ability to identify, recruit, train and retain additional qualified personnel, including orthodontists. Few orthodontists are accustomed to working in a manufacturing environment since they are generally trained to work in private practices, universities and other research institutions. Thus, we may be unable to attract and retain personnel with the advanced qualifications necessary for the further development of our business. Furthermore, we may not be successful in retaining our key personnel or their services. If we are unable to attract and retain key personnel, our business could be materially harmed.

**If we infringe the patents or proprietary rights of other parties or are subject to a patent infringement claim, our ability to grow our business will be severely limited.**

Extensive litigation over patents and other intellectual property rights is common in the medical device industry. We have been sued for infringement of third party's patents in the past and we may be the subject of patent or other litigation in the future. From time to time, we have received and may in the future receive letters from third parties drawing our attention to their patent rights. While we do not believe that we infringe upon any valid and enforceable rights that have been brought to our attention, there may be other more pertinent rights of which we are presently unaware. The defense and prosecution of intellectual property suits, interference proceedings and related legal and administrative proceedings could result in substantial expense to us and significant diversion of effort by our technical and management personnel. An adverse determination of any litigation or interference proceeding to which we may become a party could subject us to significant liabilities. An adverse determination of this nature could also put our patents at risk of being invalidated or interpreted narrowly or require us to seek licenses from third parties. Licenses may not be available on commercially reasonable terms or at all, in which event, our business would be materially adversely affected.

**We maintain single supply relationships for certain of our key machines and materials technologies, and our business and operating results could be harmed if supply is restricted or ends.**

We are highly dependent on manufacturers of specialized scanning equipment, rapid prototyping machines, resin and other advanced materials. We maintain single supply relationships for many of these machines and materials technologies. In particular, we are committed to purchase all of our resin from a single-source and our scanning and stereolithography equipment are provided by single suppliers. Technology changes by our vendors could disrupt access to required manufacturing capacity or require expensive, time consuming development efforts to adapt and integrate new equipment or processes. Our growth may exceed the capacity of one or more of these manufacturers to produce the needed equipment and materials in sufficient quantities to support our growth. In the event of technology changes, delivery delays or shortages of these items, our business and growth prospects may be harmed.

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

We have expanded rapidly since we commenced commercial sales in 1999. Our headcount increased from approximately 50 employees as of December 31, 1999 to 1,253 employees as of December 31, 2006. This expansion will continue to place significant demands on our management and other resources and will require us to continue to develop and improve our operational, financial and other internal controls, both in the U.S. and internationally. In particular, growth increases the challenges involved in a number of areas, including recruiting and retaining sufficiently skilled personnel, providing adequate training and

supervision to maintain our high quality standards, and preserving our culture and values. Our inability to effectively manage growth could harm our business.

**We rely on our direct sales force to sell our products, and any failure to maintain our direct sales force could harm our business.**

Our ability to sell our products and generate revenues depends upon our direct sales force within our domestic and international markets. As of December 31, 2006 our North America sales organization consisted of 130 people of which 109 were direct sales representatives and 21 were sales administration and management. Internationally, we have approximately 40 people engaged in sales and sales support as December 31, 2006. We do not have any long-term employment contracts with the members of our direct sales force. The loss of the services of these key personnel may harm our business. If we are unable retain our direct sales force personnel or replace them with individuals of equivalent technical expertise and qualifications, or if we are unable to successfully instill such technical expertise or if we fail to reestablish strong relationships with our customers within a relatively short period of time, our revenues and our ability to maintain market share could be materially harmed.

**Complying with regulations enforced by the Food and Drug Administration (FDA) and other regulatory authorities is an expensive and time-consuming process, and any failure to comply could result in substantial penalties.**

Our products are medical devices and are subject to extensive regulation in the U.S. and internationally. FDA regulations are wide ranging and govern, among other things:

- product design, development, manufacture and testing;
- product labeling;
- product storage;
- pre-market clearance or approval;
- advertising and promotion; and
- product sales and distribution.

Our failure to comply with applicable regulatory requirements could result in enforcement action by the FDA or state agencies, which may include any of the following sanctions:

- warning letters, fines, injunctions, consent decrees and civil penalties;
- repair, replacement, refunds, recall or seizure of our products;
- operating restrictions or partial suspension or total shutdown of production;
- refusing our requests for 510(k) clearance or pre-market approval of new products, new intended uses, or modifications to existing products;
- withdrawing clearance or pre-market approvals that have already been granted; and
- criminal prosecution.

If any of these events were to occur, they could harm our business. We must comply with facility registration and product listing requirements of the FDA and adhere to applicable Quality System regulations. The FDA enforces its Quality System regulations through periodic unannounced inspections. We and IMS, our third party shelter services provider have not yet been subject to an FDA inspection, and we cannot assure you we or IMS will successfully pass such an inspection in the future. Our failure or the failure of IMS to take satisfactory corrective action in response to an adverse inspection or the failure to



comply with applicable manufacturing regulations could result in enforcement action, and we may be required to find alternative manufacturers, which could be a long and costly process.

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

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

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

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

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

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

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

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

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

- the marketing and advertising of our products.

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

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

We currently sell our products in Europe, Canada, Mexico, Brazil, Australia, Hong Kong and Japan and may expand into other countries from time to time. We do not know whether orthodontists, GPs and consumers outside our domestic market will adopt Invisalign in sufficient numbers or as rapidly as we anticipate. In addition, sales of our products outside the U.S. are subject to foreign regulatory requirements that vary widely from country to country. The time required to obtain clearances or approvals required by other countries may be longer than that required for FDA clearance or approval, and requirements for such approvals may differ from FDA requirements. We may be unable to obtain regulatory approvals in one or more of the other countries in which we do business or in which we may do business in the future. We may also incur significant costs in attempting to obtain and maintain foreign regulatory approvals. If we experience delays in receipt of approvals to market our products outside of the U.S., or if we fail to receive these approvals, we may be unable to market our products or enhancements in international markets in a timely manner, if at all.

**Our business exposes us to potential product liability claims, and we may incur substantial expenses if we are subject to product liability claims or litigation.**

Medical devices involve an inherent risk of product liability claims and associated adverse publicity. We may be held liable if any product we develop or any product that uses or incorporates any of our technologies causes injury or is otherwise found unsuitable. Although we intend to continue to maintain product liability insurance, adequate insurance may not be available on acceptable terms, if at all, and may not provide adequate coverage against potential liabilities. A product liability claim, regardless of its merit or eventual outcome, could result in significant legal defense costs. These costs would have the effect of increasing our expenses and diverting management's attention away from the operation of our business, and could harm our business.

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

The market price of our common stock could be subject to wide price fluctuations in response to various factors, many of which are beyond our control. The factors include:

- quarterly variations in our results of operations and liquidity;
- changes in recommendations by the investment community or in their estimates of our revenues or operating results;
- speculation in the press or investment community concerning our business and results of operations;
- strategic actions by our competitors, such as product announcements or acquisitions;
- announcements of technological innovations or new products by us, our customers or competitors; and
- general market conditions.

In addition, the stock market in general, and the market for technology and medical device companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated to or disproportionate to the operating performance of those companies. These broad market and industry factors may seriously harm the market price of our common stock, regardless of our operating performance. In the past, class action litigation has often been brought against the issuing company following periods of volatility in the market price of a company's securities. If a securities class action suit is filed against us in the future, we would incur substantial legal fees, and our management's attention and resources would be diverted from operating our business in order to respond to the litigation.

**Future sales of significant amounts of our common stock may depress our stock price.**

A large percentage of our outstanding common stock is currently owned by a small number of significant stockholders. These stockholders have sold in the past, and may sell in the future, large amounts of common stock over relatively short periods of time. Sales of substantial amounts of our common stock in the public market by our existing stockholders may adversely affect the market price of our common stock. Such sales could create public perception of difficulties or problems with our business and may depress our stock price.

**Changes in, or interpretations of, accounting rules and regulations, could result in unfavorable accounting charges.**

We prepare our consolidated financial statements in conformity with accounting principles generally accepted in the United States of America. These principles are subject to interpretation by the SEC and various bodies formed to interpret and create appropriate accounting policies. A change in these policies can have a significant effect on our reported results and may even retroactively affect previously reported transactions. Our accounting policies that recently have been or may be affected by changes in the accounting rules are as follows:

- revenue recognition;
- accounting for share-based payments; and
- accounting for income taxes.

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

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

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



**ITEM 1B. UNRESOLVED STAFF COMMENTS**

None.

**ITEM 2. PROPERTIES**

Our headquarters are located in Santa Clara, California. We lease approximately 127,000 square feet of space where we house our customer support, operations, research and development and administrative personnel. We lease our Santa Clara facilities under four leases, which expire in June 2010. The combined monthly rent for the Santa Clara facilities is approximately \$75,000. Commencing July 1, 2005 and continuing on the first day of each calendar month thereafter, \$11,000 will be deducted from the \$1.3 million security deposit previously paid by us to the lessor and such amount will be applied against the monthly base rent for the Santa Clara facilities.

We operate a facility in San Jose, Costa Rica. The facility comprises approximately 63,000 square feet of manufacturing and office space. The monthly rent for the Costa Rica facility is approximately \$59,000. The lease for this facility expires at the end of 2008.

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

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

**ITEM 3. LEGAL PROCEEDINGS.**

***OrthoClear***

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

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

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

## Edgar Filing: ALIGN TECHNOLOGY INC - Form 10-K

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

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

### *OrthoClear Agreement*

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

- OrthoClear was required to immediately discontinue all design, manufacture, marketing and sales of removable dental aligners worldwide;
- OrthoClear consented to the entry of an exclusion order by the ITC, enforced by the United States Customs Service, which prevents OrthoClear from importing its dental aligner products into the U.S., either directly or through a third party and the ITC subsequently terminated its formal investigation on October 27, 2006;
- The parties agreed to dismiss all pending lawsuits against each other, including the State Action, Federal Lanham Action I, Federal Lanham Action II, and Patent Infringement Federal Action, with prejudice, and each such action has been subsequently dismissed;
- OrthoClear agreed to stop accepting new patient cases for treatment;
- OrthoClear and Muhammad Ziaullah Chishti its CEO, and Charles Wen, its President, transferred and assigned to Align all intellectual property rights with application to the treatment of malocclusion;
- OrthoClear principals Muhammad Ziaullah Chishti, Charles Wen, Peter Riepenhausen, and Christopher Kawaja signed 5-year, global non-compete agreements in the field of removable aligner therapy products and related software market;
- OrthoClear employees Joe Breeland and Jeff Tunnell signed 5-year U.S. non-compete agreements and prohibiting their personal participation in the removable aligner therapy product and related software market;
- We made Invisalign treatment available to OrthoClear patients in the United States, Canada and Hong Kong at no charge from Align. We implemented this program as the Patients First Program. *See Part II, Item 7 Management's Discussion and Analysis of Financial Condition and Results of Operations Overview for discussion of the Patients First Program.*

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

### *Ormco*

On January 6, 2003, Ormco Corporation ( Ormco ) filed suit against us in the United States District Court for the Central District, Orange County Division, asserting infringement of U.S. Patent Nos. 5,447,432, 5,683,243 and 6,244,861. Ormco is a division of Sybron Dental Specialties. In May 2006, Danaher Corporation acquired Sybron Dental Specialties. The complaint sought unspecified monetary damages and injunctive relief. On February 18, 2003, we answered the complaint and asserted counterclaims seeking a declaration by the Court of invalidity and non-infringement of the asserted



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

In connection with these claims, the Court granted five motions for summary judgment that we filed. First, on May 14, 2004, the Court granted our motion for summary judgment of non-infringement, finding that our Invisalign system does not infringe any of the asserted Ormco patents (5,477,432, 5,683,243, 6,244,861 and 6,616,644). Second, on July 2, 2004, the Court granted in part our motion for summary judgment of infringement, finding that Ormco and AOA infringe certain, but not all, claims of our patents Nos. 6,398,548 and 6,554,611 through the manufacture and sale of Red, White & Blue appliances. Third, on August 26, 2004, the Court granted our motion for summary judgment of invalidity of Ormco's asserted patents claims (5,477,432, 5,683,243, 6,244,861 and 6,616,644). As noted above, the Court earlier found that we do not infringe these patents. In addition, the Court also denied Ormco's and AOA's motion for summary judgment seeking a finding of invalidity of our asserted patent claims (6,398,548 and 6,554,611). Fourth, the Court granted our summary judgment motion that our asserted patent claims are not invalid based on the evidence currently before the Court. Although the Court granted that motion, it reopened discovery on two additional invalidity arguments Ormco and AOA asserted. Fifth, the Court also granted our summary judgment motion that our patents are not unenforceable and granted Ormco's and AOA's summary judgment motion that Ormco and AOA did not willfully infringe our patents.

On December 20, 2004, we filed a further summary judgment motion that our asserted claims are not invalid based on Ormco's and AOA's new evidence. Ormco and AOA filed a counter-summary judgment motion that our asserted claims are invalid based on this new evidence. The motions were heard by the Court on February 7, 2005. On February 24, 2005, the Court granted our motion in part, confirming the validity of all of the asserted claims of our 6,554,611 patent and two of the asserted claims of our 6,398,548 patent. The Court also granted Ormco's and AOA's motion in part, finding certain claims of our 6,398,548 patent to be invalid in view of prior use evidence. On March 10, 2005, Ormco and AOA moved for reconsideration of the Court's ruling that Claims 10 and 17 of our U.S. Patent No. 6,398,548 are not invalid. On April 8, 2005, the Court ruled that it would adhere to its previous ruling that Claims 10 and 17 of our 6,398,548 patent are not invalid.

On March 28, 2005, we filed a motion for permanent injunction to prevent Ormco and AOA from selling the infringing Red, White & Blue system. On May 26, 2005, the Court issued a permanent injunction (the Permanent Injunction) to enjoin Ormco and AOA from further infringement of Claims 10 and 17 of our 6,398,548 patent and Claims 1-3 and 7 of our 6,554,611 patent. On May 31, 2005, Ormco and AOA noticed an appeal to the Federal Circuit from the Permanent Injunction.

On February 1, 2006, we entered into a settlement agreement (the Settlement Agreement) with Ormco and AOA. In accordance with the terms of the Settlement Agreement, Ormco and AOA paid into escrow, pending the completion of the appellate process, \$884,000 to resolve the issues of past damages, willfulness and attorneys' fees for the adjudged infringement of Align's U.S. Patent Nos. 6,398,548 and 6,554,611 (the Align Patents) through the manufacture and sale of Ormco's and AOA's Red, White & Blue appliances. Our receipt of the payments out of escrow is contingent upon the Court, in a final, non-appealable judgment, finding that Ormco or AOA infringes at least one of the claims in the Align Patents. If, however, the Court issues a final, non-appealable judgment of non-infringement, invalidity or

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

There have been two appeals. After the Permanent Injunction was entered, Ormco and AOA appealed that injunction and the orders of the District Court on summary judgment on which that order was based. Oral argument took place on April 3, 2006. Following oral argument, the U.S. Court of Appeals for the Federal Circuit (CAFC) issued a ruling declaring two out of a total of seventy-one claims in our US Patent No. 6,398,548 and four out of a total of ten claims in US Patent No. 6,544,611 to be invalid as obvious. The CAFC's decision reverses the California District Court summary judgment order of validity.

The 6,398,548 patent consists of seventy-one claims; only claims 10 and 17 were at issue in the appeal and CAFC ruling. These two claims are directed to a system of appliances and method of repositioning teeth from an initial to a final tooth arrangement where at least some of the appliances are marked to show order of use. These claims contain further limitations requiring instructions as to order in which the appliances are to be worn and use of the appliances in intervals of 2-20 days.

The 6,544,611 patent consists of ten claims directed to a system for repositioning teeth that includes one or more intermediate appliances and a final appliance, provided in a single package, as well as instructions which set forth the order in which the appliances are to be worn. The CAFC's ruling pertains only to claims 1, 2, 3 and 7 in the patent.

The majority of the claims in the 6,398,548 patent, including claims that address methods of fabricating aligners, digital data sets or computer-generated models to fabricate appliances, are unaffected by the appeal and the CAFC's ruling. The 6,544,611 patent does not contain claims related to digital data, computer-generated models, or methods of fabrication.

The second appeal is from the final judgment. Once final judgment was entered, Ormco filed a Notice of Appeal from the final judgment and we filed a notice of cross-appeal. Ormco has appealed the ruling of the District Court that its patents are not infringed by us and that the asserted claims are invalid. We appealed the ruling of the District Court that certain claims of our 6,398,548 patent which were found to be infringed by Ormco's and AOA's Red, White & Blue appliances were invalid. Briefing on this appeal and cross-appeal is complete, and oral argument occurred on February 6, 2007.

*Other matters***USPTO****Ex Parte Requests:**

During fiscal 2005 and 2006, requests were filed with the United States Patent and Trademark Office ( USPTO ) by a San Francisco, California, law firm, acting on behalf of an unnamed party, requesting Ex Parte re-examination of our patents as follows:

U.S. Patent No.	Request for Reexamination Granted?	Initial Office Actions Received?	Status
5,975,893	Yes	Yes	On January 26, 2006, a first office action was issued rejecting all claims of U.S. Patent No. 5,975,893 (the 893 patent). We responded to this initial office action. A Final Office Action was issued by the USPTO on June 23, 2006 rejecting the pending claims of Align's response. On August 23, 2006, we filed an amendment in response to this Final Office Action, which included claims discussed in an interview with the Examiners. We are awaiting further action by the USPTO.
6,398,548	Yes	No	We filed a preliminary amendment on July 16, 2006. We are awaiting an initial office action.
6,309,215	Yes	Yes	On July 27, 2006, after submitting amendments, affidavits, declarations or other documents as evidence of patentability, we received an action entitled Notice of Intent to Issue Ex Parte Reexamination Certificate with respect to U.S. Patent No. 6,309,215 (the 215 patent). With this Notice, the USPTO has closed prosecution on the merits in reexamination and affirmed the patentability of all of our claims pending in reexamination in the 215 patent. While the 215 patent entered the reexamination proceedings with 16 claims, 26 additional claims were added in the reexamination by us and the 215 patent leaves the proceedings as a valid and enforceable patent with 42 claims.
6,705,863	Yes	No	We filed a preliminary amendment on May 26, 2006. We are awaiting an initial office action.
6,217,325	Yes	Yes	On July 25, 2006, we received an Office Action in U.S. Patent No. 6,217,325 (the 325 patent) confirming the patentability of 32 claims. While the 325 patent entered the reexamination proceedings with 26 claims, 15 additional claims were added by us in the reexamination. On September 25, 2006, we filed an amendment in response to the final Office Action with respect to the claims that were not allowed. We are awaiting further action by the USPTO.

6,722,880	No	N/A	On December 23, 2005, in a non-appealable, final Order, the USPTO denied the request for re-examination with respect to all twenty-one claims of U.S. Patent No. 6,722,880 (the '880 patent). Accordingly, the validity of all twenty-one claims of the '880 patent stand reaffirmed by the USPTO. On January 23, 2006, a Petition Seeking Review of Denial of Request for Re-examination of the '880 patent was filed by the same San Francisco, California law firm.
6,318,994	Yes	No	The USPTO has granted the requests for reexamination of the U.S. Patent No. 6,318,994. We are awaiting an initial Office Action.

#### Inter Parte Requests made by OrthoClear

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

Patent No.	Request for Reexamination Granted?	Initial Office Actions Received?	Status
6,629,840	Yes	Yes	In this initial Office Action dated June 13, 2006, the examiners confirmed the validity of eight of the eleven claims of U.S. Patent No. 6,629,840 (the '840 patent) without amendment and preliminarily rejected the remaining claims of the patents. The non-final initial Office Action presented us with the first opportunity to respond to the USPTO's review and interpretation of the prior art. On September 13, 2006, we submitted a response to the initial Office Action. We are awaiting further action by the USPTO.
6,685,469	No	N/A	The USPTO has granted the requests for reexamination of U.S. Patent of U.S. Patent No. 6,685,469. We are awaiting an initial Office Action.

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

#### Bay Materials

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

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

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

Litigating claims of the types discussed in Note 5 Legal Proceedings of the Notes to Consolidated Financial Statements and in Part II, Item 3 Legal Proceedings of this Annual Report on Form 10-K, whether or not ultimately determined in our favor or settled by us, is costly and diverts the efforts and attention of our management and technical personnel from normal business operations. Any of these results from litigation could adversely affect our results of operations and stock price. From time to time, we have received, and may again receive, letters from third parties drawing our attention to their patent rights. While we do not believe that we infringe any such rights that have been brought to our attention, there may be other more pertinent proprietary rights of which we are presently unaware.

#### **ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS.**

There were no matters submitted to a vote of security holders during the fourth quarter of fiscal 2006.



**PART II****ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.***Price Range of Common Stock*

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

	High	Low
Year Ended December 31, 2006:		
Fourth quarter	\$ 15.03	\$ 11.31
Third quarter	\$ 11.56	\$ 5.66
Second quarter	\$ 9.52	\$ 7.05
First quarter	\$ 9.33	\$ 6.08
Year Ended December 31, 2005:		
Fourth quarter	\$ 7.59	\$ 6.27
Third quarter	\$ 8.34	\$ 5.88
Second quarter	\$ 8.80	\$ 5.89
First Quarter	\$ 10.72	\$ 5.96

On March 6, 2007, the closing price of our common stock on the NASDAQ Global Market was \$16.40 per share. As of March 6, 2007 there were approximately 228 holders of record of our common stock. Because the majority of our shares of outstanding common stock is held by brokers and other institutions on behalf of stockholders, we are unable to estimate the total number of stockholders represented by these record holders.

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

*Performance Graph*

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

The following graph compares the cumulative total stockholder return on our common stock with that of the NASDAQ Stock Market US Index, a broad market index published by the National Association of Securities Dealers, Inc. and a peer group that we believe in good faith is an appropriate basis for comparison since it reflects the labor market in which Align competes. The comparison for each of the periods assumes that \$100 was invested on January 1, 2002 in our common stock, the stocks included in The NASDAQ Stock Market US Index and the stocks included the peer group index and that all dividends were reinvested.

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

---

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

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

**American Medical Systems**

Ariba  
Arthrocare  
Digital Insight  
Intuitive Surgical  
Kyphon

**Silicon Image**

Sonosite  
Thoratec  
Cantel Medical  
Altiris  
InPhonic

**Interwoven**

Magma Design Automation  
Vignette

**ITEM 6. SELECTED CONSOLIDATED FINANCIAL DATA**

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

The following tables set forth the selected consolidated financial data for each of the years in the five-year period ended December 31, 2006. The selected consolidated financial data is qualified in its entirety and should be read in conjunction with the Consolidated Financial Statements and related Notes thereto set forth on pages 58 to 89 and Management's Discussion and Analysis of Financial Condition and Results of Operations beginning on page 42. We have derived the statement of income data for the years ended December 31, 2006, 2005 and 2004 and the balance sheet data as of December 31, 2006 and December 31, 2005 from the consolidated audited financial statements included elsewhere in this Annual Report on Form 10-K. The statement of income data for the years ended December 31, 2003 and 2002 and the balance sheet data as of December 31, 2004, 2003 and 2002 were derived from the consolidated audited financial statements that are not included in this Annual Report on Form 10-K.

**SELECTED CONSOLIDATED FINANCIAL DATA**  
(in thousands, except per share data)

	Years Ended December 31,				
	2006	2005	2004	2003	2002
<b>Consolidated Statement of Operations Data:</b>					
Net revenues	\$ 206,354	\$ 207,125	\$ 172,830	\$ 122,725	\$ 69,698
Gross profit	\$ 141,579	\$ 143,341	\$ 115,304	\$ 71,160	\$ 24,707
Profit (loss) from operations(1)	(37,536 )	2,446	9,765	(19,937 )	(72,935 )
Other income (expense), net	3,401	283	(3 )	(101 )	116
Net profit (loss) before provision for income taxes(1)	(34,135 )	2,729	9,762	(20,038 )	(72,819 )
Provision for income taxes	828	1,316	994	84	
Net profit (loss)(1)	\$ (34,963 )	\$ 1,413	\$ 8,768	\$ (20,122 )	\$ (72,819 )
Net profit (loss) per share					
Basic	\$ (0.55 )	\$ 0.02	\$ 0.15	\$ (0.35 )	\$ (1.52 )
Diluted	\$ (0.55 )	\$ 0.02	\$ 0.14	\$ (0.35 )	\$ (1.52 )
Shares used in computing net profit (loss) per share:					
Basic	63,246	61,644	59,963	57,758	47,878
Diluted	63,246	63,152	64,089	57,758	47,878
	December 31,				
	2006	2005	2004	2003	2002
<b>Consolidated Balance Sheet Data:</b>					
Working capital	\$ 40,306	\$ 62,978	\$ 61,886	\$ 39,737	\$ 41,160
Total assets	151,558	142,110	130,712	102,202	92,856
Total long-term liabilities	219	64	25	1,849	3,837
Stockholders' equity	\$ 83,556	\$ 93,438	\$ 85,739	\$ 62,976	\$ 64,347

(1) In 2006 Profit (loss) from operations, Net profit (loss) before provision for income taxes and Net profit (loss) included a \$14.3 million charge for Patients First Program and settlement costs. See Note 2 *Patients First Program and settlement costs* of the Notes to Consolidated Financial Statements for additional information.

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

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

### Overview

Align Technology, 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 and sales of full Invisalign treatment in July 1999.

Each Invisalign treatment plan is unique to the individual patient. Our full Invisalign treatment consists of as many Aligners as indicated by ClinCheck in order to achieve the doctors' treatment goals. In the third quarter of 2005, we launched Invisalign Express, a low-cost solution for less complex orthodontic cases. Invisalign Express is a dual arch orthodontic treatment for cases that meet certain predetermined clinical criteria and consist of up to ten Aligners. Invisalign Express is intended to assist dental professionals to treat a broader range of patients by providing a lower cost option for adult relapse cases, minor crowding and spacing or as a pre-cursor to restorative or cosmetic treatment such as veneers.

We generate the vast majority of our revenues from the sales of the Invisalign system (which includes full Invisalign treatment and Invisalign Express) to orthodontists and GPs in the United States and Canada, our domestic market. Sales of the Invisalign system in our domestic GP channel and our domestic orthodontic channel represented approximately 45% and 33% of our total net revenues during fiscal 2006, respectively. Our domestic full Invisalign and Invisalign Express revenues represented 66% and 13% of our total net revenue during 2006, respectively. Our international revenues represented 16% of our total net revenue during fiscal 2006.

A number of factors, the most important of which are set forth below, may affect our results during the remainder of 2007 and beyond.

- *Settlement with OrthoClear.* In the fourth quarter of 2006, we entered into a formal agreement with OrthoClear, Inc., OrthoClear Holdings, Inc., and OrthoClear Pakistan Pvt. Ltd. ( "OrthoClear" ), together with certain individuals associated with OrthoClear (the "OrthoClear Agreement" ) to end all pending litigation between the parties. In addition, OrthoClear agreed, among other things, to stop accepting new patient cases for treatment, consent to the entry of an exclusion order by the ITC prohibiting the importation of OrthoClear aligners into the United States, assign and transfer to Align all intellectual property rights with application to the correction of malocclusion and to discontinue all design, manufacture, marketing and sales of removable dental aligners worldwide. Certain OrthoClear principles also signed five year non-compete agreements. In accordance with the terms of the OrthoClear Agreement, we made a one-time cash payment of \$20.0 million to OrthoClear Holdings, Inc. *See Part I, Item 3 Legal Proceedings of this Annual Report on Form 10-K for a more complete summary of the OrthoClear Agreement.* During the fourth quarter of 2006, we engaged a third-party firm to assist us in assessing the value of the assets received in conjunction with the OrthoClear Agreement. Based on this valuation, \$14.0 million of the \$20.0 million we paid to OrthoClear represented the fair value of the non-compete agreements. These intangible assets were capitalized on our balance sheet and are being amortized over 5 years beginning in the fourth quarter of 2006. The intellectual property transferred to us was determined not to have any

alternative future use and therefore had no fair value. We recorded the remaining \$6.0 million as settlement costs. Through the OrthoClear Agreement we achieved our primary objectives in the litigation as well as eliminated the costs and risks of protracted litigation. As a result of the OrthoClear Agreement, we expect our legal expenses will be reduced significantly in fiscal 2007 and our management and technical personnel will be able to refocus their energy and resources on our customers and product development.

- *Patients First Program* . As part of the OrthoClear Agreement, OrthoClear agreed to stop the importation of aligners into the United States and discontinue all aligner business operations worldwide. As a result, most OrthoClear patients were unable to complete their orthodontic treatment with OrthoClear. In an attempt to help minimize treatment disruptions for these patients and their doctors, we committed to make Invisalign treatment available to OrthoClear patients at no additional charge from Align. Therefore, we will receive no revenue for any additional cases we start under this program while incurring significant expenses. In the fourth quarter of 2006, we recorded an expense of \$8.3 million for the anticipated cost of completing this program. This amount is based on the number of OrthoClear cases registered under the Patients First Program as of December 31, 2006 and the estimated costs that will be incurred in order to fulfill our obligations as a result of this program. If the actual number of OrthoClear cases under the program changes or the actual costs differ significantly from our estimates, we would be required to adjust the accrual for the Patient's First Program, which could materially impact our financial statements. As of December 31, 2006, \$6.8 million remained in accrued liabilities for this program.

Additionally, this program has generated increased demands on our sales and customer service representatives and on our manufacturing processes, including increased headcount. In the fourth quarter of 2006, we hired approximately 100 additional dental technicians at our facility in Costa Rica. Training these technicians to use the sophisticated computer modeling program necessary to create ClinCheck treatment forms, takes approximately 90 to 120 days. Therefore, although we hired these additional technicians in the fourth quarter of 2006, these individuals were not able to provide meaningful contribution to our manufacturing process until the beginning of 2007. As a result of this manufacturing constraint, although we initially sought to implement the Patients First Program without impacting our existing customers, or new, paid Invisalign cases, the influx of Patients First Program cases, as well as a higher than expected number of paid Invisalign case submissions in the fourth quarter, caused a delay in ClinCheck preparation time for some new cases by approximately 10 days. Difficulties such as these in managing the deployment of this program, could cause us to lose existing customers, face potential customer disputes or limit the number of new customers who purchase our products or services as well as result in lost or delayed revenue which could cause a decline in our revenues, gross margins and net profits and adversely affect our operating results. We currently anticipate that we will be able to complete the Patients First Program by the end of the second quarter of fiscal 2007. We expect that as we complete the Patients First Program cases, the incremental capacity and workforce created as a result of this program will be utilized by the anticipated increase in paid Invisalign cases.

- *Penetration into our Domestic Market.* As specialists, orthodontists are a critical part of our business, and we expect that orthodontists will continue to treat the majority of complex cases and continue to drive research for expanding Invisalign applications. However, there exists a significantly greater number of GPs in North America than orthodontists. As the primary 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 2006, our domestic GP channel generated 45% of our total net revenue, while the orthodontic channel represented 33%. We continue to 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 2007, we expect to increase the overall marketing spend in the United States with a focus on programs designed to raise the profile of Invisalign and drive more consumers to our most experienced doctors. We anticipate that this increased consumer awareness of Invisalign will increase the market for our product. 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. As of December 31, 2006, we have integrated the Invisalign technique into the curriculums of 38 university programs, including Harvard University, Columbia University, Temple University and the University of Texas at San Antonio. We expect additional dental schools to integrate the Invisalign technique into their curriculums in the future.

- *Product Mix.* In the third quarter of 2005, we launched Invisalign Express, a low-cost solution for less complex orthodontic cases. In the fourth quarter of 2006, we experienced a decline in the number of Invisalign Express cases as compared to the third quarter of 2006. Although we expect that the number of Invisalign Express cases in the first quarter of 2007 will be relatively consistent compared to the fourth quarter of 2006, we expect to see an increasing number of Invisalign Express cases during the remaining quarters of 2007.
- *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 addition to Invisalign Express, launched in 2005, in the second half of 2006 we announced a phased rollout of ClinAdvisor, a new suite of software tools designed to make Invisalign case selection and submission processes more efficient for doctors. During 2007, we expect to extend the product features and functionality of ClinAdvisor and release it to an increasing number of practices. In addition, we plan to introduce further software enhancements directed at our more experienced doctors that will provide these doctors with a robust set of tools for greater predictability, wider applicability and more control. We are also continuing to focus our research and development efforts on a next generation Aligner material as well as 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. We expect these efforts to extend at least through 2008. 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 countries on a case by case basis. In 2006, our international channel represented approximately 16% of our total net revenue primarily as a result of growth in Europe. In 2007, we expect to increase our consumer marketing efforts in key European markets. We expect our international revenue to continue to increase in absolute dollars, and we expect international revenue as a percentage of total net revenue will be comparable in the foreseeable future.
- *Increasing Reliance on International Manufacturing Operations.* Our manufacturing efficiency has been and will be an important factor in our future profitability. Currently, two of our key production steps are performed in operations located outside of the U.S. At our facility in Costa Rica, dental technicians use a sophisticated, internally developed computer-modeling program to prepare electronic treatment plans, which are transmitted electronically back to the U.S. These electronic files form the basis of ClinCheck and are used to manufacture Aligner molds. In

addition, we use IMS, a third party based in Juarez, Mexico, for the fabrication and packaging of Aligners. Our success will depend in part on the efforts and abilities of management to effectively manage these international operations, including our relationship with IMS. In addition, we currently are and will become increasingly dependant on IMS' s and our ability to hire and retain employees generally, as well as hire and retain employees with the necessary skills to perform the more technical aspects of our operations. If our management 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 for these or other reasons we do not have sufficient number of trained dental technicians in Costa Rica to create the ClinCheck treatment forms or if IMS is unable to ship our product to our customers on a timely basis, our revenue will be delayed or lost which will cause our operating results to fluctuate. *See Part I, Item 1A Risk Factors for risks related to our international operations.*

*Stock-based compensation.* Effective January 1, 2006, we adopted Statement of Financial Accounting Standards No. 123 (Revised 2004), Share-based Payment ( FAS 123R ) using the modified prospective transition method, which requires the measurement and recognition of compensation expense for all share-based payment awards made to our employees and directors and employee stock purchases related to the Employee Stock Purchase Plan based on estimated fair values over the requisite service period. In accordance with the modified prospective method, our financial statements for the prior periods have not been restated to reflect and do not include the impact of FAS 123R. For the year ended December 31, 2006, stock-based compensation expense recognized in accordance with FAS 123R is as follows (in thousands):

	Year Ended December 31, 2006 Stock-based Compensation	% of net revenues
Cost of revenues	\$ 700	0.3 %
Sales and marketing	2,862	1.4 %
General and administrative	4,054	2.0 %
Research and development	1,294	0.6 %
Total stock-based compensation expense	\$ 8,910	4.3 %

## Results of Operations

### Comparison of Years Ended December 31, 2006, 2005 and 2004:

#### *Revenues:*

Our total net revenues decreased by \$0.7 million or 0.4% to \$206.4 million in 2006 compared to \$207.1 million in 2005. The decline in total net revenues resulted from reduced revenues in the orthodontic channel offset by increases in the GP channel, international and other revenues. In 2006, the domestic orthodontic and GP channels were impacted by lower overall average selling prices due to new pricing initiatives and the full-year effect of our lower-priced Invisalign Express product, all of which were introduced in the second half of 2005.

# Edgar Filing: ALIGN TECHNOLOGY INC - Form 10-K

Invisalign product revenues by channel and other revenue, which represented training and sales of ancillary products for the years ended December 31, 2006, 2005 and 2004, are as follows:

Net revenues	Years Ended December 31, 2006 Change % Change			2005	Change	% Change	2004
	(in millions)						
Domestic:							
Ortho full	\$ 58.4	\$ (24.3 )	-29.4 %	\$ 82.7	\$ (3.4 )	-3.9 %	\$ 86.1
Ortho Express(1)	10.2	7.5	278.8 %	2.7	2.7		
Total Ortho revenues	68.6	(16.8 )	-19.6 %	85.4	(0.7 )	-0.8 %	86.1
GP full	77.2	(7.6 )	-9.0 %	84.8	22.8	36.8 %	62.0
GP Express(1)	16.7	12.4	282.1 %	4.3	4.3		
Total GP revenues	93.9	4.8	5.3 %	89.1	27.1	43.9 %	62.0
International	32.1	8.9	38.3 %	23.2	6.8	40.6 %	16.4
Total Invisalign revenues	194.6	(3.1 )	-1.6 %	197.7	33.2	20.2 %	164.5
Other revenue	11.8	2.4	25.6 %	9.4	1.1	13.0 %	8.3
Total net revenues	\$ 206.4	\$ (0.7 )	-0.4 %	\$ 207.1	\$ 34.3	19.8 %	\$ 172.8

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

Case volume data which represents Invisalign case shipment by channel, for the years ended December 31, 2006, 2005 and 2004 are as follows:

Case Volume	Years Ended December 31, 2006 Change % Change			2005	Change	% Change	2004
	(in thousands)						
Domestic:							
Ortho full	41.8	(5.3 )	-11.1 %	47.1	(3.7 )	-7.3 %	50.8
Ortho Express(1)	13.7	10.0	268.5 %	3.7	3.7		
Total Ortho volume	55.5	4.7	9.2 %	50.8			50.8
GP full	53.0	(0.1 )	-0.1 %	53.1	12.2	29.7 %	40.9
GP Express(1)	22.4	16.5	280.6 %	5.9	5.9		
Total GP volume	75.4	16.4	27.9 %	59.0	18.1	44.1 %	40.9
International	19.2	6.0	45.0 %	13.2	4.6	52.8 %	8.6
Total Invisalign volume	150.1	27.1	22.0 %	123.0	22.7	22.5 %	100.3

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

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

Revenues from our domestic GP channel increased \$4.8 million or 5.3% in 2006 compared to 2005 primarily due to an increase in Invisalign Express revenues of \$12.4 million partially offset by a \$7.6 million



decline in full Invisalign revenues. Invisalign Express revenues increased resulting from higher case volumes in 2006 compared to 2005, since this product was launched in the third quarter of 2005. The reduction in full Invisalign revenues is attributed to lower average selling prices which reflect the full year impact of the pricing initiatives mentioned above.

International revenues increased \$8.9 million or 38.3% in 2006 compared to 2005 primarily due to a significant increase in our international Invisalign case volumes partially offset by a lower average selling price as a result of pricing initiatives introduced in the first quarter of 2006.

Other revenues, which primarily consisted of training and sales of ancillary products, increased \$2.4 million in fiscal 2006 compared to 2005 mainly due to a \$1.8 million increase in training revenues resulting from an increase in training fees.

Net revenue grew by 19.8% for the year ended December 31, 2005, compared to the year ended December 31, 2004. The growth in net 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, our international sales improved primarily as a result of increased number of participating clinicians and case utilization by our European practitioners.

For fiscal year 2007, we expect our total net revenues will increase compared to 2006 primarily due to the anticipated case volume increases in our domestic orthodontic and GP channels, as well as in international markets. We expect our average selling price to be flat to slightly lower compared to 2006 primarily due to increased participation in our volume based discount programs.

*Cost of revenues:*

	Years Ended December 31,					
	2006	Change	2005	Change	2004	
	(in millions)					
Cost of revenues	\$ 64.8	\$ 1.0	\$ 63.8	\$ 6.3	\$ 57.5	
% of net revenues	31.4	%	30.8	%	33.3	%
Gross profits	\$ 141.6	\$ (1.7 )	\$ 143.3	\$ 28.0	\$ 115.3	
% of net revenues	68.6	%	69.2	%	66.7	%

Cost of revenues includes salaries for staff involved in the production process, costs incurred by IMS, a third party shelter service provider in Juarez, Mexico, the cost of materials, packaging, shipping costs, depreciation on capital equipment used in the production process, training costs and stock-based compensation expense.

Gross margin decreased to 68.6% of net revenues in 2006 compared to 69.2% in 2005 primarily due to lower average selling prices. This decline in average selling prices is attributable to the reduction in the list price of full Invisalign and increased sales of our lower priced Invisalign Express product. Reductions in product costs driven by increased volumes and manufacturing efficiencies including the relocation of the SLA mold operations to Juarez, Mexico, partially offset the impact of lower average selling prices. In addition, as a result of these efficiencies, we also released a \$2.2 million provision for estimated losses on case refinement sales during fiscal 2006.

Gross margin improved to 69.2% of net revenues for the fiscal year ended December 31, 2005, compared to 66.7% of net 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.

## Edgar Filing: ALIGN TECHNOLOGY INC - Form 10-K

For the fiscal year 2007, we anticipate that our gross margin will be slightly higher compared to 2006 primarily due to impact of the expected increase in case volume and manufacturing efficiencies including a full year effect of the relocation of the SLA mold operations to Juarez, Mexico.

### *Sales and marketing:*

	Years Ended December 31,					
	2006	Change	2005	Change	2004	
	(in millions)					
Sales and marketing	\$ 82.0	\$ 1.9	\$ 80.1	\$ 24.2	\$ 55.9	
% of net revenues	39.7	%	38.7	%	32.4	%

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

Sales and marketing expense increased \$1.9 million in 2006 compared to 2005 primarily due to a \$2.8 million increase in payroll expense mainly attributable to an increase in headcount and the replacement of orthodontic sales representatives who left Align in the first half of 2005, and a \$2.9 million increase in stock-based compensation expense. These increases were partially offset by a \$3.9 million decrease in media, advertising and other marketing expenses due to the initial launch of our consumer marketing campaign in the second quarter of 2005.

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 headcount 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.

For fiscal 2007, we expect sales and marketing expense, including stock-based compensation, to be slightly higher than 2006, as we expand our international markets, continue to increase our investment in media programs and provide clinical education.

### *General and administrative:*

	Years Ended December 31,					
	2006	Change	2005	Change	2004	
	(in millions)					
General and administrative	\$ 64.3	\$ 22.1	\$ 42.2	\$ 8.3	\$ 33.9	
% of net revenues	31.2	%	20.4	%	19.6	%

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

General and administrative expense increased by \$22.1 million in 2006 compared to 2005 primarily due to a \$15.0 million increase in external legal fees primarily related to the OrthoClear litigation, a \$3.8 million increase in payroll related expenses primarily resulting from the hiring of additional legal and administrative staff, and a \$4.0 million increase in stock-based compensation expense. Partially offsetting these increases was a \$0.8 million decrease in bad debt expense.

## Edgar Filing: ALIGN TECHNOLOGY INC - Form 10-K

General and administrative expense increased by \$8.3 million for the year ended December 31, 2005, compared to the year ended December 31, 2004 primarily due to incremental expenses related to the OrthoClear litigation, which included a \$5.8 million increase in external legal fees, a \$1.3 million increase in consulting costs and a \$3.2 million increase in payroll expense for employee retention and the hiring of additional legal staff. This increase was partially offset by a \$2.6 million decrease in stock-based compensation expense in connection with the amortization of deferred stock-based compensation related to option grants prior to 2001.

For fiscal year 2007, we expect that general and administrative expense will decrease from fiscal 2006 primarily as a result of the significant reduction in legal and other expenses following the settlement agreement we entered into with OrthoClear in the fourth quarter of 2006.

### *Research and development:*

	Years Ended December 31, 2006		Change		2005	Change		2004
	(in millions)							
Research and development	\$	18.5	\$	(0.1 )	\$	18.6	\$	2.8
% of net revenues	9.0	%			9.0	%		9.1 %

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

Research and development expense decreased \$0.1 million in 2006 compared to 2005, primarily due to a \$1.4 million decrease in temporary services and outside consulting expenses partially offset by \$1.3 million increase in stock-based compensation.

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 service 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.

For fiscal 2007, we expect research and development spending to increase from fiscal 2006 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.

### *Patients First Program and settlement costs:*

	Years Ended December 31, 2006		Change		2005	Change		2004
	(in millions)							
Patients First Program and settlement costs	\$	14.3	\$	14.3	\$		\$	
% of net revenues	7.0	%						

Patients First Program and settlement costs consisted of a \$8.3 million charge for anticipated costs of Patients First Program combined with \$6.0 million in settlement cost, for a total of \$14.3 million. This amount is separately disclosed on our December 31, 2006 Consolidated Statement of Operations.

As part of the OrthoClear Agreement, OrthoClear agreed to stop the importation of aligners into the United States and discontinue all aligner business operations worldwide. As a result, most OrthoClear patients were unable to complete their orthodontic treatment with OrthoClear. In an attempt to help

minimize treatment disruptions for the OrthoClear patients and their doctors, we committed to make treatment available to these patients at no additional cost under the Patients First Program. We will receive no revenue for the program, and will incur significant expense to complete these cases. In the fourth quarter of 2006, we recorded an \$8.3 million charge for the anticipated costs of completing this program in accordance with FASB Statement 5, Accounting for Contingencies (FAS 5). This amount is based on the number of OrthoClear cases registered under the Patients First Program as of December 31, 2006 and the estimated costs that will be incurred to fulfill our obligations as a result of this program. If the actual number of OrthoClear cases under the program changes or the actual costs differs significantly from our estimates, we would be required to adjust the accrual for the Patients First Program, and it could materially impact our financial statements. We currently anticipate that we will be able to complete the Patients First Program by the end of the second quarter of fiscal 2007.

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

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

	Years Ended December 31,				
	2006	Change	2005	Change	2004
	(in millions)				
Interest income	\$ 3.2	\$ 1.3	\$ 1.9	\$ 1.2	\$ 0.7
Interest expense	\$ (0.3 )	\$ (0.2 )	\$ (0.1 )	\$ 0.2	\$ (0.3 )
Other income (expense), net	0.5	2.0	(1.5 )	(1.1 )	(0.4 )
Total interest and other, net	\$ 3.4	\$ 3.1	\$ 0.3	\$ 0.3	\$

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

Interest income (expense), net for the year ended December 31, 2006 increased \$1.1 million compared to 2005. The increase was primarily due to increased interest income as a result of higher effective interest rates.

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

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.

*Income tax provision:*

	Years Ended December 31,				
	2006	Change	2005	Change	2004
	(in millions)				
Provision for income taxes	\$ (0.8 )	\$ 0.5	\$ (1.3 )	\$ (0.3 )	\$ (1.0 )

We recorded an income tax provision of \$0.8 million for fiscal 2006, \$1.3 million for fiscal 2005 and \$1.0 million in fiscal 2004, representing effective tax rates of -2.4%, 48.2% and 10.2% for 2006, 2005 and 2004, respectively. As of December 31, 2006, 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, 2006, we had net operating loss carryforwards of approximately \$214.9 million for federal tax purposes and \$73.5 million for California state tax purposes. If not utilized, these carryforwards will begin to expire in 2017 for federal purposes and 2007 for California purposes. SFAS 123R prohibits recognition of a deferred income tax asset for excess tax benefits due to stock option exercises that have not yet been realized through a reduction in income taxes payable. Such unrecognized deferred tax benefits totaled \$14.1 million as of December 31, 2006 and will be accounted for as a credit to additional paid-in capital, if and when realized through a reduction in income taxes payable. The Internal Revenue Code imposes an annual limitation on the use of a corporation's tax attributes if a corporation undergoes an ownership change for tax purposes. If an ownership change is determined to have occurred, our ability to use the net operating loss carryforwards would be subject to an annual limitation. However, based on our current estimate of the total net operating losses at December 31, 2006 and our current estimate of the annual limitation, we do not expect our net operating loss carryforwards to be limited. At December 31, 2006, we had research credit carryforwards of approximately \$4.0 million for federal purposes and \$5.4 million for California state tax purposes. If not utilized, the federal credit carryforwards will begin to expire in 2017. The California state credit can be carried forward indefinitely.

We have not provided additional U.S. income taxes on undistributed earnings from non- U.S. operations as of December 31, 2006 because such earnings are intended to be reinvested indefinitely outside of the United States.

## Liquidity and Capital Resources

We fund our operations from the proceeds of the sale of our common stock, from cash generated from sales of our product and occasional borrowing under available credit facilities. As of December 31, 2006, 2005 and 2004, we had the following cash, cash equivalents and short-term investments:

	Years Ended December 31,		
	2006	2005	2004
	(in thousands)		
Cash and cash equivalents	\$ 55,113	\$ 74,219	\$ 69,659
Restricted cash	93	150	303
Short-term Investments	8,931		
Total cash, cash equivalents and short-term investments	\$ 64,137	\$ 74,369	\$ 69,962

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

Net cash provided by operating activities for the year ended December 31, 2005, was \$16.1 million, primarily from operating profits adjusted for non cash items and increases in accrued liabilities partially offset by reductions in accounts payable.

Net cash used in investing activities was \$32.8 million for the year ended December 31, 2006, primarily due to a \$14.0 million purchase of intangible assets resulting from the OrthoClear Agreement, \$10.0 million for the purchase of capital assets and \$8.9 million net purchase of short-term marketable securities. We used \$15.3 million of cash for our investing activities during 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.

Net cash provided by financing activities was \$27.7 million for the year ended December 31, 2006 and primarily consisted of \$16.2 million in proceeds from the issuance of common stock, primarily from exercises of employee stock options and \$11.5 million in net proceeds from our line of credit. Net cash provided by financing activities was \$3.7 million for the year ended December 31, 2005, which 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.

Net proceeds from the issuance of common stock related to the exercise of employee stock options have historically been a significant component of our liquidity. However, in 2006, we began granting RSUs which, unlike stock options, do not generate cash from exercise. In addition, because RSUs are taxable to the individuals when they vest, the number of shares we issued to each of our executive officers will be net of applicable payroll withholding taxes which taxes will be paid by us on their behalf. As a result, we will likely generate less cash from the proceeds of the sale of our common stock in future periods.

In December 2005, we renegotiated and amended our existing revolving line of credit to increase the available borrowings under the then existing revolving line to \$20.0 million. Included in the 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 credit facility matures on December 16, 2007, at which time all outstanding borrowings must be repaid. The 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. In December 2006, we amended our credit agreement whereby the only financial covenant for the fourth quarter of 2006 was a certain minimum cash balance. As of December 31, 2006, we are in compliance with the financial covenant of these credit facilities.

During the third quarter of 2006, we borrowed \$15.0 million against these credit facilities and made a \$20.0 million one-time payment to OrthoClear Holdings, Inc in accordance with the terms of the OrthoClear Agreement. We elected LIBOR plus two percent as an interest rate of 7.29% as of December 31, 2006. We repaid \$3.5 million of this borrowing in the fourth quarter of 2006, the outstanding balance as of December 31, 2006 was \$11.5 million and is classified as current liability.

On March 7, 2007, we renegotiated and amended our existing credit facility with Comerica Bank. The amendment, among other things, reduced financial covenants to require only a quick ratio covenant. Additionally, the amendment also increased the available borrowings under the existing revolving line of credit from \$20 million to \$25 million effective January 1, 2008. The amended credit facility matures on December 31, 2008 at which point all outstanding borrowing under this credit facility must be repaid.

**Contractual Obligations / Off Balance Sheet Arrangements**

The impact that our contractual obligations as of December 31, 2006 are expected to have on our liquidity and cash flow in future periods is as follows (in thousands):

	Total	Payments Due by Period			
		Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
Principal payment on line of credit	\$ 11,500	\$ 11,500	\$	\$	\$
Other contractual obligations:					
Operating lease obligations(1)	\$ 7,419	\$ 3,261	\$ 3,691	\$ 467	\$
Computer support services	499	499			
Total other contractual obligation	7,918	3,760	3,691	467	
Total	\$ 19,418	\$ 15,260	\$ 3,691	\$ 467	\$

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

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 had no off-balance sheet arrangements as defined in Regulation S-K Item 303(a)(4) as of December 31, 2006.

We expect that our expense levels for 2007 will remain comparable to 2006, depending on our level of business activity. We expect that any increases will be focused on continued marketing and international sales efforts and research and development expenses as we develop new products and improvements to our existing products. In addition, we may use cash to fund acquisitions of complementary businesses or technologies. Our capital requirements depend on market acceptance of our products and our ability to market, sell and support our products on a worldwide basis.

We believe that our current cash and cash equivalents 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 establishing a national brand, building manufacturing infrastructure and developing our product and process technology, 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, stock-based compensation and income taxes. We use authoritative pronouncements, historical experience and other assumptions as the basis for making estimates. Actual results could differ from those estimates.

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

### *Stock-based Compensation Expense*

Effective January 1, 2006, we adopted the modified prospective transition method of Statement of Financial Accounting Standards No. 123 (Revised 2004), *Share-Based Payment* ( FAS 123R ), which requires the measurement and recognition of compensation expense for all share-based payment awards made to employees and directors, including stock options and restricted stock units related to our 2001 Plan and our 2005 Plan and employee stock purchases related to our Employee Stock Purchase Plan based on estimated fair values over requisite employee service period. In accordance with the modified prospective transition method, our financial statements for prior periods have not been restated to reflect, and do not include, the impact of FAS 123R. Our Consolidated Financial Statements as of and for the year ended December 31, 2006 reflect the impact of FAS 123R related to share-based payment awards granted prior to, but not yet vested as of December 31, 2005 based on the grant date fair value estimated in accordance with the pro forma provisions of FASB Statement 123, *Accounting for Stock-Based Compensation* ( FAS 123 ) and stock-based payment awards granted subsequent to December 31, 2005 based on the grant date fair value estimated in accordance with the provisions of FAS 123R. In conjunction with the adoption of FAS 123R, we changed our method of attributing the value of stock-based compensation to expense from the accelerated multiple-option approach to the straight-line single option method.

We estimate the fair value of stock options using a Black-Scholes valuation model, consistent with the provisions of FAS 123R and the SEC issued Staff Accounting Bulletin No. 107 ( SAB 107 ). Option-pricing models require the input of highly subjective assumptions, including the option s expected term and stock price volatility. Judgment is also required in estimating the number of stock-based awards that are expected to be forfeited. As stock-based compensation expense recognized in our financial statements for the year ended December 31, 2006 is based on awards ultimately expected to vest, it has been reduced for estimated forfeitures. FAS 123R requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Forfeitures were estimated based on historical experience. If our estimates change or if we employ different assumptions in the application of FAS 123R in future periods, the compensation expense that we record under FAS 123R may differ significantly from what we have recorded in the current period and could materially impact our results of operations. *See Note 10 Shareholders Equity of the Notes to Consolidated Financial Statements for additional information.*

On October 6, 2005, the Compensation Committee of the Board of Directors approved the acceleration of the vesting for all unvested stock options with exercise prices greater than \$7.10. Options held by non-employee directors were excluded from the vesting acceleration. The fair market value of our



common stock on the date of acceleration was \$6.41 as quoted on the NASDAQ Global Market. As a result of the acceleration, approximately 3.8 million options or 35% of the then total outstanding options became immediately exercisable as of October 6, 2005. The purpose of the acceleration was to eliminate future compensation expense we would otherwise recognize in our statement of operations with respect to these accelerated options upon the adoption of FAS 123R.

*Long-lived assets, including finite lived purchased intangible assets*

Intangible assets other than goodwill are amortized over their useful lives, unless these lives are determined to be indefinite. Intangible assets are carried at cost less accumulated amortization. Amortization is computed over the estimated useful life of the respective asset. Intangible assets are reviewed for impairment in accordance with Statement of Financial Accounting Standards No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets* ( FAS 144 ). We perform an impairment test whenever events or changes in circumstances indicate that the carrying value of such assets may not be recoverable. Examples of such events or circumstances include significant underperformance relative to historical or projected future operating results, significant changes in the manner of use of acquired assets or the strategy for its business, significant negative industry or economic trends, and/or a significant decline in our stock price for a sustained period. Impairments are recognized based on the difference between the fair value of the asset and its carrying value, and fair value is generally measured based on discounted cash flow analyses. No intangible asset impairment was recorded for the periods presented.

*Patients First Program*

As part of the OrthoClear Settlement Agreement, OrthoClear agreed to stop the importation of aligners into the United States and discontinue all aligner business operations worldwide. As a result, most OrthoClear patients were unable to complete their orthodontic treatment with OrthoClear. In an attempt to help minimize treatment disruptions for the OrthoClear patients and their doctors, we committed to make treatment available to these patients at no additional cost under the Patients First Program . We will receive no revenue for the program, and will incur significant expense to complete these cases. In the fourth quarter of 2006, we recorded a \$8.3 million charge for the anticipated costs of completing this program in accordance with FASB Statement 5, *Accounting for Contingencies* ( FAS 5 ). This amount is based on the number of OrthoClear cases registered under the Patients First Program as of December 31, 2006 and the estimated costs that will be incurred to fulfill our obligations as a result of this program. If the actual number of OrthoClear cases under the program changes or the actual costs differs significantly from our estimates, we would be required to adjust the accrual for the Patients First Program, and it could materially impact our financial statements. We currently anticipate that we will be able to complete the Patients First Program by the end of the second quarter of fiscal 2007.

*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.

#### *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.

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.

#### *Recent Accounting Pronouncements*

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

### **ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

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

#### *Interest Rate Risk*

Changes in interest rates could impact our anticipated interest income on our cash equivalents and investments in marketable equity securities. Due to the short duration of our cash and cash equivalents an immediate 10% decrease or more in interest rates would not have a material adverse impact on our future operating results and cash flows. 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, 2006, we had \$8.9 million investments in available for sale marketable equity securities.

As of December 31, 2006, we had \$11.5 million outstanding borrowing against our line of credit, which bears interest rate of LIBOR plus two percent being 7.29% as of December 31, 2006 and are not subject to risks from immediate interest rate increases. An increase of 10% or more in interest rates may affect our future cost of financing. In the past we had used fixed rates 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, Cost 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 gains and losses. Included in other income (expense) for the year ended December 31, 2006, was an exchanges gain of \$1.1 million. For years 2005 and 2004 we experienced exchange loss of \$1.0 million and an exchange gain of \$0.3 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 \$1.2 million on our results of operations and financial position.

**ITEM 8. CONSOLIDATED FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA****Quarterly Results of Operations**

	<b>Three Months Ended 2006</b>				<b>2005</b>			
	<b>Dec 31</b>	<b>Sep 30</b>	<b>Jun 30</b>	<b>Mar 31</b>	<b>Dec 31</b>	<b>Sep 30</b>	<b>Jun 30</b>	<b>Mar 31</b>
	<b>(in thousands, except per share data) (unaudited)</b>							
Net revenues	\$ 55,191	\$ 49,034	\$ 53,221	\$ 48,908	\$ 51,164	\$ 50,866	\$ 53,940	\$ 51,155
Gross profit	37,994	32,245	36,729	34,611	34,453	35,891	37,320	35,677
Operating profit (loss)(1)	(18,067 )	(10,965 )	(3,291 )	(5,213 )	663	(1,539 )	1,193	2,129
Net profit (loss)(1)	\$ (17,269 )	\$ (10,320 )	\$ (2,610 )	\$ (4,764 )	\$ 528	\$ (1,516 )	\$ 538	\$ 1,863
Net profit (loss) per share,								
Basic	\$ (0.27 )	\$ (0.16 )	\$ (0.04 )	\$ (0.08 )	\$ 0.01	\$ (0.02 )	\$ 0.01	\$ 0.03
Diluted	\$ (0.27 )	\$ (0.16 )	\$ (0.04 )	\$ (0.08 )	\$ 0.01	\$ (0.02 )	\$ 0.01	\$ 0.03
Shares used in computing net profit (loss) per share:								
Basic	64,252	63,230	62,966	62,518	62,045	61,788	61,484	61,246
Diluted	64,252	63,230	62,966	62,518	63,247	61,788	62,953	63,148

(1) December 2006 Profit (loss) from operations and Net profit (loss) included a \$14.3 million charge for Patients First Program and settlement costs. *See Note 2 Patients First Program and settlement costs of the Notes to Consolidated Financial Statements for additional information.*

**INDEX TO CONSOLIDATED FINANCIAL STATEMENTS**

	<b>Page</b>
<u>Report of Management on Internal Control over Financial Reporting</u>	59
<u>Report of Independent Registered Public Accounting Firm</u>	60
<u>Consolidated Statements of Operations</u>	62
<u>Consolidated Balance Sheets</u>	63
<u>Consolidated Statements of Shareholders' Equity (Deficit)</u>	64
<u>Consolidated Statements of Cash Flows</u>	65
<u>Notes to Consolidated Financial Statements</u>	66

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

## REPORT OF MANAGEMENT ON INTERNAL CONTROL OVER FINANCIAL REPORTING

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

- pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the company's assets that could have a material effect on the financial statements.

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

Management assessed the effectiveness of Align's internal control over financial reporting as of December 31, 2006. In making this assessment, management used the criteria set forth in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

Based on its assessment and those criteria, management has concluded that, as of December 31, 2006, Align's internal control over financial reporting was effective to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles.

Align's independent registered public accounting firm, PricewaterhouseCoopers LLP, has issued an audit report on our assessment of Align's internal control of financial reporting. Their report may be found immediately after this report.

/s/ THOMAS M. PRESCOTT

Thomas M. Prescott

*President and Chief Executive Officer*

March 12, 2007

/s/ ELDON M. BULLINGTON

Eldon M. Bullington

*Vice President, Finance and Chief Financial Officer*

March 12, 2007

**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 consolidated financial statements and of its internal control over financial reporting as of December 31, 2006 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 under item 15(a)(i) present fairly, in all material respects, the financial position of Align Technology, Inc. and its subsidiaries at December 31, 2006 and 2005, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2006 in conformity with accounting principles generally accepted in the United States of America. In addition, in our opinion, the financial statement schedule listed in the accompanying index appearing under item 15(a)(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.

As discussed in Note 10 to the Consolidated Financial Statements, the Company changed the manner in which it accounts for stock-based compensation in fiscal 2006.

*Internal control over financial reporting*

Also, in our opinion, management's assessment, included in Management's Report 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, 2006 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, 2006, 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, CA

March 12, 2007

## ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES

## CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per share data)

	Years Ended December 31,		
	2006	2005	2004
Net revenues:			
Invisalign	\$ 194,582	\$ 197,749	\$ 164,536
Ancillary products and other services	11,772	9,376	8,294
Total net revenues	206,354	207,125	172,830
Cost of revenues:			
Invisalign	55,759	(1) 54,549	50,315
Ancillary products and other services	9,016	9,235	7,211
Total cost of revenues	64,775	63,784	57,526
Gross profit	141,579	143,341	115,304
Operating expenses:			
Sales and marketing	81,993	(1) 80,068	55,932
General and administrative	64,305	(1) 42,242	33,851
Research and development	18,474	(1) 18,585	15,756
Patients First Program and settlement costs	14,343		
Total operating expenses	179,115	140,895	105,539
Profit (loss) from operations	(37,536)	) 2,446	9,765
Interest income	3,179	1,918	713
Interest expense	(296)	) (110)	(271)
Other income (expense)	518	(1,525)	(445)
Net profit (loss) before provision for income taxes	(34,135)	) 2,729	9,762
Provision for income taxes	828	1,316	994
Net profit (loss)	\$ (34,963)	) \$ 1,413	\$ 8,768
Net profit (loss) per share:			
Basic	\$ (0.55)	) \$ 0.02	\$ 0.15
Diluted	\$ (0.55)	) \$ 0.02	\$ 0.14
Shares used in computing net profit (loss) per share:			
Basic	63,246	61,644	59,963
Diluted	63,246	63,152	64,089

(1) Amounts for the year ended December 31, 2006 include stock-based compensation expense recognized under FAS 123R for stock options, restricted stock units and employee stock purchases (*See Note 10 Shareholders Equity of the Notes to Consolidated Financial Statements*). The Company recognized \$8.9 million in total stock-based compensation expense in the year ended December 31, 2006, including \$0.7 million in cost of revenues, \$2.9 million in sales and marketing, \$4.0 million in general and administrative and \$1.3 million in research and development.

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, 2006	2005
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 55,113	\$ 74,219
Restricted cash	93	150
Marketable securities, short-term	8,931	
Accounts receivable, net of allowance for doubtful accounts of \$844 and \$1,626 at December 31, 2006 and 2005, respectively	33,635	29,305
Inventories, net	3,090	2,930
Prepaid expenses and other current assets	7,227	4,982
Total current assets	108,089	111,586
Property and equipment, net	26,904	26,427
Goodwill	478	478
Intangible assets, net	13,824	818
Other assets	2,263	2,801
Total assets	\$ 151,558	\$ 142,110
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Line of credit	\$ 11,500	\$
Accounts payable	5,034	2,489
Accrued liabilities	40,307	29,372
Deferred revenue	10,942	16,747
Total current liabilities	67,783	48,608
Other long term liabilities	219	64
Total liabilities	68,002	48,672
Commitments and contingencies (Notes 7 and 9)		
Stockholders' equity:		
Preferred stock, \$0.0001 par value; Authorized: 5,000 shares at December 31, 2006 and 2005; Issued and Outstanding: no shares at December 31, 2006 and 2005		
Common stock, \$0.0001 par value, Authorized: 200,000 shares at December 31, 2006 and 2005; Issued: 64,899 and 62,120 shares at December 31, 2006 and 2005, respectively; Outstanding: 64,859 and 62,080 shares at December 31, 2006 and 2005, respectively	6	6
Additional paid-in capital	408,921	383,836
Accumulated other comprehensive income	3	7
Accumulated deficit	(325,374)	(290,411)
Total stockholders' equity	83,556	93,438
Total liabilities and stockholders' equity	\$ 151,558	\$ 142,110

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, 2006, 2005 and 2004**
**(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, 2003	58,753	\$ 6	\$ 368,796	\$ (5,219 )	\$ (17 )	\$ 2	\$ (300,592 )	\$ 62,976
Net profit							8,768	8,768
Net change in unrealized loss from available-for sale securities						(4 )		(4 )
Comprehensive net income								8,764
Issuance of common stock relating to employee stock purchase plan	429		1,726					1,726
Issuance of common stock upon exercise of stock options	1,695		6,389					6,389
Repurchase of common stock	(1 )		(1 )					(1 )
Payments on stockholder notes receivable					17			17
Cancellations, net of deferred stock compensation			(130 )	130				
Amortization of deferred stock compensation				5,089				5,089
Charge for compensation expense on non-employee stock options			429					429
Charge for accelerated vesting of employee stock options			350					350
Balances at December 31, 2004	60,876	\$ 6	\$ 377,559	\$	\$	\$ (2 )	\$ (291,824 )	\$ 85,739
Net profit							1,413	1,413
Net change in unrealized gain from available-for sale securities						9		9
Comprehensive net income								1,422
Issuance of common stock relating to employee stock purchase plan	374		2,167					2,167
Issuance of common stock upon exercise of stock options	830		3,417					3,417
Tax benefit from stock option transactions			581					581
Charge for compensation expense on non-employee stock options			45					45
Charge for accelerated vesting of employee stock options			67					67
Balances at December 31, 2005	62,080	\$ 6	\$ 383,836	\$	\$	\$ 7	\$ (290,411 )	\$ 93,438
Net loss							(34,963 )	(34,963 )
Net change in unrealized loss from available-for sale securities						(4 )		(4 )
Comprehensive net loss								(34,967 )
Issuance of common stock relating to employee stock purchase plan	462		2,583					2,583
Issuance of common stock upon exercise of stock options	2,317		13,592					13,592
Stock-based compensation			8,910					8,910
Balances at December 31, 2006	64,859	\$ 6	\$ 408,921	\$	\$	\$ 3	\$ (325,374 )	\$ 83,556

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



## ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES

## CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

	Years Ended December 31,		2004
	2006	2005	
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>			
Net profit (loss)	\$ (34,963 )	\$ 1,413	\$ 8,768
Adjustments to reconcile net profit (loss) to net cash provided by (used in) operating activities:			
Depreciation and amortization	9,279	10,099	9,597
Stock-based compensation	8,910	45	429
Amortization of intangibles	992	352	36
Amortization of deferred stock-based compensation			5,089
Compensation expense for accelerated vesting of stock options		67	350
Provision for (benefit of) doubtful accounts	(288 )	503	541
Loss on retirement, disposal and impairment of fixed assets	40	92	70
Changes in assets and liabilities, net of acquisition effect			
Accounts receivable	(4,042 )	(985 )	(8,085 )
Inventories	(160 )	(78 )	(518 )
Prepaid expenses and other current assets	(2,245 )	229	634
Accounts payable	2,997	(1,998 )	221
Accrued and other long term liabilities	11,255	6,485	4,326
Deferred revenues	(5,805 )	(145 )	3,144
Net cash provided by (used in) operating activities	(14,030 )	16,079	24,602
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>			
Purchase of property and equipment	(10,028 )	(13,801 )	(9,061 )
Proceeds from sale of property and equipment	366		858
Restricted cash	57	153	136
Purchase of marketable securities	(18,416 )	(2,217 )	(523 )
Maturities of marketable securities	9,481	2,226	2,811
Payments for acquisition, net of cash acquired		(856 )	
Purchase for intangible assets	(14,000 )		
Other assets	(211 )	(760 )	(245 )
Net cash used in investing activities	(32,751 )	(15,255 )	(6,024 )
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>			
Proceeds from issuance of common stock	16,175	5,585	8,115
Proceeds from payment on stockholders' notes receivable			17
Repurchase of common stock			(1 )
Proceeds from line of credit	15,000		
Payments on line of credit	(3,500 )	(1,667 )	(1,667 )
Payments on capital lease obligations		(182 )	(322 )
Net cash provided by financing activities	27,675	3,736	6,142
Net increase (decrease) in cash and cash equivalents	(19,106 )	4,560	24,720
Cash and cash equivalents, beginning of year	74,219	69,659	44,939
Cash and cash equivalents, end of year	\$ 55,113	\$ 74,219	\$ 69,659

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

**ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**Note 1. Summary of Significant Accounting Policies**

*Business Description*

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

*Basis of presentation and preparation*

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

*Use of estimates and reclassifications*

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

Certain reclassifications have been made to prior period reported amounts to conform to the current year presentation.

*Fair value of financial instruments*

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

*Cash equivalents and marketable securities*

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

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

*Restricted cash*

The Company's restricted cash as of December 31, 2006 and 2005 were \$0.1 million and \$0.2 million, respectively, primarily comprised of security against a leasing arrangement in Europe.

*Foreign currency*

The Company analyzes the functional currency determination for its international subsidiaries on an annual basis, or more often if necessary. For the years ended December 31, 2006, 2005 and 2004, the Company and its subsidiaries use the U.S. dollar as its functional currency. Assets and liabilities denominated in foreign currencies are remeasured into U.S. dollars at current exchange rates for monetary assets and liabilities, and historical exchange rates for non-monetary assets and liabilities. Revenues and expenses are remeasured at average exchange rates in effect during each period. Gains or losses from foreign currency remeasurement are included in other income (expense). For the years ended December 31, 2006, 2005 and 2004, the Company included in other income (expense) a gain of \$1.1 million, a loss of \$1.0 million and a gain of \$0.3 million, respectively.

*Certain risks and uncertainties*

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

Financial instruments which potentially expose the Company to concentrations of credit risk consist primarily of cash equivalents and accounts receivable. The Company invests excess cash primarily in money market funds of major financial institutions, commercial paper and notes. The Company provides credit to customers in the normal course of business. Collateral is not required for accounts receivable, but ongoing evaluations of customers' credit worthiness are performed. The Company maintains reserves for potential credit losses and such losses have been within management's expectations. No individual customer accounted for 10% or more of the Company's accounts receivable at December 31, 2006 and 2005, or net revenues in fiscal 2006, 2005 and 2004.

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

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

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

### *Inventories*

Inventories are valued at standard cost, which approximates actual cost computed on a first-in, first-out basis, not in excess of market value.

### *Property and equipment*

Property and equipment are stated at historical cost less accumulated depreciation and amortization. Depreciation and amortization are computed using the straight-line method over the estimated useful lives of the assets. Upon sale or retirement, the asset's cost and related accumulated depreciation are removed from the general ledger and any related gain or loss is reflected in operations. Maintenance and repairs are charged to operations as incurred.

### *Development costs for internal use software*

Costs relating to internal use software are accounted for in accordance with the provisions of Statement of Position 98-1, Accounting for the Costs of Computer Software Developed or Obtained for Internal Use (SOP 98-1). In 2004, the Company implemented a new version of its enterprise resource planning system and new software for the Company's manufacturing execution system and capitalized approximately \$3.2 million in related internal use software costs. As of December 31, 2006, and 2005, capitalized internal use software at cost was \$4.7 million and \$4.4 million, respectively. The associated accumulated amortization was \$3.5 million and \$2.2 million as of December 31, 2006 and 2005, respectively. Capitalized software costs are amortized over the estimated useful lives of the software, which generally range from three to five years.

### *Acquisition*

In January 2005, the Company acquired all the membership interests of privately held General Orthodontics, LLC ( GO ). The acquisition was accounted for as a purchase and accordingly, the operating results of GO have been included in the consolidated financial statements since date of acquisition. *See Note 5 Acquisitions of the Notes to Consolidated Financial Statements for more information.*

### *Goodwill*

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

### *Long-lived assets, including finite lived purchased intangible assets*

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

The Company regularly monitors events and changes in circumstances that could indicate if the carrying values of long-lived assets, including intangible assets, may not be recoverable. When such events or changes in circumstances occur, the Company assesses the recoverability of long-lived assets by determining whether the carrying value of such assets will be recovered through future net undiscounted cash flows. If such assets are considered to be impaired, the impairment to be recognized is measured by

the amount by which the carrying amount of the assets exceeds the fair value, as measured by the discounted future cash flows.

#### *Product Warranty*

The Company warrants its products against material defects until the Invisalign case is completed. The Company accrues for estimated warranty in costs of goods sold upon 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. The Company regularly reviews the accrued balances and updates these balances based on historical warranty cost trends. Actual warranty costs incurred have not materially differed from those accrued.

#### *Allowance for Doubtful Accounts*

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

#### *Revenue Recognition*

Align recognizes revenue in accordance with SEC Staff Accounting Bulletin No. 104 Revenue Recognition ( SAB 104 ), and Emerging Issues Task Force No. 00-21 Revenue Arrangements with Multiple Deliverables ( EITF 00-21 ). SAB 104 requires that four basic criteria must be met before revenue can be recognized: persuasive evidence of an arrangement exists, delivery has occurred, the price is fixed or determinable, and collectibility is reasonably assured. Determination of whether persuasive evidence of an arrangement exists and whether delivery has occurred or services rendered involve management's judgments based on whether the fee is fixed or determinable based on the payment terms associated with the transaction and whether the sales price is subject to refund or adjustment.

Revenue from product sales, net of discounts and rebates, is recognized upon shipment. Service revenues related to the training of dental professionals and staff on the Invisalign treatment process, and case consultations are recorded when the services are completed.

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



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

#### *Shipping and Handling Costs*

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

#### *Research and development*

Research and development costs are expensed as incurred.

#### *Advertising costs*

The cost of advertising and media is expensed as incurred. For the years ended December 31, 2006, 2005 and 2004 advertising costs totaled \$9.2 million, \$11.3 million and \$6.3 million respectively.

#### *Income taxes*

We estimate our income taxes based on the various jurisdictions where we conduct business. Significant judgment is required in determining our income tax provision. Deferred tax assets and liabilities are recognized for differing treatments of certain items for tax and accounting purposes. These differences result in deferred tax assets and liabilities. 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.

#### *Stock-based compensation*

Effective January 1, 2006, the Company adopted Statement of Financial Accounting Standards ( FAS 123 ) No. 123 (Revised 2004), Share-Based Payment ( FAS 123R ), which requires the measurement and recognition of compensation expense for all stock-based payment awards made to employees and directors, including stock options, restricted stock units and employee stock purchases related to the Employee Stock Purchase Plan based on estimated fair values of these awards over the requisite employee service period. FAS 123R supersedes Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees ( APB 25 ), which the Company previously followed in accounting for stock-based awards. In March 2005, the SEC issued Staff Accounting Bulletin No. 107 ( SAB 107 ) to provide guidance on FAS 123R. The Company has applied SAB 107 in its adoption of FAS 123R.

Under the provisions of FAS 123R, the Company adopted the modified prospective transition method which requires stock-based compensation cost to be recognized for share-based payments awards granted to, but not yet vested as of, December 31, 2005 based on the grant date fair value estimated in accordance with the pro forma provisions of FASB Statement 123, Accounting for Stock-Based Compensation ( FAS 123 ) and stock-based payment awards granted subsequent to December 31, 2005 based on the grant date fair value estimated in accordance with the provisions of FAS 123R. In accordance with the modified prospective transition method, the Company's Consolidated Financial Statements as of and for the year ended December 31, 2006 reflects the impact of FAS 123R, and prior periods have not been restated to reflect, and do not include the impact of FAS 123R. In conjunction with the adoption of FAS 123R, the Company changed its method of attributing the value of stock-based compensation from accelerated multiple-option approach to the straight-line single method.

In November 2005, the Financial Accounting Standards Board ( FASB ) issued FASB Staff Position No. FAS 123(R)-3, Transition Election Related to Accounting for Tax Effects of Share-Based Payment Awards ( FSP 123R-3 ). The Company has elected to adopt the alternative transition method provided in

the FSP 123R-3 that includes simplified methods to establish the beginning balance of the additional paid-in capital pool related to the tax effect of stock-based compensation and to determine the subsequent impact on the additional paid-in capital pool and the Consolidated Statement of Cash Flows for stock-based compensation awards that are outstanding upon the adoption of FAS 123R. *See Note 10 Shareholders' Equity of the Notes to Consolidated Financial Statements for more information.*

*Comprehensive Income (loss)*

Comprehensive income (loss), as defined, includes all changes in equity (net assets) during a period from non-owner sources. Net profit (loss) and other comprehensive (loss), including unrealized gains and losses on short-term investments, are reported, net of their related tax effect.

*Recent Accounting Pronouncements*

In July 2006, the FASB issued FASB Interpretation (FIN) No. 48, *Accounting for Uncertainty in Income Taxes*, an interpretation of FASB Statement 109. FIN 48 prescribes a comprehensive model for recognizing, measuring, presenting and disclosing in the financial statements tax positions taken or expected to be taken on a tax return, including a decision whether to file or not to file in a particular jurisdiction. FIN 48 is effective for fiscal years beginning after December 15, 2006. If there are changes in net assets as a result of application of FIN 48, these will be accounted for as an adjustment to retained earnings. The Company does not expect that the adoption of FIN 48 will have a material impact on its results from operations or consolidated financial position.

In September 2006, the SEC staff issued Staff Accounting Bulletin (SAB) 108, *Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements* (SAB 108). SAB 108 requires that public companies utilize a dual-approach to assessing the quantitative effects of financial misstatements. This dual approach includes both an income statement focused assessment and a balance sheet focused assessment. The guidance in SAB 108 must be applied to annual financial statements for fiscal years ending after November 15, 2006. The adoption of SAB 108 did not have a material impact on its results from operations or consolidated financial position.

In September 2006, the FASB issued FASB Statement No. 157, *Fair Value Measurements*, which defines fair value, establishes a framework for measuring fair value under GAAP, and expands disclosures about fair value measurements. FASB Statement No. 157 applies to other accounting pronouncements that require or permit fair value measurements. The new guidance is effective for financial statements issued for fiscal years beginning after November 15, 2007, and for interim periods within those fiscal years. The Company is currently evaluating the potential impact, if any, of the adoption of FASB Statement No. 157 on its consolidated financial position, results of operations and cash flows.

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

**Note 2. Patients First Program and settlement costs**

On October 13, 2006, the Company entered into a formal agreement with OrthoClear, Inc., OrthoClear Holdings, Inc., and OrthoClear Pakistan Pvt. Ltd. ( OrthoClear ), together with certain individuals associated with OrthoClear (the OrthoClear Agreement ) to end all pending litigation between the parties. In addition, OrthoClear agreed, among other things, to stop accepting new patient cases for treatment, consent to the entry of an exclusion order by the ITC prohibiting the importation of OrthoClear aligners into the United States, assign and transfer to Align all intellectual property rights with application to the correction of malocclusion and discontinue all design, manufacture, marketing and sales of removable dental aligners worldwide. In addition, certain OrthoClear principles also signed five year non-compete agreements. *See Note 7 Legal Proceedings of the Notes to Consolidated Financial Statements for a more complete summary of the OrthoClear Agreement.* The Company evaluated this transaction under the provisions of Emerging Issues Task Force 98-3 Determining Whether a Non-Monetary Transaction Involves a Receipt of Productive Assets or of a Business (EITF 98-3) and concluded that this transaction is not a business acquisition and will be accounted for as an asset purchase.

In accordance with the terms of the OrthoClear Agreement, the Company made a \$20.0 million one-time cash payment to OrthoClear Holdings, Inc. on October 16, 2006. The Company engaged a third-party firm to assist management in assessing the fair value of the identifiable assets received in conjunction with the OrthoClear Agreement. Using an income valuation approach, it was determined that \$14.0 million represented the fair value of the non-compete agreements, which are being amortized over the estimated useful life of 5 years. The intellectual property transferred to Align was determined not to have any alternative future use and therefore had no fair value. In accordance with Emerging Issues Task Force 04-01 Accounting for Pre-existing Contractual Relationships between the Parties to a Purchase Business Combination (EITF 04-01), the remaining \$6.0 million of the \$20.0 million payment was recorded as settlement costs.

As part of the OrthoClear Agreement, OrthoClear agreed to stop the importation of aligners into the United States and discontinue all aligner business operations worldwide. As a result, most OrthoClear patients were unable to complete their orthodontic treatment with OrthoClear. In an attempt to help minimize treatment disruptions for the OrthoClear patients and their doctors, the Company committed to make treatment available to these patients at no additional cost under the Patients First Program . Therefore, Align will receive no revenue for the program, while incurring significant expense. In the fourth quarter of 2006, the Company recorded a \$8.3 million charge for the anticipated costs of completing the Patients First Program in accordance with FASB Statement 5, Accounting for Contingencies ( FAS 5 ). This amount is based on the number of OrthoClear cases registered under the Patients First Program as of December 31, 2006 and the estimated costs that will be incurred in order to fulfill the obligation as a result of this program. If the actual number of OrthoClear cases under the program changes or the actual- costs differ significantly from our estimates, Align would be required to adjust the accrual for the Patients First Program, and it could materially impact the financial statements. As December 31, 2006, \$6.8 million remained in accrued liabilities for this program. Align currently anticipates that the Patients First Program will be completed by the end of the second quarter of fiscal 2007.

### Note 3. Short-term Investments

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

	Amortized Costs	Gross Unrealized Gains	Gross Unrealized Loss	Fair Value
U.S. Government notes and bonds	\$ 4,880	\$ 2	\$	\$ 4,882
Corporate bonds	2,951			2,951
Commercial paper and asset-backed securities	1,098			1,098
Total:	\$ 8,929	\$ 2	\$	\$ 8,931

As of December 31, 2006, all short-term investments have maturity dates less than one year. For the years ended December 31, 2006 and 2005, no gains were realized on the sale of short-term investments. The Company had no short-term investments as of December 31, 2005.

### Note 4. Balance Sheet Components

Inventories consist of the following (in thousands):

	December 31, 2006	2005
Raw materials	\$ 2,021	\$ 1,492
Work in process	763	1,060
Finished goods	306	378
	\$ 3,090	\$ 2,930

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

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

	Useful Life (in years)	December 31, 2006	2005
Clinical and manufacturing equipment	5	\$ 39,741	\$ 28,298
Computer hardware	3	10,404	9,352
Computer software	3	7,719	6,498
Furniture and fixtures	7	4,835	4,698
Leasehold improvements	Term of the lease	9,197	8,443
Construction in progress		1,987	8,387
		\$ 73,883	\$ 65,676
Less: Accumulated depreciation and amortization		(46,979 )	(39,249 )
		\$ 26,904	\$ 26,427

As of December 31, 2006, construction in progress consisted primarily of costs for capital equipment expected to be placed in service in the next year.

Depreciation expense and amortization was \$9.3 million, \$10.1 million, and \$9.6 million for the years ended December 31, 2006, 2005 and 2004, respectively.

## Edgar Filing: ALIGN TECHNOLOGY INC - Form 10-K

Accrued liabilities consist of the following (in thousands):

	December 31, 2006	2005
Accrued payroll and benefits	\$ 17,768	\$ 12,330
Accrued Patients First Program costs	6,800	
Accrued sales rebate	3,895	1,409
Accrued loss		2,681
Accrued warranty	2,094	1,998
Other	9,750	10,954
	\$ 40,307	\$ 29,372

Warranty accrual during the years ended December 31, 2006 and 2005 consists of the following activity (in thousands):

Warranty accrual, December 31, 2004	\$ 1,616
Charged to costs and expenses	2,699
Actual warranty expenditures	(2,317 )
Warranty accrual, December 31, 2005	\$ 1,998
Charged to costs and expenses	2,694
Actual warranty expenditures	(2,598 )
Warranty accrual, December 31, 2006	\$ 2,094

### Note 5. Acquisitions

In January 2005, the Company acquired all of the membership interests of privately held General Orthodontics, LLC ( GO ). GO is the sole premier provider of consulting and education services to general practitioner dentists ( GP ) and orthodontists using the Invisalign orthodontic appliance. Upon the integration of GO, Align included GO's consulting services in its clinical education and training programs under the name of Invisalign Consulting Services. The consolidated financial statements include the operating results of GO from the date of acquisition.

The purchase price of \$1.3 million was accounted for as a business combination and allocated to the acquired assets, goodwill and other identified intangibles, as follows (in thousands):

Fair value of net liabilities assumed	\$ (174 )
Identified intangible assets acquired:	
Consultant relationships	980
Other	55
Goodwill	478
Total	\$ 1,339

The valuation of the consultant relationships represent the fair value of consultant services which include direct consulting services to GO's customers on the use of the Invisalign technology and training of GP dentists and orthodontists at the Company's certification training sessions. Consultant relationships and other intangible assets are being amortized on a straight-line basis over the estimated useful life of three years.

In accordance with the Membership Interest Purchase Agreement, the Company agreed to contingent earn-outs of up to \$1.0 million payable to certain former holders of GO membership interests upon the achievement of milestones defined in the agreement. These contingent payments were accrued on a

straight-line basis based on the estimated completion dates. The Company paid \$0.5 million related to milestone completion in July 2005, and the remaining \$0.5 million in April 2006.

In conjunction with the GO acquisition, the Company recorded \$0.5 million of goodwill, which represents the difference between the purchase price and the fair value of the acquired net assets and the identified intangible assets. As required by FASB Statement 142, *Goodwill and Other Intangible Assets* (FAS 142), the Company performs its annual impairment test in the fourth quarter of the fiscal year, or more frequently if indicators of potential impairment exist, to determine if the recorded goodwill is impaired. In performing this assessment, Align compared the fair value of its single business segment to its carrying value, and determined that no goodwill impairment existed as of December 31, 2006.

#### Note 6. Intangible Assets

The following is a summary of the Company's purchased intangible assets as of December 31, 2006 and 2005 (in thousands):

		December 31, 2006			December 31, 2005		
	Estimated Useful Life (in years)	Gross Carrying Value	Accumulated Amortization	Net Carrying Value	Gross Carrying Value	Accumulated Amortization	Net Carrying Value
Non-compete agreements	5	\$ 14,000	\$ 612	\$ 13,388	\$	\$	\$
Consultant relationships	3	980	626	354	980	299	681
Patent	5	180	117	63	180	81	99
Other	3	55	36	19	55	17	38
Total		\$ 15,215	\$ 1,391	\$ 13,824	\$ 1,215	\$ 397	\$ 818

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

Consultant relationships and other intangible assets represent the fair value of intangible assets acquired as the result of the GO acquisition in 2005. Consultant relationships and other intangible assets are being amortized on a straight-line basis over the estimated useful life of three years. *See Note 5 Acquisitions of the Notes to Consolidated Financial Statements for additional information.*

The Company performs an impairment test whenever events or changes in circumstances indicate that the carrying value of such assets may not be recoverable. Examples of such events or circumstances include significant underperformance relative to historical or projected future operating results, significant changes in the manner of use of acquired assets or the strategy for its business, significant negative industry or economic trends, and/or a significant decline in our stock price for a sustained period. Impairments are recognized based on the difference between the fair value of the asset and its carrying value, and fair value is generally measured based on discounted cash flow analyses. No intangible asset impairment was recorded for the periods presented.

For the years ended December 31, 2006, 2005 and 2004, total amortization expense for intangible assets was \$1.0 million, \$0.4 million and \$36,000, respectively. The total estimated annual future amortization expense for these intangible assets is as follows (in thousands):

<b>Fiscal Year</b>	
2007	\$ 3,181
2008	2,856
2009	2,800
2010	2,800
2011 and thereafter	2,187
Total	\$ 13,824

## Note 7. Legal Proceedings

### *OrthoClear*

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

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

**Patent Infringement ITC Complaint.** On January 11, 2006, the Company 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 certain patents of the Company.

**Patent Infringement Federal Action.** On January 11, 2006, the Company filed a federal court patent infringement action against OrthoClear in the Western District of Wisconsin (Madison) (the *Patent Infringement Federal Action*) asserting infringement of certain patents of the Company.

### *OrthoClear Agreement*

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

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





- OrthoClear consented to the entry of an exclusion order by the ITC, enforced by the United States Customs Service, which prevents OrthoClear from importing its dental aligner products into the U.S., either directly or through a third party and the ITC subsequently terminated the ITC action on October 27, 2006;
- The parties agreed to dismiss all pending lawsuits against each other, including the State Case, Federal Lanham Action I, Federal Lanham Action II, Patent Infringement Federal Action, with prejudice, and each such action has been subsequently dismissed;
- OrthoClear agreed to stop accepting new patient cases for treatment;
- OrthoClear and Muhammad Ziaullah Chishti its CEO, and Charles Wen, its President, transferred and assigned to Align all intellectual property rights with application to the treatment of malocclusion;
- OrthoClear principals Muhammad Ziaullah Chishti, Charles Wen, Peter Riepenhausen, and Christopher Kawaja signed 5-year, global non-compete agreements in the field of removable aligner therapy products and related software market;
- OrthoClear employees Joe Breeland and Jeff Tunnell signed 5-year U.S. non-compete agreements prohibiting their personal participation in the removable aligner therapy product and related software market;
- The Company made Invisalign treatment available to OrthoClear patients in the United States, Canada and Hong Kong at no charge from Align. The Company implemented this program as the Patients First Program.

In accordance with the terms of the OrthoClear Agreement, on October 16, 2006, the Company made a one-time cash payment of \$20.0 million to OrthoClear Holdings, Inc. *See Note 2 Patients First Programs and settlement costs of the Notes to Consolidated Financial Statements for discussion on Patients First Program.*

#### ***Ormco***

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

On February 1, 2006, the Company entered into a settlement agreement (the Settlement Agreement) with Ormco and AOA. In accordance with the terms of the Settlement Agreement, Ormco and AOA paid into escrow, pending the completion of the appellate process, \$884,000 to resolve the issues of past damages, willfulness and attorneys' fees for the adjudged infringement of two of the Company's patents (the Align Patents) through the manufacture and sale of Ormco's and AOA's Red, White & Blue appliances. The Company's receipt of the payments out of escrow is contingent upon the Court, in a final, non-appealable judgment, finding that Ormco or AOA infringes at least one of the claims

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

There have been two appeals. After the Permanent injunction was entered, Ormco and AOA appealed that injunction and the orders of the District Court on summary judgment on which that order was based. Oral argument took place on April 3, 2006. Following oral argument, the U.S. Court of Appeals for the Federal Circuit (CAFC) issued a ruling declaring two out of a total of seventy-one claims in our US Patent No. 6,398,548 and four out of a total of ten claims in US Patent No. 6,544,611 to be invalid as obvious. The CAFC's decision reverses the California District Court summary judgment order of validity.

The second appeal is from the final judgment. Once final judgment was entered, Ormco filed a Notice of Appeal from the final judgment and the Company filed a notice of cross-appeal. Ormco has appealed the ruling of the District Court that its patents are not infringed by the Company and that the asserted claims are invalid. The Company appealed the ruling of the District Court that certain claims of its 6,398,548 patent which were found to be infringed by Ormco's and AOA's Red, White & Blue appliances were invalid. Briefing on this appeal and cross-appeal is complete, and oral argument occurred on February 6, 2007.

### ***Bay Materials***

On July 25, 2005, Bay Materials, LLC (Bay) filed suit against the Company in the Superior Court of the State of California for the County of San Mateo. The complaint, as amended, asserts, among other things, breach of contract, promissory estoppel and fraud. Bay alleges that we breached the terms of a purchase order by failing to pay for unshipped goods manufactured by Bay pursuant to such order. Bay further alleges that the Company promised to purchase from Bay an alternative polyurethane product, and Bay relied on this representation to develop such an alternative product which the Company 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. On March 27, 2006, the Company filed its answer to Bay's amended complaint, and also filed a cross-complaint against Bay for breach of contract, breach of implied warranty of fitness, intentional misrepresentation, concealment, specific performance, unjust enrichment and unfair business practices. The cross-complaint seeks monetary damages against Bay exceeding \$1.0 million. In the fourth quarter of 2006, the parties agreed to settle their dispute and dismiss all claims and cross-claims against each other in exchange for a one time payment by the Company to Bay in the amount of \$750,000.

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

**Note 8. Credit Facilities**

In December 2005, the Company renegotiated and amended its existing revolving line of credit to increase the available borrowings under the then existing revolving line of credit to \$20 million. Included in the 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. The Company 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 credit facility matures on December 16, 2007, at which time all outstanding borrowings must be repaid. The 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. In December 2006, the Company amended its credit agreement whereby the only financial covenant for the fourth quarter of 2006 was a certain minimum cash balance. As of December 31, 2006, the Company is in compliance with the financial covenants of this credit facility.

During the third quarter of 2006, the Company borrowed \$15.0 million against this credit facility and made a \$20.0 million one-time payment to OrthoClear Holdings, Inc in accordance with the terms of the OrthoClear Agreement. The Company elected LIBOR plus two percent as its interest rate of 7.29% as of December 31, 2006. The Company repaid \$3.5 million of this borrowing in the fourth quarter of 2006, therefore the outstanding balance as of December 31, 2006 was \$11.5 million.

On March 7, 2007, the Company renegotiated and amended its existing credit facility with Comerica Bank. The amendment, among other things, will reduce financial covenants to require only a quick ratio covenant. Additionally, the amendment will also increase the available borrowings under the existing revolving line of credit from \$20 million to \$25 million effective January 1, 2008. The amended credit facility matures on December 31, 2008 at which point all outstanding borrowing under this credit facility must be repaid.

**Note 9. Commitments and Contingencies**

*Operating leases*

Align rents its facilities and certain equipment and automobiles under non-cancelable operating lease arrangements. Facility leases expire at various dates through 2014 and provide for pre-negotiated fixed rental rates during the terms of the lease.

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

In June 2004, the Company's European headquarters signed a lease agreement for a facility in Amsterdam, The Netherlands. This lease expires in 2014 with an option to cancel in 2009 with a lease termination fee of approximately \$238,000. The Company anticipates it will cancel this lease in 2009 and is accruing for the termination fee on a straight line basis.

The Company recognizes rent expense on a straight-line basis over the lease period, and has accrued for rent expense incurred but not paid. Total rent expense was \$3.8 million, \$4.3 million and, \$4.9 million for the years ended December 31, 2006, 2005 and 2004, respectively.

## Edgar Filing: ALIGN TECHNOLOGY INC - Form 10-K

Minimum future lease payments for non-cancelable leases as of December 31, 2006, are as follow (in thousands):

Years Ending December 31,	
2007	\$ 3,261
2008	2,268
2009	1,423
2010	467
2011	
Thereafter	
Total	\$ 7,419

### Note 10. Stockholders Equity

#### *Preferred Stock*

As of December 31, 2006, the Company has authorized 5,000,000 shares of preferred stock, \$0.0001 par value, none of which was issued and outstanding. Pursuant to the Certificate of Designation of Rights and Privileges of Series A Participating Preferred Stock filed on October 26, 2005, 200,000 shares of such preferred stock have been designated as Series A Participating Preferred Stock.

#### *Preferred Stock Rights Agreement*

On October 25, 2005, pursuant to a Preferred Stock Rights Agreement (the "Rights Agreement") between the Company and EquiServe Trust Company (now Computershare Limited), as the Rights Agent, the Company's Board of Directors declared a dividend of one right (a "Right") to purchase one one-thousandth share of the Company's Series A Participating Preferred Stock ("Series A Preferred") for each outstanding share of common stock, par value \$0.0001 per share of the Company. The dividend was paid on November 22, 2005 to stockholders of record as of the close of business on that date. Each Right entitles the registered holder, subject to the terms of the Rights Agreement, to purchase from the Company one one-thousandth of a share of Series A Preferred at an exercise price of \$37.00, subject to adjustment. The Rights will be separate from the shares of Common Stock. Rights Certificates will be issued and the Rights will become exercisable upon the earlier of (a) the tenth business day (or such later date as may be determined by the Company's Board of Directors) after a public announcement that a person or group of affiliated or associated persons ("Acquiring Person") has acquired beneficial ownership of 15% or more of the shares of Common Stock then outstanding, or (b) the tenth business day (or such later date as may be determined by the Company's Board of Directors) after a person or group announces a tender or exchange offer, the consummation of which would result in ownership by a person or group of 15% or more of the Company's then outstanding shares of Common Stock. An Acquiring Person does not include certain persons specified in the Rights Agreement. The Rights will expire on the earliest of (i) November 22, 2015, or (ii) redemption or exchange of the Rights as described below. As of December 31, 2006, no rights were exercised.

#### *Common Stock*

The holders of common stock are entitled to receive dividends whenever funds are legally available and when and if declared by the Board of Directors. The Company has not declared or paid any dividends as of December 31, 2006.

#### *Employee Stock Purchase Plan*

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

During the year ended December 31, 2006, 462,404 shares were issued under the Purchase Plan. As of December 31, 2006, the Company had reserved 8,933,456 shares of common stock for future issuance and 7,272,388 shares remain available for future issuance.

As of December 31, 2006, there was \$0.5 million of total unamortized compensation costs related to employee stock purchases. These costs are expected to be recognized over a weighted average period of 0.3 years.

#### *Stock Option Plans*

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

Starting in the first quarter of 2006, the Compensation Committee of the Board of Directors approved the grant of restricted stock units (contracts that give the recipients the right to receive shares as the units vest) to its employees and director(s) in addition to stock options. Each restricted stock unit award generally vests over 4 years with 25% on the one year anniversary of the date of grant and 6.25% vesting quarterly thereafter. Any grants of restricted stock units will reduce shares available for grant at a 2:1 ratio.

The 2005 Plan has 9,983,379 shares of the Company's common stock reserved for issuance, plus up to an aggregate of 5,000,000 shares that are or would have been returned to the 2001 Plan as a result of termination of outstanding options or repurchase of shares granted under the 2001 Plan on or after March 28, 2005. As of December 31, 2006, 2,084,687 shares have been transferred to the 2005 Plan. As of December 31, 2006, 7,904,506 shares remain available for issuance under the 2005 Plan.

#### *Executive Grants*

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

# Edgar Filing: ALIGN TECHNOLOGY INC - Form 10-K

Activity for the years ended December 31, 2005 and 2004 under the stock option and executive grant plans are set forth below (in thousands, except per share data):

	Year Ended December 31, 2005		Year Ended December 31, 2004	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Outstanding at beginning of year	9,050	\$ 10.35	8,767	\$ 7.03
Granted	5,593	7.35	2,446	17.85
Exercised	(830 )	4.04	(1,695 )	3.79
Repurchased				1.07
Cancelled	(1,506 )	11.50	(468 )	11.13
Expired	(1,003 )	15.00		
Outstanding at end of year	11,304	\$ 8.76	9,050	\$ 10.35

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

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding at December 31, 2005	11,304	\$ 8.76		
Granted	1,794	8.74		
Cancelled or expired	(1,603 )	12.37		
Exercised	(2,317 )	5.87		
Outstanding at December 31, 2006	9,178	\$ 8.86	7.5	\$ 53,160
Ending vested and expected to vest at December 31, 2006	8,847	\$ 8.88	7.4	\$ 51,217
Exercisable at December 31, 2006	6,436	\$ 9.12	6.9	\$ 37,139

The aggregate intrinsic value in the table above represents the total pretax intrinsic value (the difference between Align's closing stock price on the last trading day of fiscal 2006 of \$13.97 and the exercise price, multiplied by the number of in-the-money options) that would have been received by the option holders had all option holders exercised their options on December 31, 2006. This amount changes based on the fair market value of Align's stock.

The total intrinsic value of stock options exercised for the years ended December 31, 2006 and 2005 were \$13.2 million, and \$ 3.3 million, respectively. As of December 31, 2006, there was \$10.0 million of total unamortized compensation costs related to stock options. These costs are expected to be recognized over a weighted average period of 2.5 years. For the year ended December 31, 2006, total recognized tax benefit from exercised options was immaterial.

## Edgar Filing: ALIGN TECHNOLOGY INC - Form 10-K

The options outstanding and currently exercisable by exercise price at December 31, 2006 are as follows (in thousands, except per share data):

Range of Exercise Prices	Options Outstanding			Options Exercisable		
	Shares	Weighted Average Remaining Years	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price	
\$ 0.05 4.95	1,259,157	4.7	\$ 3.70	1,256,444	\$ 3.70	
5.30 6.15	1,021,906	6.4	5.96	836,389	5.95	
6.47 6.95	1,070,047	8.8	6.68	274,826	6.67	
6.98 7.25	285,000	9.0	7.10	145,000	7.23	
7.35 7.35	1,161,679	8.2	7.35	1,121,679	7.35	
7.40 8.33	996,597	8.2	7.81	878,764	7.76	
8.38 8.38	1,089,463	9.1	8.38			
8.39 16.51	1,035,967	7.7	11.82	726,546	11.88	
\$ 16.93 22.43	1,258,350	7.0	18.81	1,196,787	18.82	
	9,178,166	7.5	\$ 8.86	6,436,435	\$ 9.12	

### *Restricted Stock Units*

Starting in the first quarter of 2006, the Company began granting restricted stock units that generally vest over 4 years with 25% vesting on the one year anniversary of the date of grant and 6.25% vesting quarterly thereafter. The fair value of each award is based on the Company's closing stock price on the date of grant. As of December 31, 2006, the total fair value of vested restricted stock awards was zero. A summary of the nonvested shares for the year ended December 31, 2006 is as follows:

	Shares (in thousands)	Weighted Average Grant Date Fair Value
Nonvested as of December 31, 2005	\$	\$
Granted	442	8.69
Vested		
Forfeited	(23 )	8.22
Nonvested as of December 31, 2006	\$ 419	\$ 8.71

As of December 31, 2006, there was \$2.7 million of total unamortized compensation costs related to restricted stock units. These costs are expected to be recognized over a weighted average period of 3.2 years.

### *Stock-based compensation*

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

### Valuation assumptions

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

	The Years Ended December 31,					
	2006		2005		2004	
<b>Stock Options:</b>						
Expected term (in years)	5.0		4.5		5.0	
Expected volatility	76.2	%	85.3	%	55.9	%
Risk-free interest rate	4.6	%	4.1	%	3.4	%
Expected dividend						
Weighted average fair value at grant date	\$ 5.67		\$ 4.80		\$ 9.17	
<b>Employee Stock Purchase Plan:</b>						
Expected term (in years)	1.3		1.2		2.0	
Expected volatility	48.2	%	62.0	%	55.3	%
Risk-free interest rate	5.0	%	3.8	%	1.8	%
Expected dividend						
Weighted average fair value at grant date	\$ 2.69		\$ 3.12		\$ 7.17	

The expected term of stock options represents the weighted-average period the stock options are expected to remain outstanding. Upon the adoption of FAS 123R, the Company used a midpoint model to determine the expected term of stock options based on the Company's historical exercise and post vesting cancellation experience, and the remaining contractual life of its outstanding options.

The increase in expected life assumption used in the Black-Scholes option pricing for the year ended December 31, 2006 compared to the year ended December 31, 2005, is the result of granting options with shorter vesting in 2005.

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

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

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

### Summary of Stock-based Compensation Expense

Stock-based compensation expense recognized in the Consolidated Statements of Operations for the year ended December 31, 2006 is based on awards ultimately expected to vest and has been reduced for estimated forfeitures. FAS 123R requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Forfeitures were estimated based on historical experience. In the Company's pro forma information required under FAS 123 for periods prior to fiscal 2006, the Company accounted for forfeitures as they occurred. The following



## Edgar Filing: ALIGN TECHNOLOGY INC - Form 10-K

table summarizes stock-based compensation expense related to all of the Company's stock-based awards and employee stock purchases under FAS 123R for the year ended December 31, 2006:

(In thousands, except per share amounts)	For the Year Ended December 31, 2006
Cost of revenues	\$ 700
Sales and marketing	2,862
General and administrative	4,054
Research and development	1,294
Total share-based compensation	\$ 8,910

In connection with the grant of stock options prior to Align's initial public offering (IPO) in 2001 and certain grants subsequent to the IPO, the Company recorded deferred stock compensation and amortized stock-based compensation expense over the option vesting period of four years using the straight-line method. The Company had fully amortized the deferred stock-based compensation balance as of December 31, 2004. Align recorded \$5.1 million in amortization of deferred stock-based compensation during fiscal 2004. If the employee terminated employment, which resulted in the cancellation of any unvested options, the Company reversed the unamortized deferred stock-based compensation related to those options. Align reversed \$0.1 million of unrecognized deferred compensation for terminated employees during fiscal 2004.

For options granted to non-employees, the Company recorded stock-based compensation expense of \$45,000 and \$0.4 million for the fiscal years of 2005 and 2004, respectively.

During fiscal 2005 and 2004, the Company accelerated the vesting of options to several employees in connection with related severance packages. In accordance with FASB Interpretation No. 44 Accounting for Certain Transactions Involving Stock Compensation (FIN 44), the acceleration charges were measured based on the intrinsic value method, which is the difference between the market value of common stock at the acceleration date and the exercise price of the option. Acceleration charges for December 31, 2005 and 2004 were \$67,000 and \$0.4 million, respectively.

Stock based compensation expense for the years ended December 31, 2005 and 2004 are as follows (in thousands):

	Years Ended December 31,	
	2005	2004
Cost of revenues	\$	\$ 894
Sales and marketing	22	651
General and administrative	90	2,736
Research and development		1,586
	\$ 112	\$ 5,867

### *Option Acceleration*

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

future compensation expense the Company would otherwise recognize in its statement of operations with respect to these accelerated options upon the adoption of FAS 123R.

*Pro Forma Information Under FAS 123 for Periods Prior to Fiscal 2006*

Prior to January 1, 2006, the Company accounted for stock-based employee compensation using the intrinsic value method under Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees ( APB 25 ) and related interpretations and complied with the disclosure requirements of SFAS 148, Accounting for Stock-Based Compensation Transition and Disclosure an amendment of FASB Statement No. 123. Under the intrinsic method, the difference between the market price on the date of grant and the exercise price is charged to the results of operations over the vesting period. Accordingly, the Company was not required to recognize compensation cost for stock options issued to its employees or shares issued under the Purchase Plan because options were issued at market price on the date of grant.

FAS 123R requires the Company to present pro forma information for the comparative period prior to the adoption as if it had accounted for all of its stock options under the fair value method of FAS 123. The following table illustrates the pro forma information regarding the effect on net earnings and net earnings per share for the year ended December 31, 2005 and 2004 as if the Company had accounted for the stock-based employee compensation under the fair value method of accounting:

(In thousands, except per share amounts)	Years Ended December 31,	
	2005	2004
Net profit, as reported	\$ 1,413	\$ 8,768
Add: Stock-based employee compensation expense included in reported net earnings under APB No. 25, net of related tax effects	70	5,956
Deduct: Total stock-based employee compensation determined under the fair value method for all awards, net of related tax effects	(40,342 )	(17,933 )
Pro forma net loss	\$ (38,859 )	\$ (3,209 )
Basic net profit (loss) per share:		
As reported	\$ 0.02	\$ 0.15
Pro forma	\$ (0.63 )	\$ (0.05 )
Diluted net earnings (loss) per share:		
As reported	\$ (0.02 )	\$ 0.14
Pro forma	\$ (0.63 )	\$ (0.05 )

**Note 11. Employee Benefit Plan**

In January 1999, the Company adopted a defined contribution retirement plan under Section 401(k) of the Internal Revenue Code. This plan covers substantially all employees who meet minimum age and service requirements and allows participants to defer a portion of their annual compensation on a pre-tax basis. Company contributions to the plan may be made at the discretion of the Board of Directors. There have been no contributions by the Company since the inception of the plan.

# Note 12. Income Taxes

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

	Years Ended December 31,	
	2006	2005
Deferred tax assets, net:		
Net operating loss carryforwards	\$ 80,008	\$ 73,087
Research and development credit carryforwards	8,026	7,350
Deferred revenue	1,151	1,858
Accruals, allowances & other not currently deductible for tax purposes	12,968	7,693
Deferred tax assets	102,153	89,988
Less: Valuation allowance	(102,153 )	(89,988 )
Net deferred tax asset	\$	\$

The Company has provided a full valuation allowance at December 31, 2006 because Align believes that the net deferred tax assets are unlikely to be realized.

At December 31, 2006, the Company had net operating loss carryforwards of approximately \$214.9 million for federal purposes and \$73.5 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 Company has research credit carryforwards of approximately \$4.0 million for federal purposes and \$5.4 million for California state tax purposes. If not utilized, the federal credit carryforwards will begin to expire in 2017. The California state credit can be carried forward indefinitely.

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

	Years Ended December 31,					
	2006		2005		2004	
U.S. federal statutory income tax rate	35.00	%	35.00	%	34.00	%
State income taxes, net of federal tax benefit	5.15	%	5.14	%	6.00	%
Deferred tax benefits utilized	-21.59	%	-236.81	%	-94.37	%
Foreign losses not benefited	-12.25	%	209.43	%	46.90	%
Impact of differences in foreign tax rates	1.27	%	2.05	%		
Amortization of stock-based compensation	-7.67	%			13.27	%
Non-deductible foreign exchange losses	-0.74	%	16.74	%		
Non-deductible meals & entertainment charges	-1.29	%	14.38	%	2.19	%
Other items not individually material	-0.31	%	2.31	%	2.19	%
	-2.43	%	48.24	%	10.18	%

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

	Years Ended December 31,		
	2006	2005	2004
Federal	\$ (27 )	\$ 505	\$ 282
State	55	221	197
Foreign	800	590	515
Total provision for income taxes	\$ 828	\$ 1,316	\$ 994



### Note 13. Net profit (loss) per share

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

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

	Years Ended December 31,		
	2006	2005	2004
Numerator:			
Net profit (loss)	\$ (34,963 )	\$ 1,413	\$ 8,768
Denominator:			
Weighted-average common shares outstanding	63,246	61,644	60,036
Less: Unvested common shares subject to repurchase			(73 )
Total shares, basic	63,246	61,644	59,963
Effect of dilutive securities:			
Add: Dilutive common stock equivalents		1,508	4,053
Unvested common shares subject to repurchase			73
Total shares, diluted	63,246	63,152	64,089
Net profit (loss) per share, basic	\$ (0.55 )	\$ 0.02	\$ 0.15
Net profit (loss) per share, diluted	\$ (0.55 )	\$ 0.02	\$ 0.14

For the year ended December 31, 2006, 2005 and 2004 stock options and restricted stock units totaling 6.5 million, 6.6 million and 1.3 million, respectively, were excluded from diluted net loss per share because of their anti-dilutive effect.

### Note 14. Supplemental Cash Flow Information

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

	Years Ended December 31,		
	2006	2005	2004
Taxes paid	\$ 992	\$ 1,298	\$ 258
Interest paid	\$ 223	\$ 80	\$ 190
Non-cash investing and financing activities:			
Fixed assets acquired as exchange	\$	\$	\$ 834
Deferred revenue assumed in the GO acquisition	\$	\$ 635	\$
Accrued liabilities assumed in the GO acquisition	\$	\$ 39	\$
Fixed assets acquired with accounts payable or accrued liabilities	\$ 541	\$ 1,112	\$ 45
Deferred stock-based compensation	\$	\$	\$ 130

**Note 15. Segments and Geographical Information***Segment*

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

*Geographical Information*

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

	<b>For the Years Ended December 31,</b>		
	<b>2006</b>	<b>2005</b>	<b>2004</b>
Net revenues:			
Domestic	\$ 172,635	\$ 182,903	\$ 156,837
Europe	28,076	20,750	14,502
Other International	5,643	3,472	1,491
Total net revenues	\$ 206,354	\$ 207,125	\$ 172,830

	<b>As of December 31,</b>	
	<b>2006</b>	<b>2005</b>
Long-lived assets:		
Domestic	\$ 40,744	\$ 27,281
Europe	745	990
Other International	1,979	2,253
Total long-lived assets	\$ 43,468	\$ 30,524

**Note 16. Subsequent Events**

On March 7, 2007, the Company renegotiated and amended its existing credit facility with Comerica Bank. The amendment, among other things, reduced financial covenants to require only a quick ratio covenant. Additionally, the amendment also increased the available borrowings under the existing revolving line of credit from \$20 million to \$25 million effective January 1, 2008. The amended credit facility matures on December 31, 2008 at which point all outstanding borrowing under this credit facility must be repaid.

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

None

**ITEM 9A. CONTROLS AND PROCEDURES**

*Evaluation of disclosure controls and procedures.*

Under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, we have evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). Based upon that evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that our disclosure controls and procedures are effective as of December 31, 2006 to provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our Chief Executive Officer and our Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure, and that such information is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission rules and forms.

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

See Report of Management on Internal Control over Financial Reporting on page 53 of this Annual Report on Form 10-K, which is incorporated herein by reference.

*Attestation report of the registered public accounting firm.*

See Report of Independent Registered Public Accounting Firm on page 54 of this Annual Report on Form 10-K, which is incorporated herein by this reference.

*Changes in internal control over financial reporting.* There have been no changes in our internal control over financial reporting during the quarter ended December 31, 2006 that have materially affected or are reasonably likely to material affect, our internal control over financial reporting

**ITEM 9B. OTHER INFORMATION**

*Amendment to Credit Agreement*

On March 7, 2007, we entered into an Amendment to Credit Agreement with Comerica Bank (the Credit Amendment) to the Amended and Restated Loan and Security Agreement dated as of December 16, 2005, as amended (the Credit Facility). The Credit Amendment amends the Credit Facility to:

- extend the maturity date of the Credit Facility from December 16, 2007 to December 31, 2008;
- automatically increase the aggregate principal amount of the Credit Facility from \$20 million to \$25 million on January 1, 2008;
- change the financial statement reports from a monthly obligation to quarterly;
- amend the financial covenants to delete all financial covenants other than the quick ratio and amending such ratio from 1.75 to 1.00 (excluding deferred revenue) to 1.25 to 1.00 (excluding deferred revenue);
- include in the definition of permitted transfers transfers related to the Costa Rica tax restructuring;





- amend the definition of permitted indebtedness by increasing the amount of permitted indebtedness of a subsidiary to the Company from 5% to 10% and including a carve out for Costa Rica tax restructuring; and
- raise the cross-default amount from \$2 million to \$5 million.

A copy of the Amendment is attached hereto as Exhibit 10.8A.

*Amendment to Form of RSU Agreement*

On March 8, 2007, Align and Thomas M. Prescott entered into an amendment to each of the award agreements evidencing grants of restricted stock units awarded to Mr. Prescott on February 24, 2006 and February 20, 2007. The amendment served to make restricted stock unit acceleration terms in the original restrict stock unit awards consistent with the option acceleration terms included in Mr. Prescott's amended and restated employment agreement dated as of April 19, 2005. Specifically, the amendment deletes the term that accelerated the vesting of the restricted stock units upon termination of Mr. Prescott's employment for cause or good reason and amends the term related to acceleration of vesting upon a change of control to provide that all of Mr. Prescott's restricted stock units will immediately vest upon the occurrence of such an event. The form of amendment is attached hereto as Exhibit 10.14D and should be reviewed for additional information.

Our Compensation Committee also adopted a form of Restricted Stock Unit Award Agreement attached hereto as Exhibit 10.14C to be used in connection with any future grants of restricted stock units awarded to Mr. Prescott.

*Amendment to 2005 Incentive Plan*

On March 7, 2007, our Board of Directors approved an amendment to the Align Technology, Inc. 2005 Incentive Plan (the Plan Amendment). The Plan Amendment amends Section 15 of the 2005 Incentive Plan by:

- reducing the number of options to purchase shares of common stock granted to a new outside director on the date such person first becomes a member of the Board from 75,000 shares to 30,000 shares;
- increasing the annual equity awards automatically granted to each continuing director (other than the Chairman of the Board) on the date of each annual meeting of our stockholders from an option to purchase 8,000 shares to (A) an option to purchase 10,000 shares *plus* (B) a grant of 3,000 restricted stock units (the Second Awards); and
- clarifying that the Second Awards shall vest on the earlier of (i) the one year anniversary of the date of grant and (ii) the date of the next annual meeting of the Company's stockholders following the date of grant; and

A copy of the Plan Amendment is attached hereto as Exhibit 10.14.

**PART III**

## Edgar Filing: ALIGN TECHNOLOGY INC - Form 10-K

Certain information required by Part III is omitted from this Form 10-K because we intend to file a definitive Proxy Statement for our 2007 Annual Meeting of Stockholders (the Proxy Statement ) not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K, and certain information to be included therein is incorporated herein by reference.

### **ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE**

The information required by this Item concerning our directors is incorporated by reference to the Proxy Statement under the section captioned Election of Directors. The information required by this Item concerning our executive officers is set forth in Part I, Item 1 Business of this Annual Report on Form 10-K. The information required by this item concerning compliance with Section 16(a) of the Exchange Act is incorporated by reference to the section entitled Section 16(a) Beneficial Ownership Reporting Compliance contained in the Proxy Statement.

#### **Code of Ethics**

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

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

### **ITEM 11. EXECUTIVE COMPENSATION**

The information required by this Item is incorporated by reference to the Proxy Statement under the section captioned Executive Compensation.

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

The information required by this Item is incorporated by reference to the Proxy Statement under the sections captioned Security Ownership of Certain Beneficial Owners and Management and Equity Compensation Plan Information.

**Equity Compensation Plan Information**

The following table provides information as of December 31, 2006 about our common stock that may be issued upon the exercise of options and rights granted to employees, consultants or members of our Board of Directors under all existing equity compensation plans, including the 1997 Equity Incentive Plan, the Employee Stock Purchase Plan, the 2001 Stock Incentive Plan and the 2005 Incentive Plan, each as amended, and certain individual arrangements.

Plan Category	Number of securities to be issued upon exercise of outstanding options and restricted stock units(a)		Weighted average exercise price of outstanding options (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column(a))
Equity compensation plans approved by security holders	9,597,145	(1)(2)	\$ 8.86	15,176,894 (3)
Equity compensation plans not approved by security holders				
<b>Total</b>	<b>9,597,145</b>		<b>\$ 8.86</b>	<b>15,176,894</b>

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

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

(3) This number reflects securities available for future issuance under the 2005 Stock Incentive Plan and the Employee Stock Purchase Plan. In January 2001, all outstanding options under the 1997 Equity Incentive Plan were subsumed under the 2001 Stock Incentive Plan. Since that date no options have been granted under the 1997 Equity Incentive Plan. In May 2005, stockholder approval was obtained for the 2005 Incentive Plan and the 2001 Stock Incentive Plan was terminated. Since that date, no further options have been granted under the 2001 Stock Incentive Plan. The 2005 Incentive Plan has 9,983,379 shares of common stock reserved for issuance, plus up to an aggregate of 5,000,000 shares that are or would have been returned to the 2001 Stock Incentive Plan as a result of termination of outstanding options or repurchase of shares granted under the 2001 Stock Incentive Plan after March 28, 2005. As of December 31, 2006 2,084,687 shares have been transferred to the 2005 Incentive Plan. As of December 31, 2006, the number of shares available for future issuance under the 2005 Incentive Plan was 7,904,504. Any grants of restricted stock units will reduce shares available for grant at a 2:1 ratio. The Employee Stock Purchase Plan provides that the number of shares of our common stock reserved for issuance thereunder will automatically increase on the first trading day of January in each calendar year by an amount equal to three percent (3%) of the total number of shares of common stock outstanding on the last trading day in December of the immediately preceding calendar year, with this annual increase not to exceed 1,500,000 shares. As of December 31, 2006, the total number of shares of our common stock available for future issuance under the Employee Stock Purchase Plan was 7,272,388.

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

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

**ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES**

## Edgar Filing: ALIGN TECHNOLOGY INC - Form 10-K

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

93

---

**PART IV**

**ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES.**

(a)

1. Consolidated Financial Statements

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

Report of Independent Registered Public Accounting Firm

60

Consolidated Statements of Operations for the years ended December 31, 2006, 2005

and 2004

62

Consolidated Balance Sheets as of December 31, 2006 and 2005

63

Consolidated Statements of Stockholders' Equity (Deficit) for the years ended December 31, 2006, 2005 and 2004

64

Consolidated Statements of Cash Flows for the years ended December 31, 2006, 2005

and 2004

65

Notes to Consolidated Financial Statements

66

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

Schedule II Valuation and Qualifying Accounts and Reserves

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

**SCHEDULE II: VALUATION AND QUALIFYING ACCOUNTS AND RESERVES**

	Balance at Beginning of Period (in thousands)	Additions (reductions) to Costs and Expenses	Write offs	Reclass from Other Accounts	Balance at End of Period
<b>Allowance for doubtful accounts:</b>					
Year ended December 31, 2004	\$ 1,259	\$ 540	\$ (311 )	\$ 5	\$ 1,493
Year ended December 31, 2005	\$ 1,493	\$ 457	\$ (324 )	\$	\$ 1,626
Year ended December 31, 2006	\$ 1,626	\$ (332 )	\$ (450 )	\$	\$ 844
<b>Allowance for deferred tax assets:</b>					
Year ended December 31, 2004	\$ 74,928	\$ 13,611	\$	\$	\$ 88,539
Year ended December 31, 2005	\$ 88,539	\$ 1,449	\$	\$	\$ 89,988
Year ended December 31, 2006	\$ 89,988	\$ 12,165	\$	\$	\$ 102,153
<b>Allowance for excess and obsolete inventory and abandoned product:</b>					
Year ended December 31, 2004	\$ 253	\$ (72 )	\$ (138 )	\$	\$ 43
Year ended December 31, 2005	\$ 43	\$ 150	\$ (15 )	\$	\$ 178
Year ended December 31, 2006	\$ 178	\$ 10	\$	\$	\$ 188

### 3. Exhibits

Exhibit Number Incorporated by reference herein					Filed herewith
Exhibit Number	Description	Form	Date	Number	
3.1	Amended and Restated Certificate of Incorporation of registrant.	Form S-1, as amended (File No. 333-49932)	12/28/2000	3.1	
3.2	Amended and Restated Bylaws of registrant.	Form S-1, as amended (File No. 333-49932)	12/28/2000	3.2	
3.3	Certificate of Designations of Rights, Preferences and Privileges of Series A Participating Preferred Stock registrant	Form 8-K	10/27/2005	3.1	
4.1	Form of Specimen Common Stock Certificate.	Form S-1, as amended (File No. 333-49932)	01/17/2001	4.1	
4.2	Preferred Stock Rights Agreement dated October 25 between the registrant and EquiServe Trust Company, N.A.	Form 8-K	10/27/2005	4.1	
10.1	Lease Agreement by and between James Lindsey and registrant, dated June 20, 2000, for office space located at 881 Martin Avenue, Santa Clara, CA.	Form S-1, as amended (File No. 333-49932)	11/14/2000	10.4	
10.2	First Amendment to Lease Agreement dated February 2, 2005 for office space located at 881 Martin Avenue, Santa Clara, CA	Form 8-K	02/09/2005	10.1	
10.3	Lease Agreement dated August 30, 2001 by and between James S. Lindsey and registrant for office space located at 821 Martin Avenue, Santa Clara, CA.	Form 10-K fiscal year ended December 31, 2002	03/27/2003	10.28	
10.4	First Amendment to Lease Agreement dated February 2, 2005 for office space located at 821 Martin Avenue, Santa Clara, CA.	Form 8-K	02/09/2005	10.3	

96



# Edgar Filing: ALIGN TECHNOLOGY INC - Form 10-K

10.5	Lease Agreement dated March 4, 2004 by and between James S. Lindsey and registrant for office space located at 831 Martin Avenue, Santa Clara, CA.	Form 10-Q for quarter ended March 31, 2004	05/06/2004	10.40
10.6	First Amendment to Lease Agreement dated February 2, 2005 for office space located at 831 Martin Avenue, Santa Clara, CA.	Form 8-K	02/09/2005	10.2
10.7	Shelter Agreement dated December 22, 2005 between registrant and International Manufacturing Solutions Operaciones, S.R.L.	Form 8-K	12/28/2005	10.1
10.8	Amended and Restated Loan and Security Agreement dated December 16, 2005 between registrant and Comerica Bank	Form 8-K	12/19/2005	10.1
10.8A	Amendment to Amended and Restated Loan and Security Agreement dated March 7, 2007 between registrant and Comerica Bank			*
10.9	Form of Resale Restriction Agreement with T. Prescott, E. Bullington, R. George, L. Hedge and Gil Laks	Form 8-K	10/11/2005	10.1
10.10	Registrant's 2001 Stock Incentive Plan.	Form S-1 as amended (File No. 333-49932)	12/28/2000	10.13
10.11	Form of option agreement under Align's 2001 Stock Incentive Plan	Form 10-Q for quarter ended September 30, 2004	11/05/2004	10.13.1
10.12	Registrant's Employee Stock Purchase Plan.	Form S-1 as amended (File No. 333-49932)	12/28/2000	10.14
10.13	Form of Indemnification Agreement by and between registrant and its Board of Directors and its executive officers.	Form S-1 as amended (File No. 333-49932)	01/17/2001	10.15

97

# Edgar Filing: ALIGN TECHNOLOGY INC - Form 10-K

10.14	Amended and restated 2005 Incentive Plan				*
10.14A	Form of restricted stock unit award agreement under registrant's 2005 Incentive Plan (General Form; Officer Form: Director Form)	Form 10-K	03/01/2006	10.14B	
10.14B	Form of option award agreement under registrant's 2005 Incentive Plan	Form 10-Q	08/04/2005	10.4	
10.14C	Form of restricted stock unit award agreement under registrant's 2005 Incentive Plan with Thomas M. Prescott				*
10.14D	Form of restricted stock unit award agreement amendment under registrant's 2005 Incentive Plan with Thomas M. Prescott				*
10.15	Amended and Restated Employment Agreement dated April 19, 2005 between Thomas M. Prescott and registrant.	Form 8-K	04/19/2005	10.1	
10.16	Employment Offer Letter dated July 10, 2002 for Roger E. George, Vice-President of Legal Affairs and General Counsel.	Form 10-Q for quarter ended September 30, 2002	11/14/2002	10.18	
10.17	Employment Offer Letter dated August 22, 2002 for Eldon M. Bullington, Chief Financial Officer and Vice-President, Finance.	Form 10-Q for quarter ended September 30, 2002	11/14/2002	10.20	
10.18	Form of Employment Agreement entered into by and between registrant and each of Dan Ellis, Darrell Zoromski,, Hossein Arjomand, Gil Laks and Michael Henry	Form 10-K	03/01/2006	10.20	
10.19	Form of Employment Agreement with Sonia Clark	Form 8-K	09/25/2006	10.01	
10.20	Lease Agreement dated February 26, 2003 between KPMG FIDES (COSTA RICA) S.A., PARQUE GLOBAL S.A. and registrant.	Form 10-Q for quarter ended March 31, 2003	05/13/2003	10.36	

98

# Edgar Filing: ALIGN TECHNOLOGY INC - Form 10-K

10.21	Lease Agreement between Schootsepoort Onroerendgoed Beheer, for Stichting Philips Pensioenfond and Align Technology, Inc.	Form 10-Q for quarter ended June 30, 2004	08/05/2004	10.41
10.22	Summary of 2006 Incentive Awards for Named Executive Officers	Form 8-K	01/12/2007	Item 5.02 only
10.23	Settlement Agreement and Mutual Releases dated as of October 12, 2006 by and between registrant and OrthoClear, Inc., among others	Form 8-K	10/19/2006	10.1
21.1	Subsidiaries of the registrant.			*
23.1	Consent of PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firm.			*
31.1	Certifications of Chief Executive Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2003.			*
31.2	Certifications of Chief Financial Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2003.			*
32	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2003.			*

---

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

# Edgar Filing: ALIGN TECHNOLOGY INC - Form 10-K

## SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, on March 12, 2007.

ALIGN TECHNOLOGY, INC.

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

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

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

Signature	Title	Date
/s/ THOMAS M. PRESCOTT	President and Chief Executive Officer	March 12, 2007
Thomas M. Prescott	(Principal Executive Officer)	
/s/ ELDON M. BULLINGTON	Chief Financial Officer and Vice President,	March 12, 2007
Eldon M. Bullington	Finance(Principal Financial Officer and	
	Principal Accounting Officer)	
/s/ H. KENT BOWEN	Director	March 12, 2007
H. Kent Bowen		
/s/ DAVID E. COLLINS	Director	March 12, 2007
David E. Collins		
/s/ JOSEPH LACOB	Director	March 12, 2007
Joseph Lacob		
/s/ C. RAYMOND LARKIN	Director	March 12, 2007
C. Raymond Larkin		
/s/ GEORGE J. MORROW	Director	March 12, 2007
George J. Morrow		
/s/ GREG J. SANTORA	Director	March 12, 2007
Greg J. Santora		
/s/ WARREN S. THALER	Director	March 12, 2007
Warren S. Thaler		

# Edgar Filing: ALIGN TECHNOLOGY INC - Form 10-K

Exhibit Number	Description	Form	Date	Exhibit Number Incorporated by reference herein		Filed herewith
				Number	Number	
3.1	Amended and Restated Certificate of Incorporation of registrant.	Form S-1, as amended (File No. 333-49932)	12/28/2000		3.1	
3.2	Amended and Restated Bylaws of registrant.	Form S-1, as amended (File No. 333-49932)	12/28/2000		3.2	
3.3	Certificate of Designations of Rights, Preferences and Privileges of Series A Participating Preferred Stock registrant	Form 8-K	10/27/2005		3.1	
4.1	Form of Specimen Common Stock Certificate.	Form S-1, as amended (File No. 333-49932)	01/17/2001		4.1	
4.2	Preferred Stock Rights Agreement dated October 25 between the registrant and EquiServe Trust Company, N.A.	Form 8-K	10/27/2005		4.1	
10.1	Lease Agreement by and between James Lindsey and registrant, dated June 20, 2000, for office space located at 881 Martin Avenue, Santa Clara, CA.	Form S-1, as amended (File No. 333-49932)	11/14/2000		10.4	
10.2	First Amendment to Lease Agreement dated February 2, 2005 for office space located at 881 Martin Avenue, Santa Clara, CA	Form 8-K	02/09/2005		10.1	
10.3	Lease Agreement dated August 30, 2001 by and between James S. Lindsey and registrant for office space located at 821 Martin Avenue, Santa Clara, CA.	Form 10-K fiscal year ended December 31, 2002	03/27/2003		10.28	
10.4	First Amendment to Lease Agreement dated February 2, 2005 for office space located at 821 Martin Avenue, Santa Clara, CA.	Form 8-K	02/09/2005		10.3	
10.5	Lease Agreement dated March 4, 2004 by and between James S. Lindsey and registrant for office space located at 831 Martin Avenue, Santa Clara, CA.	Form 10-Q for quarter ended March 31, 2004	05/06/2004		10.40	

# Edgar Filing: ALIGN TECHNOLOGY INC - Form 10-K

10.6	First Amendment to Lease Agreement dated February 2, 2005 for office space located at 831 Martin Avenue, Santa Clara, CA.	Form 8-K	02/09/2005	10.2	
10.7	Shelter Agreement dated December 22, 2005 between registrant and International Manufacturing Solutions Operaciones, S.R.L.	Form 8-K	12/28/2005	10.1	
10.8	Amended and Restated Loan and Security Agreement dated December 16, 2005 between registrant and Comerica Bank	Form 8-K	12/19/2005	10.1	
10.8A	Amendment to Amended and Restated Loan and Security Agreement dated March 7, 2007 between registrant and Comerica Bank				*
10.9	Form of Resale Restriction Agreement with T. Prescott, E. Bullington, R. George, L. Hedge and Gil Laks	Form 8-K	10/11/2005	10.1	
10.10	Registrant's 2001 Stock Incentive Plan.	Form S-1 as amended (File No. 333-49932)	12/28/2000	10.13	
10.11	Form of option agreement under Align's 2001 Stock Incentive Plan	Form 10-Q for quarter ended September 30, 2004	11/05/2004	10.13.1	
10.12	Registrant's Employee Stock Purchase Plan.	Form S-1 as amended (File No. 333-49932)	12/28/2000	10.14	
10.13	Form of Indemnification Agreement by and between registrant and its Board of Directors and its executive officers.	Form S-1 as amended (File No. 333-49932)	01/17/2001	10.15	
10.14	Amended and restated 2005 Incentive Plan				*
10.14A	Form of restricted stock unit award agreement under registrant's 2005 Incentive Plan (General Form; Officer Form: Director Form)	Form 10-K	03/01/2006	10.14B	

# Edgar Filing: ALIGN TECHNOLOGY INC - Form 10-K

10.14B	Form of option award agreement under registrant's 2005 Incentive Plan	Form 10-Q	08/04/2005	10.4	
10.14C	Form of restricted stock unit award agreement under registrant's 2005 Incentive Plan with Thomas M. Prescott				*
10.14D	Form of restricted stock unit award agreement amendment under registrant's 2005 Incentive Plan with Thomas M. Prescott				*
10.15	Amended and Restated Employment Agreement dated April 19, 2005 between Thomas M. Prescott and registrant.	Form 8-K	04/19/2005	10.1	
10.16	Employment Offer Letter dated July 10, 2002 for Roger E. George, Vice-President of Legal Affairs and General Counsel.	Form 10-Q for quarter ended September 30, 2002	11/14/2002	10.18	
10.17	Employment Offer Letter dated August 22, 2002 for Eldon M. Bullington, Chief Financial Officer and Vice-President, Finance.	Form 10-Q for quarter ended September 30, 2002	11/14/2002	10.20	
10.18	Form of Employment Agreement entered into by and between registrant and each of Dan Ellis, Darrell Zoromski,, Hossein Arjomand, Gil Laks and Michael Henry	Form 10-K	03/01/2006	10.20	
10.19	Form of Employment Agreement with Sonia Clark	Form 8-K	09/25/2006	10.01	
10.20	Lease Agreement dated February 26, 2003 between KPMG FIDES (COSTA RICA) S.A., PARQUE GLOBAL S.A. and registrant.	Form 10-Q for quarter ended March 31, 2003	05/13/2003	10.36	
10.21	Lease Agreement between Schootsepoort Onroerendgoed Beheer, for Stichting Philips Pensioenfond and Align Technology, Inc.	Form 10-Q for quarter ended June 30, 2004	08/05/2004	10.41	
10.22	Summary of 2006 Incentive Awards for Named Executive Officers	Form 8-K	01/12/2007	Item 5.02 only	

# Edgar Filing: ALIGN TECHNOLOGY INC - Form 10-K

10.23	Settlement Agreement and Mutual Releases dated as of October 12, 2006 by and between registrant and OrthoClear, Inc., among others	Form 8-K	10/19/2006	10.1	
21.1	Subsidiaries of the registrant.				*
23.1	Consent of PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firm.				*
31.1	Certifications of Chief Executive Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2003.				*
31.2	Certifications of Chief Financial Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2003.				*
32	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2003.				*

---

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

---