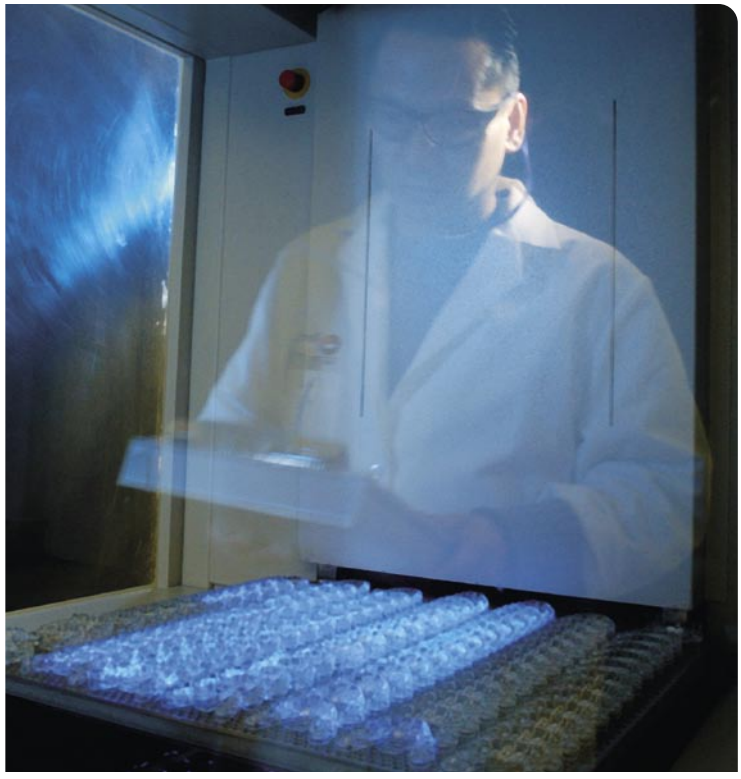
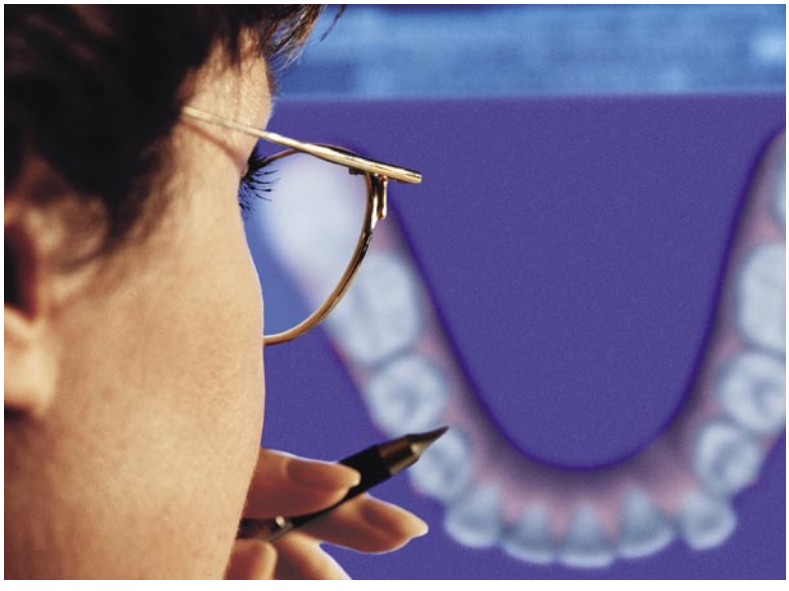
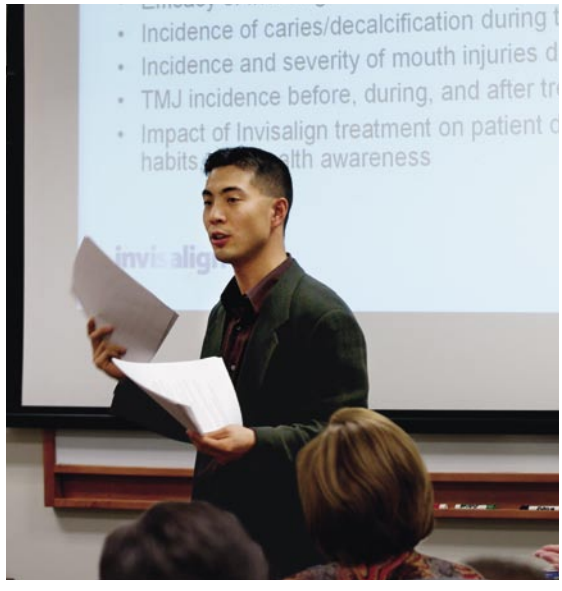
ONE OF A KIND







There is no other product on the market today that can match Invisalign® in its ability to satisfy patients' demands for a less obtrusive and less painful method of straightening teeth, as well as provide orthodontists and dentists with a proven, efficient and profitable alternative treatment method.

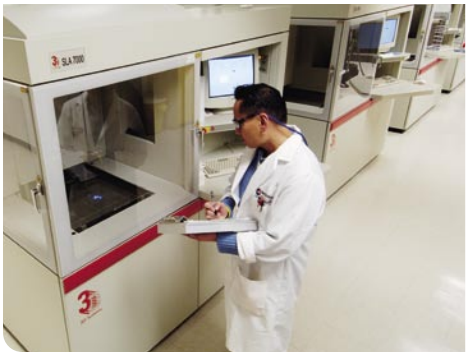
ONE-OF-A-KIND **PRODUCT**

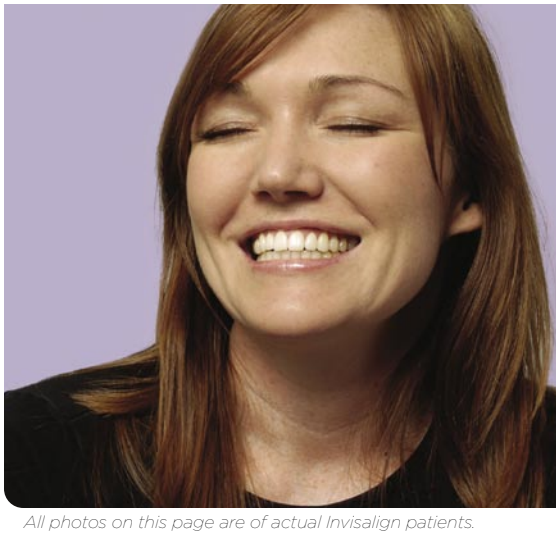
One of a kind. Totally unique. Custom-made. These are not terms typically used to describe a product that numbers in the millions. Invisalign is the only product on the market today that combines the benefits of aesthetic, removable orthodontic appliances with extremely precise, 3-D, virtual treatment-planning technology. The result is a proven, one-of-a-kind treatment solution with the potential to help millions of patients get the smile they have always wanted.

More than 250,000 patients have entered treatment with Invisalign, and in the fourth quarter of 2004, we achieved a significant milestone with production of our 10 millionth totally unique aligner. Align remains one of the largest manufacturers of mass-customized products in the world. The success and widespread adoption of the Invisalign system is due in large part to Align's commitment to ongoing innovation in manufacturing and product technologies.

In 2004 we made several operational improvements in order to enhance automation and to support future growth in case submissions. Early in the year we installed a FlexLink® material handling system in our Juarez production facility, and upgraded our CT scanning process software to shorten turnaround time on the scanning of impressions. More recently, we doubled the size of our Treat Operations facility in Costa Rica, paving the way for more technicians responsible for the treatment planning and design of cases.

Our commitment to innovation and improvements is not limited to manufacturing efficiencies. Developing new technologies that improve treatment for our customers and their patients is a critical priority at Align. The drive to create Invisalign 2.0 is well underway, with particular focus on evolutionary new tools for our ClinCheck software, next-generation aligner material, a patient compliance indicator and early clinical trials for a product that combines Invisalign's unique technology with traditional bracket therapy for more difficult cases.

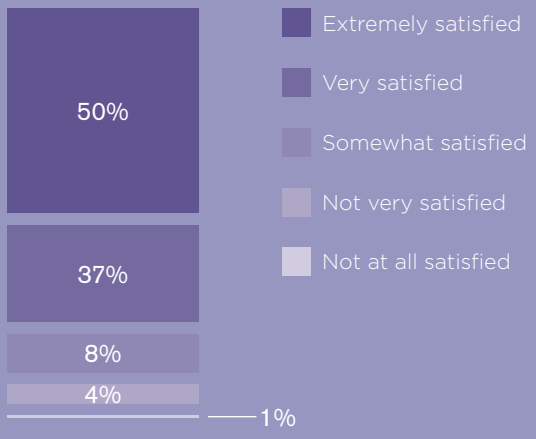




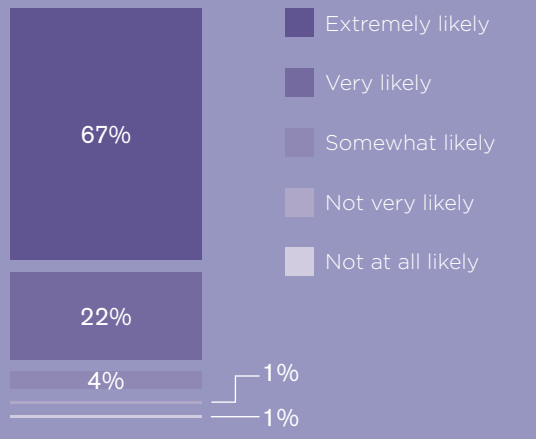
With help from an Invisalign-certified orthodontist, *Trading Spaces* Kia Steave-Dickerson (above) happily "traded in" her smile for her newly "remodeled" one. Like Kia, other Invisalign patients (left & below) are extremely satisfied with their results, and 89% of them would recommend Invisalign treatment to their friends.

All photos on this page are of actual Invisalign patients.

How satisfied are you with your treatment?



Would you recommend Invisalign to your friends?



Survey of patients completed in Q3 2004

ONE-OF-A-KIND **SOLUTION**

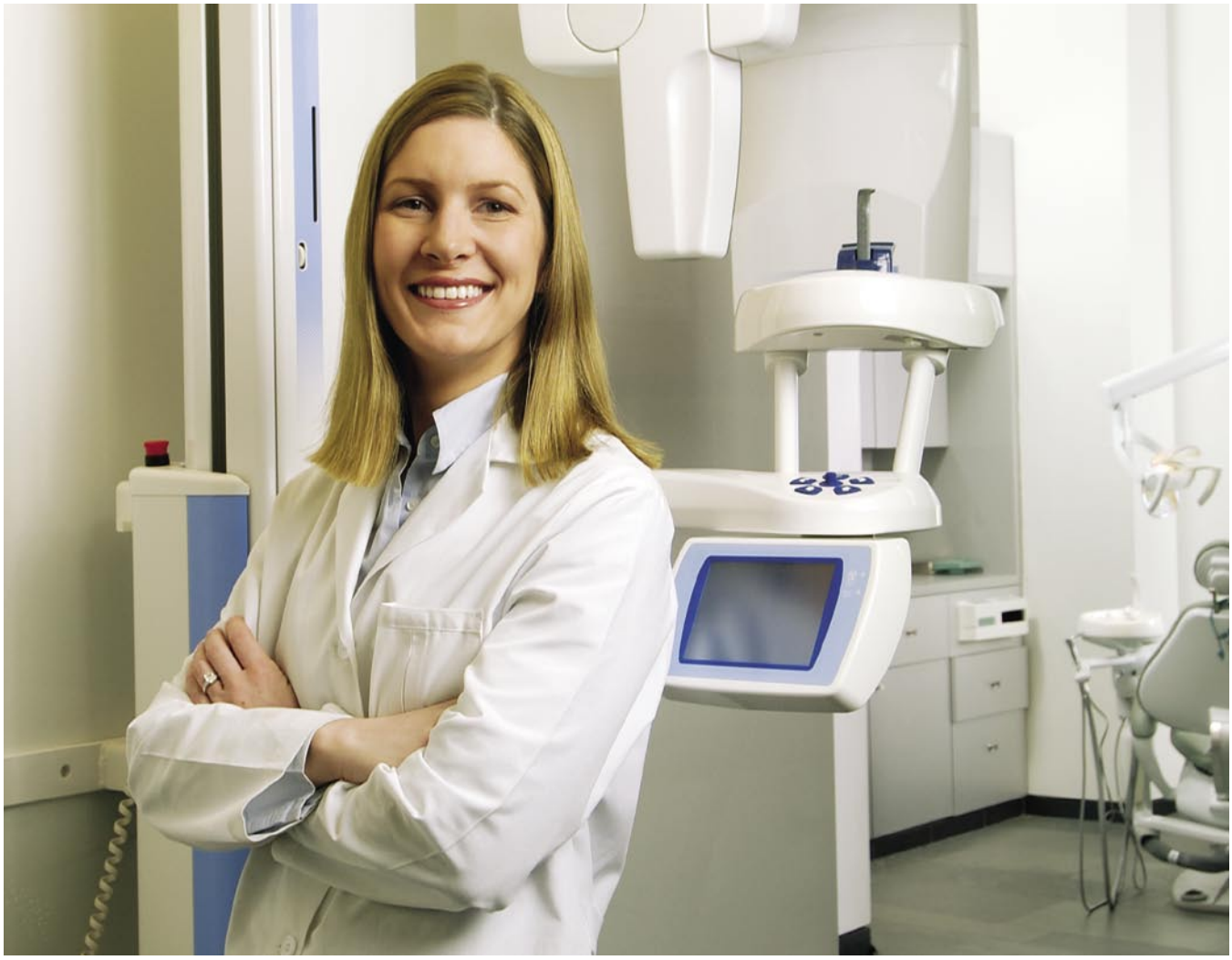
Every Invisalign patient is unique – they vary in age, demographics, and level of orthodontic need, from mild to severe. But they all have one important thing in common – a desire for a healthy, more attractive smile.

In 2004 we conducted extensive patient and consumer research in an effort to define and better understand what patients want and need from treatment. We also wanted to better understand how patients felt about their treatment – both during and after completing therapy. Our research found that 87% of patients surveyed are very or extremely satisfied with their Invisalign treatment, and 89% of patients would recommend Invisalign to their friends.

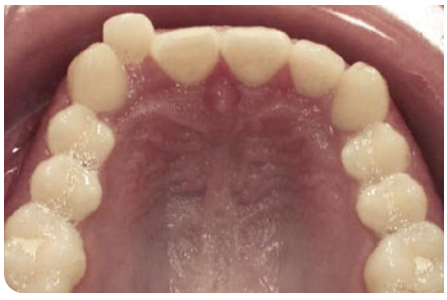
Kia Steave-Dickerson, of the popular home makeover show *Trading Spaces*, is one of those patients. As a television personality, interior designer and frequent lecturer, Kia wanted to close a large gap between her front teeth and achieve a more attractive smile, but knew that metal braces would not fit her career or lifestyle. For 15 years, she contemplated braces but was afraid to start treatment – until a *MAD Magazine* spoof of her smile led her to Invisalign. "I truly believe that this product is the most wonderful and fantastic investment I could have ever made in myself and *for* myself," she said. "You must see the 'before' photos to be truly astonished by the result I have today. The product changed my life."

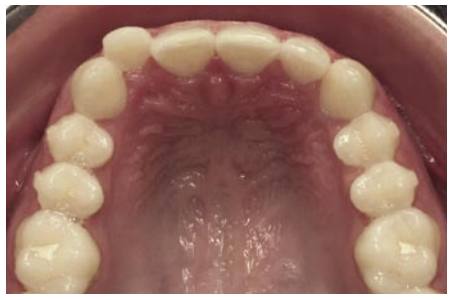
For thousands of patients like Kia, Invisalign is not just a great treatment option – it is the only one they will consider.

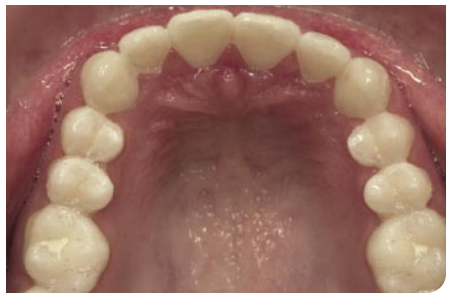
At Invisalign Wall Street in New York City, orthodontists like Dr. Jessica Greenberg (below) cater to their clients by delivering Invisalign in a high-tech atmosphere.



Patient treatment: Initial visit before invisalign, at 6 months and after completed treatment (9 months).







ONE-OF-A-KIND **VALUE PROPOSITION**

Dr. Leo Wheat, Jr. (left) has successfully incorporated Invisalign treatment into his general dentistry practice. Dr. Wheat and his staff offer Invisalign along with other comprehensive dental services.

Our customers have long understood the primary benefits of making Invisalign part of their practice – Invisalign helps them to achieve great results for their patients and offers an effective, aesthetic treatment option for patients unwilling to accept treatment with traditional braces.

Invisalign treatment is also a profitable service offering for doctors and a means of growing their practices. For orthodontists, Invisalign not only provides a treatment option that eliminates many traditional barriers to patient acceptance, it also reduces chair time while increasing per hour profitability. For our general practitioner (GP) dentist customers, Invisalign offers an important complement to their cosmetic and restorative business, one that helps maintain healthy tooth enamel and support periodontal health and hygiene goals for their patients.

As a result, doctors are treating more patients with Invisalign and making our product a bigger part of their practices. In some cases, Invisalign is the *only* part of their practice, as an increasing number of specialty practices emerge focused solely on Invisalign treatment.

Align is committed to becoming the most valuable part of our customers' businesses. Align is the only company in the orthodontic industry today that devotes significant resources to creating consumer awareness and expanding the market for orthodontic treatment through direct-to-consumer advertising and practice development programs for doctors. That commitment will increase in 2005 with the launch of a new consumer branding campaign designed to raise the profile of orthodontic treatment benefits, and drive more consumers to our customers.

Align also provides doctors with the most extensive continuing education and training programs in the industry. In 2005 we will evolve our clinical support programs to become more of an active treatment partner to our doctors. We believe that providing educational tools and a multi-level clinical support structure will help every Invisalign doctor become more confident and more successful with treatment – and create happier, more satisfied customers overall.

THOMAS M. PRESCOTT
President and Chief Executive Officer

DEAR **FELLOW SHAREHOLDERS**

It takes many people to bring a one-of-a-kind product to market.

Our customers are the cornerstone of our company. Some lead others to use Invisalign more effectively, while others help us make the product and the user experience even better than it is today. All of them bring smiles to patients around the world.

Thank you to our 30,000 customers for learning about Invisalign and taking the steps to make it a part of your practices.

Our 1,000 employees are the driving force behind the product. Our sales and marketing teams plan, educate and encourage. They help doctors integrate Invisalign into their practices, and they help bring patients to the doctors. Our research and development team improves the user experience and drives system improvements. Our operations team ensures a quality product every time. And all of us support the ongoing development of the company and the product.

We started 2004 with specific goals that would help Align become a leader in the world of straightening teeth. Our strong customer and employee base enabled us to achieve record revenues and margins, and for the first time, profitability. Align grew from a small start-up in 1999 to a company with $172.8 million in revenue today. We have operations in some of the largest markets in the world and we continue to expand.

We are proud of our achievements and we know that this is just the beginning. Our journey continues as we build a product that is easy for doctors to use and that patients love.

CONTINUING IMPROVEMENTS

In 2004, we continued to improve our processes and systems that will position Align for future growth. In manufacturing, we installed a FlexLink material-handling system and a manufacturing execution system which help us follow the flow of each unique aligner.

For doctors, we launched a new version of our VIP website, enabling them to better track and manage their cases. We began a data mining project which will help us focus on predictability and reliability of treatment plans and tooth movements.

For the first time in many years, we offered five certification classes specifically for orthodontists. We also conducted more than 350 educational events, helping doctors do more with Invisalign. We trained 4,200 GP dentists, bringing our total of trained U.S. GPs to 13,800. Our certified doctors are responsible for making more than 250,000 people worldwide happy with their new smiles.

The University of Illinois at Chicago joined New York University in bringing Invisalign certification to their students and making the Invisalign system an integral part of their

program. These programs are instrumental in helping Align achieve recognition among the burgeoning number of doctors entering the marketplace.

IMPROVING FINANCIALS

2004 was a year in which Align greatly improved financial performance.

Revenues were up 41% to $172.8 million. Gross margins improved 8.7 percentage points. And operating margin increased 21.9 percentage points. Align's GAAP net profit was $8.8 million compared to a net loss of $20.1 million in 2003. Align's non-GAAP net profit was $14.4 million compared to a non-GAAP net loss of $4.6 million in 2003.*

We also ended the year with a strong balance sheet – $70 million in cash and cash equivalents – and we generated $24.6 million in cash flow from operations. We are proud of the work everyone did to make 2004 the best year in Align's financial history.

THE JOURNEY CONTINUES

2005 promises to be a year for many changes at Align that we believe will make us a better company and make Invisalign the best product for our customers.

While we began many projects in 2004 that are intended to make Invisalign the preferred alternative for straightening teeth and Align Technology a leader in the orthodontic industry, we believe our work has just begun.

We will continue to improve our systems and processes and build the infrastructure necessary to support future growth. We have projects already in place that will manage the order flow of aligners, ensure our processes are sound and enable us to provide leading-edge services to our customers.

We will also launch two pilots – Invisalign Seven and the bracket positioning template (also known as combination treatment). Both products will provide additional opportunities for patient treatments.

Our consumer campaign will launch in mid-2005. You'll see new advertising, new media and a new website. The campaign will focus on educated patients and experienced doctors.

We're excited about our plans for 2005. For the past few years, we have had the systematic goals of turning the company from small, entrepreneurial start-up to a profitable operating company. We've done that, and it's now time to focus on our future.

We hope you'll continue this journey with us as we build the best orthodontic company for our customers, employees and shareholders.

Sincerely,

Thomas M. Prescott
President and Chief Executive Officer

** See the reconciliation of GAAP to non-GAAP financials on the "Financial Highlights" page.*

Financial Highlights

(in thousands, except per share data)	2004	2003	2002
Statement of Operations			
Total Revenues	$ 172,830	$ 122,725	$ 69,698
Gross Profit	115,304	71,160	24,707
Total Operating Expenses	105,539	91,097	97,642
Net Profit (Loss)	$ 8,768	$ (20,122)	$ (72,819)
Net Profit (Loss) Per Fully Diluted Share	$ 0.14	$ (0.35)	$ (1.52)
Shares Used in Computing Net Profit (Loss) Per Fully Diluted Share	64,089	57,758	47,878
Balance Sheet			
Cash, Cash Equivalents and Marketable Securities	$ 69,962	$ 47,670	$ 41,506
Working Capital	61,886	39,737	41,160
Total Assets	130,712	102,202	92,856
Total Long-Term Liabilities	25	1,849	3,837
Stockholder's Equity	85,739	62,976	64,347
Reconciliation of GAAP to Non-GAAP Financials			
Net Profit (Loss)	$ 8,768	$ (20,122)	$ (72,819)
Stock-based Compensation Included in:			
Cost of Revenues	894	2,560	3,399
Operating Expenses	4,720	12,471	16,886
Restructuring Costs Included in:			
Cost of Revenues	—	—	559
Operating Expenses	—	507	4,635
Non-GAAP Net Profit (Loss)	$ 14,382	$ (4,584)	$ (47,340)
Non-GAAP Net Profit (Loss) Per Fully Diluted Share	$ 0.22	$ (0.08)	$ (0.99)

In addition to historical information, this Annual Report 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 relating to our commitment to develop new technologies, our expectations regarding the anticipated benefits of projects initiated in 2004 and in 2005, improving our systems and processes and building the infrastructure necessary to support future growth, our expectation that we will launch Invisalign Seven, the bracket positioning template and a consumer campaign in 2005, as well as other statements regarding our business strategies. 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 might cause such a difference include, but are not limited to, risks relating to Align's ability to sustain or increase profitability or revenue growth in future periods while controlling expenses, Align's ability to maintain the adequacy of its internal controls, acceptance of Invisalign by consumers and dental professionals, Align's ability to manage its rapid growth, competition from manufacturers of traditional braces and new competitors, and risks related to any deterioration in the general economic condition or specifically in the markets in which Align sells its products. For a detailed listing of potential factors affecting our business and these forward-looking statements, please refer to "Risk Factors" in Align's Annual Report on Form 10-K for the fiscal year ended December 31, 2004. Align undertakes no obligation to revise or update publicly any forward-looking statements for any reason.

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, 2004

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	**94-3267295**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification Number)**

881 Martin Avenue
Santa Clara, California 95050
(Address of principal executive offices, including Zip Code)

(408) 470-1000
Registrant's telephone number, including area code:

Securities registered pursuant to Section 12(b) of the Act:
None

Securities registered pursuant to Section 12(g) of the Act:
Common Stock, $0.0001 par value

Indicate by check mark whether 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 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 the 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 Registrant is an accelerated filer (as defined in Rule 12b-2 of the Securities Exchange Act of 1934). Yes ☒ No ☐

As of June 30, 2004, the last business day of the Registrant's most recently completed second fiscal quarter, there were 47,825,000 shares of Registrant's common stock outstanding, and the aggregate market value of such shares held by non-affiliates of Registrant (based upon the closing sale price of such shares on the NASDAQ National Market on June 30, 2004) was approximately $908,675,000. Shares of Registrant's common stock held by each executive officer and director and by each entity or person that, to the Registrant's knowledge, owned 5% or more of Registrant's outstanding common stock as of June 30, 2004 have been excluded in that such persons may be deemed to be affiliates of the Registrant. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

On February 28, 2005, 61,401,712 shares of Registrant's common stock were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of Registrant's definitive Proxy Statement relating to its 2005 Annual Stockholders' Meeting to be filed pursuant to Regulation 14A within 120 days after the Registrant's fiscal year end of December 31, 2004 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, 2004

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PART I

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 on our revenue growth, our expectation that the percentage of revenue generated by general practitioner dentists in fiscal 2005 will represent a larger percentage of our revenue than revenue generated by orthodontists, our expectations regarding further expansion into North American and international markets, including initiating strategic moves in Asia, specifically in Japan, the number of new doctors we anticipate certifying in 2005, our expectation that sales and marketing and research and development expenses will increase in 2005 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 the following discussion, and in particular, the risks discussed below under the subheading "Risk Factors" and in other documents we file with the Securities and Exchange Commission. 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.

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 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. Align Technology received FDA clearance to market Invisalign in 1998.

Under the Corporate Information/Investor Relations section of our corporate website which can be accessed at either *www.aligntech.com* or *www.invisalign.com*, we make our annual report on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K, our proxy statement on Form 14A related to 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. All such filings are available free of charge. The information in, or that can be accessed through, our web site is not part of this report.

Industry Background

Malocclusion

Malocclusion, the misalignment of teeth, is one of the most prevalent clinical dental conditions, affecting over 200 million individuals, or approximately 75% of the U.S. population. Approximately two million people annually elect treatment by orthodontists in the U.S., generating industry revenues of approximately $7 billion. 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

Currently, dental professionals apply traditional techniques and principles of orthodontic treatment developed in the early 20th century. In the U.S., dental professionals treat malocclusion primarily with metal archwires and brackets, commonly referred to as braces. Occasionally, dental professionals attempt to improve treatment aesthetics by using ceramic, tooth-colored brackets or bond brackets on the inside, or lingual surfaces, of the patient's teeth. Dental professionals also augment braces with elastics, metal bands, headgear and other ancillary devices.

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

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

Limitations of Traditional Orthodontic Treatment

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

- *Unattractive appearance*. Braces call attention to the patient's condition and treatment. In addition, braces trap food, which can further compromise appearance. Braces can also result in permanent discoloration of teeth. Many adults associate braces with adolescence. As a result of these and other limitations, less than one percent of American adults with malocclusion elect traditional orthodontic treatment annually.
- *Oral discomfort*. Braces are sharp and bulky and can abrade and irritate the interior surfaces of the mouth. The tightening or adjustment of braces results in root and gum soreness and discomfort, especially in the few days immediately following an orthodontic visit.
- *Poor oral hygiene*. Braces compromise oral hygiene by making it more difficult to brush and floss. These problems can result in tooth decay and periodontal damage. Additionally, the bonding of brackets to teeth can cause permanent markings on the teeth.
- *Inability to project treatment*. Historically, dental professionals have not had a means to model the movement of teeth over a course of treatment. Accordingly, dental professionals must rely on intuition and judgment to plan and project treatment. As a result, they cannot be precise about the direction or distance of expected tooth movement between patient visits. This lack of predictability may result in unwanted tooth movements and can limit the dental professional's ability to estimate the duration of treatment. Because most orthodontic treatment is performed on a fixed price basis, extended treatment duration reduces profitability for the dental professional.
- *Physical demands on dental professional*. The manipulation of wires and brackets requires sustained manual dexterity and visual acuity, and may place other physical burdens on the dental professional.

- *Root resorption*. The sustained high levels of force associated with conventional treatment can result in root resorption, which is a shortening of tooth roots. This shortening can have substantial adverse periodontal consequences for the patient.
- *Emergencies*. At times, braces need to be repaired or replaced on an emergency basis. Such emergencies cause significant inconvenience to both the patient and the dental professional.

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

The Align Solution

Invisalign 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 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 treatment for their patients. We use a dental impression and a treatment prescription submitted by a dental professional to develop a customized, three-dimensional treatment plan that simulates appropriate tooth movement in a series of two-week increments. ClinCheck™ allows the dental professional to view this three-dimensional simulation with a high degree of magnification and from any angle. Accordingly, ClinCheck™ enables the dental professional to project tooth movement with a level of accuracy not previously possible.

Upon review of the ClinCheck™ simulation, the dental professional may immediately approve the projected treatment, or may provide us with feedback for modification. We reflect any requested adjustments in a modified simulation. Upon the dental professional's approval of the ClinCheck™ simulation, we use the data underlying the simulation, in conjunction with stereolithography technology, to manufacture Aligner molds. A third party manufacturer in Mexico uses these molds to fabricate the patient's Aligners.

Aligners. Aligners are custom-manufactured, thin, clear plastic, removable dental appliances that are manufactured in a series to correspond to each two-week stage of the ClinCheck™ simulation. Aligners are customized to perform the treatment prescribed for an individual patient by dental professionals using ClinCheck™. Each Aligner covers a patient's teeth and is nearly invisible when worn. Aligners are commonly worn in pairs, over the upper and lower dental arches. Aligners are generally worn for consecutive two-week periods which correspond to the approved ClinCheck™ treatment simulation. After two weeks of use, the patient replaces them with the next pair in the series. This process is repeated until the final Aligners are used and treatment is complete. Upon completion of the treatment, the dental professional may, at his or her discretion, have the patient use an Invisalign retainer or go directly to a conventional retainer.

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 Invisalign are consistent with those of traditional orthodontics. Dental professionals can complete our initial training within two days. Subsequently, we provide additional clinical support and we encourage them to attend continuing education classes, seminars and workshops.
- *Expanded patient base*. Currently, approximately two million people annually elect treatment by orthodontists in the U.S. These patients represent approximately 1 percent of the population of people with malocclusion. Of these, we estimate approximately 40 percent, or approximately 800,000 patients have mature dentition with mild to moderate malocclusion and are therefore potential candidates for Invisalign. We believe that Invisalign will allow dental professionals to attract patients who would not otherwise seek orthodontic treatment.
- *Decreased dental professional and staff time*. Invisalign eliminates the need for time-intensive processes such as adjusting archwires during the course of treatment and removing the appliances at the conclusion of treatment. As such, use of Invisalign reduces dental professional and staff chair time and can increase practice throughput.
- *Practice productivity*. We believe that as dental professionals move to a higher volume of Invisalign patients, the dental professionals will be able to better leverage their existing resources, including office space and staff time, resulting in an increase in daily patient appointments and practice productivity.

Benefits to the Patient

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

Limitations of Invisalign

In some instances, Invisalign 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 Invisalign to the patient may be greater than for conventional braces. Dental professionals must also incorporate our manufacturing cycle times into their overall treatment plan. Once a dental professional submits a case to us, there is generally a turn-around time of a month or more before the corresponding Aligners are delivered. Aligners may not be appropriate for all cases, such as severe malocclusion, which may require Aligners to be used in combination with conventional braces for optimal results. In addition,

because Aligners are removable, treatment using Invisalign depends on patients wearing their Aligners as recommended. Some patients may experience a temporary period of adjustment to wearing Aligners that may mildly affect speech. In some instances, patients have experienced scratched or irritated gums, cheeks and lips and in some rare instances allergic reactions have occurred. We believe that these limitations are generally outweighed by the many benefits of Invisalign to both patients and dental professionals.

Our Target Market and Patient Base

Medical devices are classified into one of three classes based on the controls necessary to reasonably assure their safety and effectiveness. Class I or II devices require the manufacturer to submit a pre-market notification to the Food and Drug Administration, or the FDA, requesting permission for commercial distribution, which is known as 510(k) clearance. We obtained our 510(k) clearance in September 1998. Our 510(k) clearance allows us to market Invisalign to treat patients with any type of malocclusion 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.

As noted above, approximately two million people annually elect treatment by orthodontists in the U.S. These patients represent approximately one percent of the population of people with malocclusion. Of these, we estimate 40 percent, or more than 800,000 patients, have mature dentition and are therefore potential candidates for Invisalign.

Our market research indicates that the vast majority of people with malocclusion who desire treatment do not elect traditional treatment because of its many limitations. We believe that, since Invisalign addresses the primary limitations of braces, persons with malocclusion will be more likely to seek treatment. We believe that adults, who are particularly sensitive to the aesthetic limitations of traditional treatment, represent our most immediate and significant market expansion opportunity.

Commercial sales of Invisalign commenced in the U.S. in July 1999. As of December 31, 2004 approximately 250,000 patients worldwide are either currently in, or have completed, treatment using Invisalign. Internationally, we operate through three business units divided among the geographic regions of Europe, Asia-Pacific and Latin America. In 2004, international sales accounted for 9.9% of our net revenues.

In each of fiscal 2004, 2003 and 2002, no single customer accounted for 10% or more of our total revenues.

Business Strategy

Our objective is to establish Invisalign as the standard method for treating orthodontic malocclusion. Key elements of our strategy include the following:

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

Educate future orthodontists and general practitioners. By educating dental students and orthodontic residents on the benefits of the Invisalign technique, we believe they will be more likely to use this technology in their future practices and offer Invisalign as a treatment option. Currently, we have incorporated the Invisalign technique into selected orthodontic and dental undergraduate curriculums. In 2005, we intend to continue the integration of Invisalign into the programs of additional universities and post-graduate institutions.

Stimulate demand for Invisalign treatment. Our market research indicates that the vast majority of people with malocclusion who desire treatment do not elect traditional treatment because of its many limitations. 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. We advertise nationally using a broad marketing mix to drive consumer and dental professional demand and to reinforce the breadth of applicability of Invisalign. In October 2001, we expanded our training of dental professionals in our domestic market to include general practitioner dentists. As of December 31, 2004, we had trained approximately 29,700 dental professionals worldwide on the use and benefits of Invisalign.

Improving the collaboration and referral relationships between orthodontists and GPs. We have two customer channels: the orthodontist and the general practitioner dentist, or GP. We have historically generated a majority of our revenues from orthodontists. There exists, however, 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 believe that improved collaboration is beneficial to the orthodontist and the GP and will accelerate growth in Invisalign cases and consequently increase our revenues. In addition, although we expect that orthodontists will continue to treat the majority of complex cases and continue to drive research for expanding Invisalign applications, we expect that the percentage of revenue generated by GPs will increase, largely due to the fact that there are significantly more GPs than orthodontists. In 2005, we expect that GPs will generate a majority of our revenue. We believe this expected increase in the number of cases treated by GPs will result in an increase in the overall market for Invisalign as patients that would not have otherwise sought orthodontic treatment are introduced to Invisalign by GPs. Information regarding risks related to our expectation that orthodontists and GPs will collaborate may be found in Part II, Item 7 of this Report on Form 10-K under the heading “Risk Factors.”

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.

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. Information regarding risks associated with failure to protect our proprietary technology and our intellectual property rights may be found in Part II, Item 7 of this Report on Form 10-K under the heading “Risk Factors.”

Expand utilization within clinician practices. Invisalign can be used to provide complete treatment for patients with mature dentition over a broad range of malocclusions. In addition, we believe that Invisalign can be incorporated into many treatment plans for severe malocclusion, including severe crowding treated either with or without extraction and treatment requiring orthognathic surgery. We initiated new studies in fiscal 2004 with universities worldwide to further explore these treatments as we continue to make additional improvements to our product.

Manufacturing

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

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

As of December 31, 2004, we employed a manufacturing staff in the U.S. and Costa Rica of approximately 539 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. We outsource the fabrication and packaging of Aligners to a contract manufacturer based in Juarez, Mexico. Information regarding risks associated with our manufacturing process and foreign operations may be found in Part II, Item 7 of this Report on Form 10-K under the heading "Risk Factors."

The Invisalign Treatment Process

The Invisalign treatment process comprises the following five stages:

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

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

Preparation of computer-simulated treatment and viewing of treatment using ClinCheck™. In Costa Rica we transform this initial digital model into a customized, three-dimensional treatment plan that simulates appropriate tooth movement in a series of two-week increments. This simulation is then reviewed for adherence to prescribed clinical, treatment and quality standards. Upon passing review, the simulation is then made available to the prescribing dental professional via ClinCheck™, which is available on our websites located at *www.invisalign.com* and *www.aligntech.com*. The dental professional then reviews the ClinCheck™ simulation

and determines whether to ask us to make adjustments. By reviewing and amending the treatment simulation, the dental professional retains control over the treatment plan and, thus, participates in the customized design of the Aligners. At this point, the dental professional may also invite the patient to review ClinCheck™, allowing the patient to see the projected course of treatment. The dental professional then approves the proposed treatment and, in doing so, engages us for the manufacture of corresponding Aligners.

Construction of molds corresponding to each step of treatment. We use the approved ClinCheck™ simulation to construct a series of molds of the patient's teeth. Each mold is a replica of the patient's teeth at each two-week stage of the simulated course of treatment. These molds are fabricated at our Santa Clara, California manufacturing facility using stereolithography that we have adapted for use in orthodontic applications.

Manufacture of Aligners and shipment to the dental professional. From these molds, our contract manufacturer in Mexico fabricates Aligners by pressure-forming polymeric sheets over each mold. The Aligners are then trimmed, polished, cleaned and packaged. Following final inspection, the Aligners are shipped directly to the prescribing dental professional. We ship all of the Aligners in a single batch. In certain cases, dental professionals may use Invisalign in conjunction with clear 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 prescription form, quantifying the amount of space to be created through enamel reduction, location, and timing of IPR.

Throughput Management

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

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

Quality Assurance

Align's quality system is in compliance with the Food & Drug Administration's Medical Device regulations, 21CFR Part 820, and Health Canada's Medical Device Regulations. We are certified to EN ISO 13485:2003, internationally recognized standards for Medical Device manufacturing and ISO 13485:1996, recognized standards of the Council of Canada. Align has a formal, documented quality system by which quality objectives are defined, understood and achieved. Systems, processes and procedures are implemented to ensure high levels of product and service quality. We monitor the effectiveness of the quality system based on internal data and direct customer feedback and strive to continually improve our systems and processes, taking corrective action, as needed.

Since we custom manufacture Aligners on a build-to-order basis, we do not offer refunds on our products. Because each ClinCheck™ and each Aligner is unique, we inspect 100% of the product at various points in the manufacturing process, to ensure that the product meets our customers' expectations. Aligners are subject to the Invisalign product warranty, which covers defects in materials and workmanship. Our materials and workmanship warranty is in force until the Invisalign case is completed. In the event the Aligners fall within the

scope of the Invisalign product warranty, we will replace the Aligners at our expense. Our warranty is contingent upon proper use of the Aligners for the purposes for which they are intended. If a patient chooses not to wear the Aligners, and as a result, requests additional Invisalign treatment, the dental professional pays the additional expense of the replacement Aligners.

The Invisalign product warranty does not provide any assurances regarding the outcome of treatment using Invisalign. Actual treatment results may deviate significantly from the approved ClinCheck™ treatment plan. Deviations not covered under warranty have typically been the result of unpredictable biological factors, such as variations in bone density or tooth topography and abnormal jaw growth. 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.

In the event that a dental professional wishes to effect additional adjustments to a patient's treatment when the actual treatment results are in accordance with the approved ClinCheck™ treatment plan, the dental professional may request a case refinement or additional Aligners. Our pricing policy includes the future delivery of one case refinement in the price of each case and offers additional case refinements at the dental professional's expense. In addition, should a dental professional request a replacement for a lost Aligner, we charge the dental professional for the cost of the replacement Aligner.

Sales and Marketing

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

Professional Marketing

Our sales and support staff has been engaged in marketing Invisalign to orthodontists since July 1999. In 2001, we began marketing Invisalign to general practitioner dentists in our domestic market. We provide training, certification, marketing and clinical support to orthodontists and general practitioner dentists in the U.S. and Canada, which we consider our domestic market, and internationally.

As of December 31, 2004, we had trained approximately 29,700 dental professionals worldwide to use Invisalign. Of those dental professionals trained, approximately 70% are dental professionals in our domestic market (United States and Canada). Within our domestic market, we have trained approximately 7,700 orthodontists and approximately 13,800 general practitioner dentists. 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 prescription form, clinical tips and techniques, guidance on pricing and instructions on interacting with our ClinCheck™ software and the many other features of our website.

Invisalign relies on the same orthodontic principles that apply to traditional treatment, and we present our training material in a manner consistent with dental professionals' training and experience. Our success in training a large number of dental professionals confirms our belief that training represents a minimal barrier to adoption for most dental professionals.

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.

There are over 131,000 active general practice dentists in the U.S. and Canada. 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.

Consumer Marketing

Our national consumer marketing efforts primarily focus on television advertising and are supported by other advertising media and public relations. We advertise nationally using a broad marketing mix to drive consumer and dental professional demand.

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

- an orthodontist;
- a general practice dentist;
- direct-to-consumer mail advertising and public relations efforts;
- other Invisalign patients;
- our toll-free support line (1-800-INVISIBLE); and
- our website, which can be accessed at either *www.invisalign.com* or *www.aligntech.com*.

Our marketing efforts have generated substantial consumer interest directed toward our telephone support line and our website. Our telephone support line and our website not only provide consumers with information on Invisalign, but also allow us to channel consumer interest to dental professionals. We have outsourced the telephone support function to a national call center operator.

Research and Development

Prior to commercial launch in July 1999, our research and development strategy had three primary objectives: developing the Invisalign product, establishing the ability of Invisalign to treat malocclusion and developing software and processes to enable the manufacturing of Aligners in volume. Since our commercial launch, our research and development effort has 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 $15.8 million for fiscal 2004 and $13.1 million for each of fiscal 2003 and 2002.

In an effort to demonstrate Invisalign's broad treatment capabilities, a series of clinical case studies and articles have been published that highlight the applicability of Invisalign to malocclusion cases, including those of severe complexity. We are also undertaking post-marketing studies and making additional technological improvements to the product and manufacturing process. Our product development team is testing enhanced materials and a number of complementary products that we expect will provide additional revenue opportunities.

Intellectual Property

We believe our intellectual property position represents a substantial business advantage. As of December 31, 2004, we had 56 issued U.S. patents, 82 pending U.S. patent applications, and numerous foreign issued patents, as well as pending foreign patent applications.

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. Information regarding risks associated with failure to protect our proprietary technology and our intellectual property rights may be found in Part II, Item 7 of this Report on Form 10-K under the heading "Risk Factors."

Competition

We compete for the attention of dental professionals with manufacturers of traditional orthodontic appliances (or wires and brackets), which include 3M Company, Sybron Dental Specialties and Dentsply International, Inc. We also compete directly with established companies that manufacture and distribute products that are similar in use to Invisalign, including the product called Red, White & Blue manufactured and distributed by Ormco Orthodontics, a wholly owned subsidiary of Sybron Dental Specialties. In the future, we may face competition from early stage and more mature companies who enter our target markets to manufacture and distribute products that are similar in use to Invisalign. Information regarding risks associated with increased competition may be found in Part II, Item 7 of this Report on Form 10-K under the heading "Risk Factors."

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

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

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

Government Regulation

FDA's Quality System Regulation for Medical Devices. The Invisalign Aligners are regulated as a Class I medical device by the Food and Drug Administration ("FDA"). Accordingly, our product development, manufacturing processes, packaging, labeling, handling, storage and distribution activities are subject to extensive regulations enforced by both state and federal regulatory authorities.

The Aligners are manufactured by The TECMA Group, LLC, a contract manufacturer based in Mexico. As a medical device company, we are required to ensure that our contract manufacturer complies with the FDA's Quality System regulations. As a result, we have ensured that TECMA is registered with the FDA as a medical device manufacturer and its manufacturing processes comply with regulatory requirements. In addition, TECMA is certified to ISO 9000 standards and is subject to inspection by an independent ISO agency. TECMA has dedicated an area in its facilities and trained personnel for the manufacture and distribution of Invisalign. We conduct frequent visits to the Mexico facility to monitor TECMA's performance and its compliance with regulatory requirements and we also perform independent audits of their quality system.

In November 1998, we received 510(k) pre-market clearance by the FDA for the Invisalign system, allowing us to market Invisalign in the U.S. The manufacture and distribution of Invisalign are subject to continuing oversight by the FDA, including routine inspections to determine compliance with Quality System

regulations. Our facility is registered with the State of California as a medical device manufacturer and is subject to state inspections.

During inspections of our facility and those of our contract manufacturer, if the FDA determines that we or our contract manufacturer have failed to comply with the applicable FDA regulations, it can institute a wide variety of enforcement actions, ranging from a public Warning Letter to more severe sanctions, including but not limited to financial penalties, withdrawal of our right to market products and criminal prosecution.

Health Canada's Medical Device Regulations. We sell the Invisalign system throughout Canada. As such, we are required to comply with the Health Canada's Medical Device Regulations and we believe we are in compliance with their regulations.

European Union's MDD Requirements & ISO 13485. In Europe, the Invisalign system is regulated as a custom device and as such, we follow the Medical Device Directives and are registered with an applicable Competent Authority in Europe. Our facilities are ISO 13485 certified, which facilitates commercialization of Invisalign in Europe and other countries outside of the United States.

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 health information. Confidentiality of patient records and the circumstances under which these records may be maintained and 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 the law requires that we execute Business Associate Agreements with orthodontists and other healthcare professionals and comply with the Privacy Standard when we handle patient information and records. We have designed our service offerings to enable compliance with HIPAA and applicable corresponding state laws and regulations. Compliance with these laws and regulations is costly. Our success may be dependent on the success of healthcare participants in dealing with HIPAA requirements and the Privacy Standard. Additionally, the HIPAA Security Standard, which goes into effect in April 2005, requires that we implement safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of the electronic protected health information that we create, receive, maintain or transmit pursuant to our Business Associate Agreements with health care professionals. Compliance with the Security Standard could require complex changes in our internal systems and could be costly.

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 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 of the Social Security Act 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 payment 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, 2004, we had approximately 969 employees, approximately 413 of whom were employed in the U.S., 461 in Costa Rica, 52 in Europe, 22 in Russia, 9 in Latin America, 11 in Asia/Pacific and 1 in the United Arab Emirates. As of December 31, 2004, of our U.S. employees, approximately 89 were employed in manufacturing, 93 were employed in various management, administrative and operations support positions, 74 were marketing and customer support staff, 98 were employed in sales, 33 were employed in engineering and 26 were employed in research and development.

Executive Officers

The following table sets forth certain information regarding our executive officers as of March 3, 2005:

Name	Age	Position
Thomas M. Prescott	49	President and Chief Executive Officer
Eldon M. Bullington	53	Vice President, Finance and Chief Financial Officer
Roger E. George	39	Vice President, Legal and Corporate Affairs General Counsel and Corporate Secretary
Len M. Hedge	47	Vice President, Operations
David S. Thrower	40	Vice President, Global Marketing
Patricia L. Wadors	40	Vice President, Human Resources
Cecilia Claudio	50	Vice President, Engineering and Chief Information Officer
Robert D. Mitchell	43	Vice President, World Wide Sales and Customer Care
Rok Sribar	40	Vice President, Research & Development

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.

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

Len M. Hedge has served as our Vice President, Operations since March 2002, and served as our Vice President of Manufacturing from January 1999 to March 2003. Mr. Hedge served as Vice President of Operations for Plynetics Express Corporation, a rapid-prototyping and stereolithography services supplier, from December 1996 to December 1998. From October 1991 to December 1996, Mr. Hedge worked at Beckman Instruments Corporation as Manager for Prototype Manufacturing and Process Development.

David S. Thrower has served as our Vice President, Global Marketing since August 2002. Prior to joining Align, Mr. Thrower served as Senior Vice President of Global Marketing and Sales for BioSource International, a publicly-held life science reagent company, from October 2000 until July 2003. Prior to BioSource, Mr. Thrower served as Senior Vice President, Global Marketing at GN ReSound, Inc. a hearing and communications device company, from July 1998 until December 1999. Mr. Thrower also has previous experience in large and small independent management consulting firms, including five years with Boston-based Bain & Company.

Patricia L. Wadors has served as our Vice President, Human Resources since January 2004. Prior to joining Align, Ms. Wadors spent eight years Applied Materials in both Human Resources and Operations. Her last position at Applied Materials was Senior Director of Human Resources for the PDC Product Group. Prior to Applied Materials, Ms. Wadors held Human Resources positions at Merck Pharmaceutical, Viacom International and Calvin Klein Cosmetics.

Cecilia Claudio has served as our Vice President, Engineering and Chief Information Officer since September 2004. Prior to joining Align, Ms. Claudio was Executive Vice President and Chief Information Officer of Zurich Financial Services, an insurance-based financial services provider and the parent company of Farmers Insurance Group, Inc., where Claudio served as Senior Vice President and Chief Information Officer from 1998 to 2003. Prior to this, Ms. Claudio held information technology and computer service positions at Xerox, Mervyn's, The Gap and Olivetti Worldwide. Ms. Claudio is the named Executive-in-Residence at Clearstone Venture Partners, a venture capital firm investing in California-based technology innovation. In addition, Ms. Claudio currently serves on the Board of Directors of Sybase, Inc.

Robert D. Mitchell has served as our Vice President, Worldwide Sales and Customer Care since July 2004. Prior to joining Align, Mr. Mitchell spent 16 years at Bloomington, IN-based Cook Incorporated, a leading designer, manufacturer and global distributor of minimally invasive medical device technology for diagnostic and therapeutic procedures. At Cook, Mr. Mitchell held a number of senior management positions and spent several years working outside of the United States as a Sales and Marketing Director. Most recently, Mr. Mitchell was the Vice President and Director for Global Sales and Marketing—Radiology, Cardiology, Vascular Surgery, Critical Care, Surgical.

Rok Sribar has served as our Vice President, Research & Development since February 2005. Prior to joining Align, Mr. Sribar spent eight months at Symbol Technologies, an enterprise mobility company, where he was Vice President, responsible for company-wide Product Lifecycle Management. Prior to this, Mr. Sribar spent four years with Sun Microsystems, most recently as Senior Director responsible for company-wide Product Lifecycle Process and related business systems. From 1994 to 2000, Mr. Sribar worked for General Electric Company, most recently at GE Medical Systems, where he was Manager of Digital X-Ray Detectors Engineering organization.

Our executive officers are appointed by the Board of Directors and serve until their successors have been duly appointed and qualified or until their earlier resignation or removal. There are no family relationships among any of our directors or executive officers.

ITEM 2. PROPERTIES.

Our headquarters are located in Santa Clara, California. We lease approximately 110,000 square feet of space where we house our manufacturing, customer support, software engineering and administrative personnel. We lease our Santa Clara facilities under three leases, which expire in June 2010. The combined monthly base

rent for the Santa Clara facilities is approximately $235,000. Commencing July 1, 2005, however, the combined monthly rent will be reduced to approximately $61,000. In addition to the amended lease terms, on the first day of each calendar month on and after July 1, 2005, $10,575 will be deducted from the $1,269,000 security deposit previously paid by us to the lessor and such amount will be applied against the monthly base rent for the Santa Clara facilities. Upon the occurrence of certain events, we will lease an additional 15,704 square feet of space at our Santa Clara facilities for a monthly rent of $25,000.

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 $53,000. 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 $27,000. The lease for this facility expires in 2014.

We operate a facility in Moscow, Russia. The facility comprises approximately 6,000 square feet of office space where we conduct certain research and development activities. The monthly rent for the Russian facility is approximately $17,000. The lease for this facility expires on April 10, 2005, and we do not expect to purchase or lease property in Moscow, Russia after this time.

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.

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. Among other things, the complaint alleges tort, contract, statutory and common law causes of action arising from OrthoClear and the individual defendants' alleged plan to unlawfully utilize Align's intellectual property, confidential information and employees. The complaint also alleges that OrthoClear, Chishti and other defendants are in breach of contractual obligations, statutory law and common law for attempting to intentionally interfere and disrupt our ongoing business operations and improperly gain access to our customer relationships and trade secrets. The complaint seeks injunctive relief and monetary damages in an amount to be determined.

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

On February 18, 2005, the Court granted our request for and issued a Temporary Restraining Order ("TRO") prohibiting OrthoClear and the individual OrthoClear defendants from engaging, assisting, or participating, directly or indirectly, in soliciting, inducing to leave, recruiting, or encouraging any current Align employee or consultant to terminate or alter his or her employment or business relationship with Align or attempting to do the same. The Court also granted our request and issued a TRO prohibiting OrthoClear and the individual OrthoClear defendants from disclosing, using, lecturing upon or publishing any of our proprietary information without our express prior written permission. In addition, in response to a cross-application for TRO filed by certain OrthoClear defendants, the Court enjoined Chishti and the Align Parties from disparaging each other in such a manner as to violate the mutual non-disparagement clause contained in the Separation Agreement between Align and Chishti dated as of March 27, 2002. The Court also enjoined the Align Parties from advising any Align

employee or consultant that he or she will be subject to criminal charges or a civil lawsuit if that person elects to change his or her employment status with Align, unless Align has good cause to believe criminal conduct has been or will be committed or that a civil cause of action will lie against the employee or consultant. The Court also required the Align Parties to refrain from taking any actions inconsistent with Federal or State securities laws relating to the issuance or redemption of Align stock. The Court scheduled an Order to Show Cause hearing why a Preliminary Injunction should not be issued in accordance with the terms of the TRO for March 8, 2005. On March 1, 2005, the Court signed a Stipulated Preliminary Injunction Order, whereby the Court ordered that the March 8th hearing date be vacated and further ordered that the express terms of the TRO remain in place until the earlier of (i) trial, (ii) written agreement of the parties or further Court order setting an earlier termination, or (iii) as to the preliminary injunction regarding non-solicitation or recruiting of Align employees or consultants only, October 27, 2005. Align denies the allegations in the Cross-Complaint, and will vigorously defend against such claims. No trial date has been set in the case.

On January 6, 2003, Ormco Corporation ("Ormco") filed suit against us in the United States District Court for the Central District, Orange County Division, asserting infringement of U.S. Patent Nos. 5,447,432, 5,683,243 and 6,244,861. The complaint seeks 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 responded to Ormco's counterclaims on April 2, 2003. 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 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 asserted. Fifth, the Court also granted our summary judgment motion that our patents are not unenforceable and granted Ormco's summary judgment motion that Ormco 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 new evidence. Ormco 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 motion in part, finding certain claims of our 6,398,548 patent to be invalid in view of prior use evidence. At this stage, only our remedies for Ormco's adjudged infringement remain at issue.

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

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

There were no matters submitted to a vote of security holders during the fourth quarter of fiscal 2004.

PART II

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

(a) Price Range of Common Stock

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

	High	Low
Year Ended December 31, 2004:		
Fourth quarter	$16.34	$ 8.97
Third quarter	$18.72	$13.90
Second quarter	$22.80	$17.36
First quarter	$21.79	$16.69
Year Ended December 31, 2003:		
Fourth quarter	$18.61	$12.85
Third quarter	$14.30	$10.45
Second quarter	$12.60	$ 5.75
First quarter	$ 6.13	$ 2.63

On March 1, 2005, the last reported sale price of our common stock on The NASDAQ National Market was $7.40 per share. As of February 28, 2005 there were approximately 319 holders of record of our common stock.

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.

The information required by this item regarding equity compensation plans is incorporated by reference to the information set forth in Item 12 of this Annual Report on Form 10-K.

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, 2004. The selected consolidated financial data is qualified in its entirety and should be read in conjunction with the Consolidated Financial Statements and related Notes thereto set forth on pages 50 to 72 and "Management's Discussion and Analysis of Financial Condition and Results of Operations" beginning on page 22. We have derived the consolidated statements of operations data for the years ended December 31, 2004, 2003 and 2002 and the balance sheet data as of December 31, 2004 and December 31, 2003 from the consolidated audited financial statements included elsewhere in this Annual Report on Form 10-K. The consolidated statement of operations data for the years ended December 31, 2001 and 2000 and the balance sheet data as of December 31, 2002, 2001 and 2000 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)
(unaudited)

	Year Ended December 31,				
	2004	2003	2002	2001	2000
Consolidated Statement of Operations Data:					
Total revenues	$172,830	$122,725	$ 69,698	$ 44,808	$ 6,741
Gross profit (loss)	$115,304	$ 71,160	$ 24,707	$ (2,022)	$ (13,510)
Profit (loss) from operations	9,765	(19,937)	(72,935)	(100,769)	(81,115)
Other income (expense), net	(3)	(101)	116	1,730	(7,633)
Net profit (loss) before provision for income taxes	9,762	(20,038)	(72,819)	(99,039)	(88,748)
Provision for income taxes	994	84	—	10	—
Net profit (loss)	8,768	(20,122)	(72,819)	(99,049)	(88,748)
Dividend related to beneficial conversion feature of preferred stock	—	—	—	(11,191)	(53,516)
Net profit (loss) available to common stockholders	$ 8,768	$ (20,122)	$(72,819)	$(110,240)	$(142,264)
Net profit (loss) per share available to common stockholders, basic	$ 0.15	$ (0.35)	$ (1.52)	$ (2.61)	$ (25.64)
Shares used in computing net profit (loss) per share available to common stockholders, basic	59,963	57,758	47,878	42,247	5,548
Net profit (loss) per share available to common stockholders, diluted	$ 0.14	$ (0.35)	$ (1.52)	$ (2.61)	$ (25.64)
Shares used in computing net profit (loss) per share available to common stockholders, diluted	64,089	57,758	47,878	42,247	5,548

	December 31,				
	2004	2003	2002	2001	2000
Consolidated Balance Sheet Data:					
Working capital	$ 61,886	$ 39,737	$ 41,160	$ 62,172	$ 18,273
Total assets	130,712	102,202	92,856	118,218	70,561
Total long-term liabilities	25	1,849	3,837	980	1,455
Convertible preferred stock and preferred stock warrants	—	—	—	—	130,691
Stockholders' equity (deficit)	$ 85,739	$ 62,976	$ 64,347	$ 97,827	$ (84,674)

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. Align Technology received FDA clearance to market Invisalign in 1998, and we began commercial operations in July 1999.

The Invisalign product is manufactured in phases. The initial step in our manufacturing process is the creation of electronic treatment plans using ClinCheck™, an internally developed computer-modeling program. These treatment plans are developed in our operations facility in Costa Rica and are transmitted electronically back to the prescribing dental profession via ClinCheck™. ClinCheck™ allows dental professionals to simulate treatment in three dimensions by modeling two-week stages of tooth movement. Upon the dental professional's approval of the ClinCheck™ simulation, we use the data underlying the simulation, in conjunction with stereolithography technology, to manufacture Aligner molds. A third party manufacturer in Mexico uses these molds to fabricate Aligners. Aligners are thin, clear plastic, removable dental appliances that are manufactured in a series to correspond to each two-week stage of the ClinCheck™ simulation. Aligners are customized to perform the treatment prescribed for an individual patient by dental professionals using ClinCheck™. After the Aligners are produced, the third party manufacturer ships the finished products to our customers.

We have two customer channels: the orthodontist and the GP. We have historically generated a majority of our revenues from orthodontists. There exists, however, 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 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. We are committed to improving the collaboration and referral relationships between orthodontists and GPs. We believe that improved collaboration is beneficial to the orthodontist and the GP and will accelerate growth in Invisalign cases and consequently increase our revenues. In addition, although we expect that orthodontists will continue to treat the majority of complex cases and continue to drive research for expanding Invisalign applications, we expect that the percentage of revenue generated by GPs will increase, largely due to the fact that there are significantly more GPs than orthodontists. In 2005, we expect to generate the majority of our revenue from GPs. We believe the expected increase in the number of cases treated by GPs will result in an increase in the overall market for Invisalign as patients that would not have otherwise sought orthodontic treatment are introduced to Invisalign by their GPs.

Sales to orthodontists and GPs in our domestic market represented approximately 90% of our total revenue during fiscal 2004. We expect to continue to increase our penetration into our domestic market. We will also focus our efforts towards the expansion of our international markets. In fiscal 2005, we expect to increase our infrastructure and support in key countries in Europe and initiate strategic moves in Asia, specifically in Japan, in order to take advantage of this emerging opportunity.

Clinical education and ongoing training are critical to our customers' success with Invisalign. We certify several thousand new orthodontists and GPs to use Invisalign annually, and we certified approximately 4,200 orthodontists and GPs during fiscal 2004, and we expect to certify approximately 4,000 during fiscal 2005. Additionally, we share product enhancements, treatment tips and techniques, and clinical research data with our

customers on an ongoing basis through continuing education in the form of hundreds of provider workshops, study clubs and online educational centers. This information ensures that our customers understand Invisalign's expanding applications and best uses, and feel confident about treating more of their patients with Invisalign.

Net revenue for the year ended December 31, 2004 was $172.8 million, an increase of 41% as compared to the year ended December 31, 2003. The increase was driven primarily by an increase in the number of cases submitted for the domestic general practitioner channel. Revenues during the fourth quarter of fiscal 2004 were reduced by approximately $1.9 million as a result of our case refinement policy change described below. In certain instances, adjustments to a patient's teeth are made in the final stages of orthodontic treatment. To make these final adjustments and move a patient's teeth to the final desired position, dental professionals may elect to use Invisalign as a finishing treatment tool and order newly manufactured Aligners. These newly manufactured Aligners, or "case refinement", are not provided with the Aligners produced as part of the initial treatment plan and are manufactured only upon the request of the dental professional if final adjustments are desired. Align's case refinement policy allows doctors to order one case refinement as part of their original lab fee, provided they submit the order prior to the point in time when the case is deemed completed, or the "case expiration". Prior to the policy change announced in the fourth quarter of 2004, Align deemed the case expiration date to occur on the 90th day after the expected end of treatment. Under the new policy, the case expiration date is deemed to occur on the 180th day after the expected end of treatment. Gross profit percentage increased in fiscal 2004 to 67% from 58% for fiscal 2003. The increase was primarily attributable to improved fixed cost absorption related to increasing volumes and continued manufacturing process improvements in both our treatment operations facility in Costa Rica and in the aligner fabrication process.

We recently filed a multi-claim lawsuit against one of our founders and certain former employees. Among other things, the lawsuit alleges tortious and illegal actions arising out of the defendants' plan to unlawfully utilize our intellectual property, confidential information and employees. In addition, the lawsuit alleges that the defendants are in breach of contractual obligations, statutory law, and common law, for the purpose of attempting to intentionally interfere and disrupt our on-going operations and improperly gain access to our customer relationships and trade secrets. On February 15, 2005, OrthoClear, Chishti and certain other defendants filed a multi-claim cross-complaint against Align and certain of our executive officers, senior management and a director alleging conspiracy, breach of contract, libel, slander, unjust enrichment, international interference with prospective economic advantage and unfair competition. See Part I Item 3 of this Form 10-K for a more complete summary of this legal proceeding. We are in the early stages of evaluating the impact, if any, the events underlying this litigation may have on our business, competitive position in the market, our ability to retain our sales representatives and other matters related to the sale of our product. In addition, although this lawsuit is in the early stages, litigation of this type, whether or not ultimately determined in our favor or settled by us, is costly and diverts the efforts and attention of our management and technical personnel from normal business operations. As a result, this litigation could adversely affect our results of operations and cause a decline in our stock price.

Changes to previously announced fiscal 2004 fourth quarter and fiscal year-end results

On January 26, 2005, we announced our results for the fourth quarter and fiscal year ended December 31, 2004. Subsequent to that date, we adjusted the cost of revenues for the quarter and year ended December 31, 2004 to include an additional $383,000 resulting from asset impairment charges identified by the Company relating to manufacturing fixed assets at our international manufacturing facility. Net profit for the quarter and year ended December 31, 2004 was reduced by $383,000 and there was no change to basic or diluted earnings per share.

Set forth below is a reconciliation of our reported results from our January 26, 2005 press release to amounts reported in the Annual Report on Form 10-K which reflects the adjustment (in thousands):

For the year ended December 31, 2004	Previously Announced	Increase (Decrease)	Reported in Annual Report
Consolidated Statement of Operations Data:			
Cost of revenues	$ 57,143	$ 383	$ 57,526
Gross profit	115,687	(383)	115,304
Profit from operations	10,148	(383)	9,765
Net profit	$ 9,151	$(383)	$ 8,768

Set forth below is a reconciliation of our reported fourth quarter results from our January 26, 2005 press release to amounts reflected in Item 8, Consolidated Financial Statements and Supplementary Data, Quarterly Results of Operations, which reflects the adjustment (in thousands):

For the quarter ended December 31, 2004	Previously Announced	Increase (Decrease)	Reported in Annual Report
Consolidated Statement of Operations Data:			
Cost of revenues	$14,578	$ 383	$14,961
Gross profit	29,077	(383)	28,694
Profit from operations	1,039	(383)	656
Net profit	$ 1,504	$(383)	$ 1,121

Results of Operations

Comparison of Years Ended December 31, 2004 and 2003:

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

(Amounts in $ million)	Year Ended December 31, 2004	Year Ended December 31, 2003	Increase*	Percentage Increase
Domestic:				
Orthodontic	$ 86.1	$ 72.1	$14.0	19%
GP	$ 62.0	$ 31.5	$30.5	97%
International	$ 16.4	$ 11.7	$ 4.7	40%
Total Invisalign	$164.5	$115.3	$49.2	43%
Other revenue	$ 8.3	$ 7.4	$ 0.9	12%
Total Revenue	$172.8	$122.7	$50.1	41%

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

Cost of revenues. Cost of revenues for the year ended December 31, 2004 was $57.5 million compared to $51.6 million for the year ended December 31, 2003. Cost of revenues includes the salaries for staff involved in production, the cost of materials and packaging, shipping costs, depreciation on the capital equipment used in the production process, training costs and the cost of facilities. Also included in cost of revenues are stock-based compensation expenses of $0.9 million and $2.6 million for the years ended December 31, 2004 and 2003,

respectively. Gross profit for the year ended December 31, 2004 was $115.3 million or 67% of revenue, compared to a gross profit of $71.2 million or 58% of revenue for the year ended December 31, 2003. The higher gross profit for the year ended December 31, 2004 as compared to the year ended December 31, 2003 is primarily attributable to improved fixed cost absorption related to increasing volumes, continued manufacturing process improvements in both our treatment operations facility in Costa Rica and in the aligner fabrication process.

Sales and marketing. Sales and marketing expenses for the year ended December 31, 2004 were $55.9 million compared to $43.7 million for the year ended December 31, 2003. Sales and marketing expenses include sales force compensation (combined with travel related costs and expenses for professional marketing programs), conducting workshops and market surveys, advertising and dental professional trade show attendance. Sales and marketing expenses include stock-based compensation expenses of $0.7 million and $2.2 million for the years ended December 31, 2004 and 2003, respectively. The increase in sales and marketing expense of $12.2 million for the year ended December 31, 2004 as compared to the year ended December 31, 2003 resulted primarily from an increase in spending of $4.4 million related to incremental headcount in our North American sales and marketing work force, $0.9 million related to North America sales force training, $2.7 million related to our international workforce and outside services, and $5.9 million related to increases in media, advertising costs, marketing promotions and other related expenses. The increase in spending was partially offset by the decrease of $1.5 million in stock-based compensation expense. The increases during fiscal 2004 have been consistent with our marketing and sales initiatives and we expect these initiatives to continue in fiscal 2005. Accordingly, we expect sales and marketing expense to increase during fiscal 2005 as we continue to invest in sales force staffing, new media programs, web site enhancements, direct-to-consumer advertising and clinical education.

General and administrative. General and administrative expenses for the year ended December 31, 2004 were $33.9 million compared to $34.3 million for the year ended December 31, 2003. General and administrative expenses included salaries for administrative personnel, outside consulting services, legal expenses and general corporate expenses. General and administrative expenses include stock-based compensation expenses of $2.7 million and $7.1 million for the years ended December 31, 2004 and 2003, respectively. The $0.4 million decrease in general and administrative expenses for the year ended December 31, 2004 as compared to the year ended December 31, 2003 was primarily due to the decrease in stock-based compensation expense of $4.4 million and legal fees of $2.4 million. The decrease in litigation spending was primarily due to the settlement charge of $2.1 million included in general and administrative expenses for the year ended December 31, 2003 related to the conclusion of the Discus arbitration proceedings. The decreased expenses for the year ended December 31, 2004 as compared to the year ended December 31, 2003 was partially offset by increases of $4.2 million in payroll expenses related to additional headcount and $2.1 million in general corporate expenses.

Research and development. Research and development expenses for the year ended December 31, 2004 were $15.8 million and $13.1 million for the year ended December 31, 2003. Research and development expenses include the costs associated with software engineering, the cost of designing, developing and testing our products and conducting clinical and post-marketing trials. We expense our research and development costs as they are incurred. Research and development expenses included $1.6 million and $3.2 million of stock-based compensation for the years ended December 31, 2004 and 2003, receptively. The increase in research and development for the year ended December 31, 2004 as compared to the year ended December 31, 2003 of $2.7 million resulted from increased spending of $3.2 million for product improvement initiatives and the $1.1 million severance charge related to the departure of our vice president of engineering, partially offset by a $1.6 million decrease in stock-based compensation expense. For the fiscal 2005, we expect to increase research and development spending for new products, conducting clinical research and product improvement initiatives.

Interest and other income (expense), net. Interest income was $0.7 million for the year ended December 31, 2004 as compared to $0.5 million the year ended December 31, 2003. Interest and other expense was $0.7 million the year ended December 31, 2004 as compared to $0.9 million the year ended December 31, 2003. 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.

Income tax provision. Income tax provision for 2004 and 2003 was $1.0 million and $0.1 million, respectively. Our effective tax rate was 10.2% and 0.42% for fiscal 2004 and 2003, respectively. Our expected effective tax rate for fiscal 2005 is 10.0%. As of December 31, 2004, we had aggregate federal and state net operating loss carryforwards of $324.2 million. As of December 31, 2004, we have recorded a full valuation allowance for our existing net deferred tax assets due to uncertainties regarding their realization. We have aggregate federal and state research tax credit carryforwards of $6.9 million as of December 31, 2004. The federal and state net operating loss carryforwards expire beginning in the year 2017 for federal and 2005 for state purposes, if not utilized. Utilization of the federal net operating losses and credit carryforwards may be limited by the change of ownership provisions contained in Section 382 of the Internal Revenue Code. The federal research credit carryforwards expire beginning in the year 2017, if not utilized. The state research credit carryforward does not expire.

Stock-based compensation. In connection with the grant of stock options to employees and non-employees prior to 2001, we recorded deferred stock-based compensation as a component of stockholders' equity. Deferred stock-based compensation for options granted to employees is the difference between the fair value of our common stock on the date such options were granted and their exercise price. For stock options granted to non-employees, the fair value of the options, estimated using the Black-Scholes valuation model, is initially recorded on the date of grant. As the non-employee options vest, we remeasure the remaining unvested options, with the change in fair value from period to period represented as a change in deferred compensation. This stock-based compensation is amortized as charges to operations over the vesting periods of the options. For fiscal 2004 and 2003, we recorded amortization of deferred compensation of $5.1 million and $12.8 million, respectively.

We recorded expenses of $0.4 million and $1.3 million for fiscal 2004 and 2003, respectively, related to options granted to non-employees after January 26, 2001.

Historically, we have accelerated the vesting of options to several employees in connection with severance packages. These accelerations were accounted for as a charge to the consolidated statements of operations. We recorded $0.4 million for fiscal 2004 related to the departure of our vice president of engineering, and we recorded $1.0 million for fiscal 2003 related to certain other executives. This charge is equal to the intrinsic value of the options which was calculated as a difference between the exercise price of the accelerated options and the fair value of the common stock on the date of acceleration.

Comparison of Years Ended December 31, 2003 and 2002:

Revenues. Invisalign product revenues by channel and other revenue, which represented training and sales of ancillary products, for the year ended December 31, 2003 and 2002 are as follows:

(Amounts in $ million)	Year Ended December 31, 2003	2002	Increase*	Percentage Increase
Domestic:				
Orthodontic	$ 72.1	$48.7	$23.4	48%
GP	$ 31.5	$ 9.5	$22.0	232%
International	$ 11.7	$ 5.5	$ 6.2	113%
Total Invisalign	$115.3	$63.7	$51.6	81%
Other revenue	$ 7.4	$ 6.0	$ 1.4	23%
Total Revenue	$122.7	$69.7	$53.0	76%

* **Primary reasons for increase**: For the year ended December 31, 2003, growth in the domestic orthodontic and general practitioner channels over fiscal 2002 resulted primarily from higher case volumes driven by an increase in the number of participating clinicians, with the highest percentage increase resulting from the general practitioner channel.

Cost of revenues. Cost of revenues for the year ended December 31, 2003 was $51.6 million compared to $45.0 million for the year ended December 31, 2002. Cost of revenues include the salaries for staff involved in production, the cost of materials and packaging, shipping costs, depreciation on the capital equipment used in the production process, under/over absorbed manufacturing capacity, training costs and the cost of facilities. Included in cost of revenues are stock-based compensation expenses of $2.6 million and $3.4 million for the year ended December 31, 2003 and 2002, respectively. The year ended December 31, 2002 included restructuring charges of $0.6 million. Gross profit for the year ended December 31, 2003 was $71.2 million or 58% of revenue, compared to a gross profit of $24.7 million or 35% of revenue for the year ended December 31, 2002. The higher gross profit for the year ended December 31, 2003 as compared to fiscal 2002 is primarily attributable to a combination of manufacturing process efficiencies, and improved fixed cost absorption related to increasing volumes.

Sales and marketing. Sales and marketing expenses for the year ended December 31, 2003 were $43.7 million compared to $45.3 million for the year ended December 31, 2002. Sales and marketing expenses include sales force compensation (combined with expenses for professional marketing programs), conducting workshops and market surveys, advertising and attending dental professional trade shows. Sales and marketing expenses for the year ended December 31, 2003 and 2002 include stock-based compensation expenses of $2.2 million and $3.0 million, respectively. The decrease in sales and marketing expenses for the year ended December 31, 2003 as compared to the year ended December 31, 2002 resulted primarily from a decrease in spending of $2.3 million for international media and advertising and $1.7 million related to our restructuring of and reductions in our international sales and marketing work force. The year ended December 31, 2002 included restructuring charges of $1.2 million and no restructuring charges for the year ended December 31, 2003. The reduction of the international sales and marketing work force in fiscal 2003 and the restructuring charges in fiscal 2002 were part of the plan during the second half of fiscal 2002 to streamline worldwide operations. The decrease in sales and marketing expenses for the year ended December 31, 2003 as compared to the year ended December 31, 2002 were partially offset by an increase in spending of $3.9 million related to incremental headcount in our North American sales force and $0.5 million in incremental media and advertisement costs for the year ended December 31, 2003 as compared to the year ended December 31, 2002.

General and administrative. General and administrative expenses for the year ended December 31, 2003 were $34.3 million compared to $39.3 million for the year ended December 31, 2002. General and administrative expenses included salaries for administrative personnel, outside consulting services, legal expenses and general

corporate expenses. General and administrative expenses for the year ended December 31, 2003 and 2002 include stock-based compensation expenses of $7.1 million and $10.7 million, respectively. The decrease in general and administrative expenses for the year ended December 31, 2003 as compared to the year ended December 31, 2002 resulted primarily from a decrease in stock-based compensation of $3.6 million. Salary expense decreased in fiscal 2003 by $2.5 million related to reductions in the North American and international administrative work forces and restructuring charges decreased by $2.9 million to $0.5 million for the year ended December 31, 2003 as compared to $3.4 million for the year ended December 31, 2002. Additionally, depreciation, amortization and overhead expenses also decreased by approximately $3.4 million in fiscal 2003. Partially offsetting the decreases in spending were increases of $1.7 million in outside consultant costs and $3.6 million in incremental legal expenses related our litigation matters. Also offsetting the overall decrease in spending was a litigation settlement charge of $2.1 million included in general and administrative expenses for the year ended December 31, 2003 related to the conclusion of the Discus arbitration proceedings.

Research and development. Research and development expenses for both the years ended December 31, 2003 and 2002 were $13.1 million. Research and development expenses included the costs associated with software engineering, the cost of designing, developing and testing our products and conducting clinical and post-marketing trials. We expense our research and development costs as they are incurred. Research and development expenses included $3.2 million of stock-based compensation for both the years ended December 31, 2003 and 2002, respectively.

Interest and other income (expense), net. Interest and other income (expense) was ($0.1) million for the year ended December 31, 2003 and $0.1 million for the year ended December 31, 2002. Interest and other expenses increased by $0.2 million for the year ended December 31, 2003 compared to the year ended December 31, 2002. Interest income decreased by $0.4 million for the year ended December 31, 2003 as compared to the year ended December 31, 2002, primarily due to lower interest rates paid on cash, cash equivalent and marketable securities balances. Included in other expense is foreign currency translation gain, which increased $0.4 million for the year ended December 31, 2003 compared to the year ended December 31, 2002.

Stock-based compensation. In connection with the grant of stock options to employees and non-employees prior to 2001, we recorded deferred stock-based compensation as a component of stockholders' equity. Deferred stock-based compensation for options granted to employees is the difference between the fair value of our common stock on the date such options were granted and their exercise price. For stock options granted to non-employees, the fair value of the options, estimated using the Black-Scholes valuation model, is initially recorded on the date of grant. As the non-employee options vest, we revalue the remaining unvested options, with the change in fair value from period to period represented as a change in deferred compensation. This stock-based compensation is amortized as charges to operations over the vesting periods of the options. For the year ended December 31, 2003 and 2002, we recorded amortization of deferred compensation of $12.8 million and $16.0 million, respectively. Additionally, we recorded expenses of $1.3 million and $2.0 million for the years ended December 31, 2003 and 2002, respectively, related to options granted to non-employees.

We have accelerated the vesting of options to several employees in connection with severance packages. This acceleration was accounted for as a charge to the consolidated statements of operations. We recorded charges of $1.0 million and $2.2 million for the years ended December 31, 2003 and 2002, respectively. Each respective charge is equal to the intrinsic value difference between the exercise price of the accelerated options and the fair value of the common stock on the date of acceleration.

Recent Accounting Pronouncements

In December 2004, the FASB issued SFAS No. 123 (revised 2004), "Share-Based Payment" ("SFAS 123(R)") which requires the measurement of all employee share-based payments to employees, including grants of employee stock options, using a fair-value-based method and the recording of such expense in our consolidated statements of income. The accounting provisions of SFAS 123(R) are effective for reporting periods

beginning after June 15, 2005. We will adopt SFAS 123(R) effective as of the third quarter of fiscal 2005. The pro forma disclosures previously permitted under SFAS 123 no longer will be an alternative to financial statement recognition. See Note 2, Stock-based compensation, on page 59 for the pro forma net income and net income per share amounts, for fiscal 2002 through fiscal 2004, as if we had used a fair-value-based method similar to the methods required under SFAS 123(R) to measure compensation expense for employee stock incentive awards. Although we have not yet determined whether the adoption of SFAS 123(R) will result in amounts that are similar to the current pro forma disclosures under SFAS 123, we are evaluating the requirements under SFAS 123(R) and expect the adoption to have a significant adverse impact on our consolidated statements of income and net income per share.

Liquidity and Capital Resources

Historically, we have funded our operations with the proceeds from the sale of our common and preferred stock and from cash generated from sales of our product. As of December 31, 2004, we had $69.7 million of cash and cash equivalents and $0.3 million of restricted cash. We had an accumulated deficit of $291.8 million as of December 31, 2004.

Net cash provided by operating activities totaled $24.6 million and $12.1 million for the years ended December 31, 2004 and 2003, respectively. Net cash provided by operating activities for the year ended December 31, 2004 resulted primarily from operating profit and year over year changes in working capital. For the year ended December 31, 2003, net cash provided by operating activities resulted primarily from increases in accrued liabilities and deferred revenue, partially offset by operating losses.

Net cash used in investing activities totaled $6.0 million and $4.3 million for the years ended December 31, 2004 and 2003, respectively. For the year ended December 31, 2004, net cash used in investing activities resulted primarily from the purchase of property and equipment for capacity expansion and manufacturing improvements, including approximately $3.2 million for the implementation of the new version of our enterprise resource planning system and a new software application for our manufacturing process. Partially offsetting these purchases were proceeds from the sale of equipment and maturities of marketable securities during fiscal 2004. For the year ended December 31, 2003, net cash used in investing activities resulted primarily from the purchase of property and equipment for capacity expansion and manufacturing improvements and purchases of marketable securities, partially offset by maturities of marketable securities.

Net cash provided by financing activities was $6.1 million and $1.6 million for the years ended December 31, 2004 and 2003, respectively. For the year ended December 31, 2004, net cash provided by financing activities consisted of proceeds from the issuance of common stock, primarily from exercises of employee stock options, partially offset by payments on debt obligations related to the equipment-based term loan and capital lease obligations. For the year ended December 31, 2003, net cash provided by financing activities consisted of proceeds from the issuance of common stock, primarily from exercises of employee stock options, and proceeds from payment on stockholders' notes receivable, partially offset by payments on debt obligations related to the equipment-based term loan and capital lease obligations.

In December 2003 we negotiated a $15.0 million revolving line of credit based on domestic accounts receivable which accrues interest at a rate of 0.5% above prime. Accessing the accounts receivable based revolving line of credit is restricted based on qualifying accounts receivable and compliance with certain loan covenants. We have not drawn down the revolving line of credit.

In December 2002, we obtained and accessed a $5.0 million equipment-based term loan, which accrues interest at a rate of 2.25% above prime. We did not drawn down on any new funds in fiscal 2004. As of December 31, 2004, the equipment-based term loan had an outstanding balance of $1.7 million. Principal payments are due in 36 monthly installments beginning in January 2003. Annual principal payment of $1.7 million is due for fiscal 2005.

During the quarter ended December 31, 2004, we determined that we were out of compliance with our loan covenants for the accounts receivable-based revolving line of credit and equipment-based term loan requiring certain financial ratios and measurements to be maintained. The loan covenant requirements were amended as of January 28, 2005. As a result of the amendment, we are in full compliance with our loan covenants for the quarter ended December 31, 2004.

Contractual Obligations / Off Balance Sheet Arrangements

The impact that our contractual obligations as of December 31, 2004 are expected to have on our liquidity and cash flow in future periods is as follows:

		Payments Due by Period			
	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
			(in thousands)		
Equipment-based term loan, including current portion (1)	$1,667	$1,667	$ —	$ —	$—
Capital lease obligations, including current portion (1)	187	187	—	—	—
Operating lease obligations (2)	5,969	2,736	3,092	141	—
Computer support services	613	613	—	—	—
Manufacturing services	1,000	1,000	—	—	—
Total	$9,436	$6,203	$3,092	$141	$—

(1) Amounts represent the expected cash payments of our long-term debt and do not include any fair value adjustments.

(2) In February 2005, we renewed our Santa Clara leases under more favorable terms beginning in July 2005. See Note 10—Subsequent Events to the consolidated financial statements.

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

As discussed under "Item 3—Legal Proceedings", we are currently involved in litigation with OrthoClear, Inc., one of our founders and several former employees. This litigation is in its preliminary stages and it is not yet possible to determine its ultimate outcome. At this time we cannot estimate the impact this litigation may have on our future cash requirements.

We expect that our operating expenses will increase commensurate with an overall increase in the level of our business activity, including increased sales and the related costs of products sold, continuing efforts to automate our manufacturing processes, and development and improvements to our product. We also expect operating expenses to increase due to our consumer advertising campaign, dental professional marketing efforts, continued international sales and marketing efforts, increases in the size of our sales force and dental professional training staff, and increases in our research and development expenses as we develop new products and enhancements to Invisalign. 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 our efforts to develop new software and increase the automation of our manufacturing process, execute our

consumer marketing campaign and dental professional marketing efforts, develop clinical research and education plans, or to otherwise 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, accounts receivable, legal contingencies and income taxes. We use authoritative pronouncements, historical experience and other assumptions as the basis for making estimates. Actual results could differ from those estimates.

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

Revenue Recognition

We recognize revenue in accordance with SEC Staff Accounting Bulletin, or SAB, No. 104, Revenue Recognition, and EITF 00-21. SAB No. 104 requires that four basic criteria must be met before revenue can be recognized: persuasive evidence of an arrangement exists; shipments have occurred; the fee is fixed and determinable; and collectibility is reasonably assured. Determination of whether persuasive evidence of an arrangement exists and whether delivery has occurred or services have been 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. EITF 00-21 addresses the issue of accounting for arrangements that involve the delivery of multiple products or services. Should changes in conditions cause management to determine these criteria are not met for certain future transactions, revenue recognized for any reporting period could be adversely affected.

Revenue from the sale of Invisalign and ancillary products is recognized upon product shipment, provided that no significant obligations remain, transfer of title has occurred and collection of the receivable is deemed probable. The costs of producing the ClinCheck™ treatment plan, which are incurred prior to the production of Aligners, are deferred and recognized as related revenues are earned. In certain instances, adjustments to a patient's teeth are made in the final stages of orthodontic treatment. To make these final adjustments and move a patient's teeth to the final desired position, dental professionals may elect to use Invisalign as a finishing treatment tool and order newly manufactured Aligners. These newly manufactured Aligners, or "case refinement", are not provided with the Aligners produced as part of the initial treatment plan and are manufactured only upon the request of the dental professional if final adjustments are desired. Align's case refinement policy allows doctors to order one case refinement as part of their original lab fee, provided they submit the order prior to the point in time when the case is deemed completed, or the "case expiration". Prior to our policy change during the fourth quarter of fiscal 2004, we deemed the case expiration date to occur on the 90th day after the expected end of treatment. Under the new policy, the case expiration date is deemed to occur on the 180th day after the expected end of treatment.

From June 2001 through April 2003, we offered our dental professionals the opportunity, at the time of the creation of the initial treatment plan, to purchase at a discount a one-time, non-refundable case refinement. Revenue, in the amount of the stand-alone sales price of the undelivered element, is deferred until the earlier of shipment of the case refinement or, if case refinement was never requested, the point in time when the case is deemed completed, or "case expiration". In cases where the dental professional did not purchase case refinement in advance, case refinement revenues, if any, are recognized when the new Aligners are shipped.

We updated our domestic and international pricing policies in May 2003 and January 2004, respectively, to include the future delivery of one case refinement in the price of each case and to offer additional case refinements at a price of $125 each and at a comparable price internationally, which we believe represents its fair value based on competitive product offerings. Revenue deferrals associated with future case refinement after May 1, 2003 are $125 per case and a comparable price internationally after January 2004. This revenue deferral amount represents the fair value of a case refinement as determined in accordance with EITF 00-21, which addresses the issue of accounting for arrangements that involve the delivery of multiple products or services. These revenue deferrals will be recognized when the case refinement has been shipped or upon case expiration, whichever is earliest.

Service revenues earned for training of dental professionals and staff for Invisalign are recorded as the services are performed. Service revenues earned under agreements with third parties are based on negotiated rates, which are intended to approximate a mark-up on our anticipated costs.

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

Warranty Expense

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 in 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 for the additional expense. The Invisalign product warranty does not provide any assurances regarding the outcome of treatment using Invisalign.

We generally warrant our products for a specific period of time against material defects. We accrue for estimated warranty costs upon shipment of products. We provide for the estimated future costs of warranty obligations in costs of goods sold when the related revenue is recognized. The accrued warranty costs represent the best estimate at the time of sale of the total costs that we expect to incur to repair or replace product which fails while still under warranty. 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 estimate amounts. On a quarterly basis, we 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 required to accrue additional warranty cost in the future, it would negatively affect operating results.

Allowance for Doubtful Accounts

We maintain allowances for doubtful accounts for estimated losses resulting from the inability of our customers to make payments. We periodically review these estimated allowances, including an analysis of the customers' payment history and information regarding the customers' creditworthiness. If the financial condition of any of our customers were to deteriorate, resulting in their inability to make payments, an additional allowance may be required which would negatively impact our operating results.

Accounting for long-lived assets

We assess the impairment of long-lived assets periodically in accordance with the provisions of SFAS No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets." An impairment review is performed whenever events or changes in circumstances indicate that the carrying value may not be recoverable. Factors

that could trigger an impairment review include, but are not limited to, significant underperformance relative to expected historical or projected future operating results, significant changes in the manner of use of the acquired assets or the strategy for the overall business, significant negative industry or economic trends, a significant decline in the stock price for a sustained period and the market capitalization relative to net book value. If these factors or their related assumptions change in the future, we may be required to record impairment charges which would negatively impact operating results.

Legal contingencies

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

Deferred Tax Valuation Allowance

We have established a full valuation allowance to reduce our deferred tax assets to the amount that is more likely than not to be realized. Deferred tax assets and liabilities are determined based on the difference between the financial statement and tax bases of assets and liabilities using the enacted tax rates in effect for the year in which the differences are expected to affect taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to the amounts expected to be realized.

While we have considered potential future taxable income and ongoing prudent and feasible tax planning strategies in assessing the need for the full valuation allowance, in the event that we were to determine that we would be able to realize our deferred tax assets in the future, an adjustment to the deferred tax asset would increase net income in the period such determination was made.

RISK FACTORS

We have only recently experienced significant revenue growth and achieved profitability. If we fail to sustain or increase profitability or revenue growth in future periods, 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. Since inception, we incurred significant operating losses and we have only achieved profitability since the fourth quarter of fiscal 2003. From inception through July 2000, we spent significant funds on organizational and start-up activities, recruiting key managers and employees, developing Invisalign and developing our manufacturing and customer support resources. We also spent significant funds on clinical trials and training programs to train dental professionals in the use of Invisalign.

We continue to incur significant operating expenses to:

- develop new software and increase the automation of our manufacturing processes;
- execute our consumer advertising campaign and dental professional marketing efforts;
- increase the size of our sales force and clinical education support staff;
- execute clinical research and education plans;
- develop technological improvements to our products;
- continue our international sales and marketing efforts;
- protect our intellectual property; and
- undertake quality assurance and improvement initiatives.

As noted above, we have only recently achieved profitability, and, as a result, to sustain or increase profitability in future periods, we will need to continue to increase our revenue, while controlling our expenses. We generated positive operating cash flow for the first time during fiscal year 2003, and we cannot be certain that we will be able to sustain or increase such positive cash flow from operations, from period to period, in the future. In fact, for fiscal 2005, we expect to increase our sales and marketing expenses as a result of several factors, including our consumer advertising campaign, dental professional marketing efforts, continued international sales and marketing efforts and increases in the size of our sales force and dental professional training staff. In addition, legal expenses associated with the OrthoClear litigation could result in an additional increase to our general and administrative expenses in fiscal 2005. Furthermore, we expect our cash and cash equivalents to decline in the first quarter of 2005 as we fund these and other business expenditures. Because our business is evolving it is difficult to predict our future operating results or levels of growth, and we may not be able to sustain our historical growth rates in future periods. If we do not sustain or increase profitability or revenue growth or otherwise meet the expectations of securities analysts or investors, the market price of our common stock will likely decline.

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

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

- the development and marketing of directly competitive products by potential competitors;
- changes in the timing of product orders;

- unanticipated delays in production caused by insufficient capacity, any disruptions in the manufacturing process or the introduction of new production processes;
- inaccurate forecasting of revenue, production and other operating costs;
- costs and expenditures in connection with ongoing litigation; and
- increased expenses resulting from several factors, including increased headcount in our sales and marketing department.

To respond to these and other factors, we may need to make business decisions that could adversely affect our operating results. 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 revenue for a particular period falls below our expectations, we may be unable to adjust spending quickly enough to offset any unexpected shortfall in revenue growth or any decrease in revenue levels.

Due to these and other factors, we believe that quarter-to-quarter comparisons of our operating results may not be meaningful. You should not rely on our results for any one quarter as an indication of our future performance.

We are currently involved in litigation with several former employees stemming from our efforts to protect our intellectual property. This litigation may be costly and could distract our management and cause a decline in our results of operations and stock price.

We seek to diligently protect our intellectual property rights. On February 2, 2005 we filed a complaint against OrthoClear, Inc., OrthoClear Holdings, Inc., one of our founders and several former employees. Among other things, the complaint alleges tort, contract, statutory and common law causes of action arising from OrthoClear and the individual defendants' alleged plan to unlawfully utilize our intellectual property, confidential information and employees. The complaint also alleges that OrthoClear, Chishti and other defendants are in breach of contractual obligations, statutory law and common law for attempting to intentionally interfere and disrupt our ongoing business operations and improperly gain access to our customer relationships and trade secrets. The complaint seeks injunctive relief and monetary damages in an amount to be determined. On February 15, 2005, OrthoClear, Chishti, Riepenhausen, Breeland, Tunnell, Kawaja and Wen filed a multi-claim Cross-Complaint against Align, Thomas Prescott, Roger George, Eldon Bullington, David Thrower, Patricia Wadors, Gil Laks and Kelsey Wirth alleging conspiracy, breach of contract, libel, slander, unjust enrichment, intentional interference with prospective economic advantage, and unfair competition. Although this lawsuit is in the early stages, litigating claims of this type, whether or not ultimately determined in our favor or settled by us, is costly and diverts the efforts and attention of our management and technical personnel from normal business operations. Any of these results from our litigation could adversely affect our results of operations and stock price.

In addition, we are currently a party to various other legal proceedings and claims. Management does not believe that the ultimate outcome of these other legal proceedings and claims will have a material adverse effect on our financial position or results of operations. However, in the Ormco litigation, there is no assurance that the court's decision will not be overturned on appeal. In addition, litigation is subject to inherent uncertainties and unfavorable rulings could occur. An unfavorable ruling could include monetary damages or, in cases where injunctive relief is sought, an injunction prohibiting us from selling our products. If an unfavorable ruling were to occur in any specific period, there exists the possibility of a material adverse impact on the results of operations of that period or future periods.

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

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 operations, sales and operating results.

We rely on the efficient and uninterrupted operation of complex information technology systems. All information technology systems are vulnerable to damage or interruption from a variety of sources. As our business has grown in size and complexity, the growth has placed, and will continue to place, significant demands on our information technology systems. To effectively manage this growth, we will need to continually upgrade and enhance our information systems to more effectively manage our operations.

In October 2004, we implemented a new version of our enterprise resource planning system and new software for our manufacturing execution system. Throughout 2005 we will integrate additional functionality into our manufacturing execution system, which will more efficiently integrate this system with our other system applications, such as customer facing and manufacturing tools. System upgrades and enhancements require significant capital 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.

In addition, experienced computer programmers and hackers may be able to penetrate our network security and misappropriate our confidential information or that of third parties, create system disruptions or cause shutdowns. Furthermore, sophisticated hardware and operating system software and applications that we either internally produce or procure from third parties may contain defects in design and manufacture, including "bugs" and other problems that can unexpectedly interfere with the operation of the system. The costs to eliminate or alleviate security problems, viruses and bugs could be significant, and the efforts to address these problems could result in interruptions that may have a material adverse impact on our operations, sales and operating results.

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

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, ("Section 404") and the rules and regulations promulgated by the SEC to implement Section 404, we are required to furnish a report to include 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.

Management's assessment of internal controls over financial reporting requires management to make subjective judgments and, because this requirement to provide a management report is newly effective, some of our judgments will be in areas that may be open to interpretation. Therefore our management report may be uniquely difficult to prepare and our auditors, who are required to issue an attestation report along with our management's report, may not agree with management's assessments. 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), we could lose investor confidence in the accuracy and completeness of our financial reports, which would have an adverse effect on our stock price.

We depend on the sale of Invisalign for the vast majority of our revenues, and if demand for Invisalign declines or fails to develop as we expect or if dental professionals or consumers do not adopt Invisalign in sufficient numbers or as rapidly as we anticipate, or if orthodontists and GPs do not collaborate as we expect, our revenue will decline.

We expect that revenue from the sale of Invisalign will continue to account for a substantial portion of our total revenue for the foreseeable future. Continued and widespread market acceptance of Invisalign by both dental professionals and consumers is critical to our future success. If orthodontists and GPs experience a reduction in consumer demand for orthodontic services or consumers prove unwilling to adopt Invisalign as rapidly as we anticipate or in the volume that we anticipate, or if orthodontists and GPs do not collaborate as we expect, our operating results could be harmed. Factors that could cause Invisalign not achieve market acceptance at the rate at which we expect, or at all, are described more fully below.

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

Our success depends upon increasing acceptance of Invisalign by dental professionals. Invisalign requires dental professionals 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, dental professionals may be reluctant to adopt it until more historical clinical results are available. Also, increasing adoption and cumulative use by dental professionals will depend on factors such as the capability, safety, efficacy, ease of use, price, quality and reliability of our products and our provision of effective sales support, training and service. In the future, unanticipated poor clinical performance of Invisalign could result in significant adverse publicity and, consequently, reduced acceptance by dental professionals. If Invisalign does not achieve growing acceptance in the orthodontic and GP communities, our operating results will be harmed.

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

In addition, our success depends upon the acceptance of Invisalign by a substantially larger number of dental professionals as well as potential patients to whom we are now actively marketing. Invisalign represents a significant change from traditional orthodontic treatment, and patients may be reluctant to accept it or may not find it preferable to conventional treatment. In addition, patients 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 dental professionals and patients 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 and greater comfort and hygiene compared to conventional orthodontic 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 impacted by general macroeconomic conditions in North America and internationally, which fluctuate and could be affected by unstable global economic, political or other conditions.

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

Our success depends in part upon improving the collaboration and referral relationships between orthodontists and GP dentists. Although orthodontists have historically generated a majority of our revenues, there exists a significantly greater number of general practitioners in North America than orthodontists and we expect to generate the majority of our revenue from GPs in 2005. As the primary care dental provider, 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.

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 our ClinCheck™ product and are used to manufacture Aligner molds. A third party manufacturer in Mexico fabricates Aligners and ships the completed products to our customers. Our costs associated with these operations are denominated in Costa Rican colons, Mexican pesos and U.S. dollars.

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

- political, social and economic instability;
- acts of terrorism and acts of war;
- difficulties in staffing and managing international operations; import and export license requirements and restrictions;
- controlling quality of the manufacturing process;
- 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, our operating results may be harmed.

Our success depends in part on our proprietary technology and if we are unable to successfully enforce our intellectual property rights, our competitive position may be harmed.

Our success will depend in part on our ability to maintain existing intellectual property and to obtain and maintain further intellectual property protection for our products, both in the U.S. and in other countries. Our inability to do so could harm our competitive position. As of December 31, 2004, we had 56 issued U.S. patents, 82 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. In addition, any protection afforded by foreign patents may be more limited than that provided under U.S. patents and intellectual property laws. We also rely on protection of our copyrights, trade secrets, know-how and proprietary information. We generally enter into confidentiality agreements with our employees, consultants and our collaborative partners upon commencement of a relationship with us. However, these agreements may not provide meaningful protection against the unauthorized use or disclosure of our trade secrets or other confidential information, and adequate remedies may not exist if unauthorized use or disclosure were to occur. See Part I Item 3 of this Form 10-K for a summary of the OrthoClear litigation. Our inability to maintain the proprietary nature of our

technology through patents, copyrights or trade secrets would impair our competitive advantages and could have a material adverse effect on our operating results, financial condition and future growth prospects. In particular, a failure of our proprietary rights might allow competitors to copy our technology, which could adversely affect our pricing and market share.

If we 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, while these actions have been dismissed, we may be the subject of patent or other litigation in the future.

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

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

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

We currently outsource key portions of our manufacturing process. We rely on a third party manufacturer in Mexico to fabricate Aligners and to ship the completed product to customers. As a result, if this third party manufacturer fails to deliver its components or if we lose its services, we may be unable to deliver our products in a timely manner and our business may be harmed. Any difficulties encountered by the third party manufacturer with respect to hiring 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.

In addition, 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. 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 delivery delays or shortages of these items, our business and growth prospects may be harmed.

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

We have expanded rapidly since we commenced commercial sales in 1999. Our headcount increased from approximately 50 employees as of December 31, 1999 to approximately 969 employees as of December 31, 2004. This expansion will continue to place significant demands on our management and other resources and will require us to continue to develop and improve our operational, financial and other internal controls, both in the U.S. and internationally. In particular, rapid growth increases the challenges involved in a number of areas, including recruiting and retaining sufficient skilled personnel, providing adequate training and supervision to maintain our high quality standards, and preserving our culture and values. Our inability to effectively manage this level of growth could harm our business.

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.

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

Currently, our Invisalign product competes directly against a product called Red, White and Blue, which is manufactured and distributed by Ormco, a subsidiary of Sybron Dental Specialties. 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. For instance, on February 2, 2005 we filed a lawsuit against OrthoClear, Inc., OrthoClear Holdings, Inc., Zia Chishti and several former employees. We believe that OrthoClear intends to introduce and market a competitive product into the market place. Although we intend to vigorously defend our intellectual property rights and prevent OrthoClear from releasing any product that infringes on our intellectual property, if OrthoClear is ultimately successful in entering the market with a competitive product, our business could be harmed.

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

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

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

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

- Warning letters, fines, injunctions, consent decrees and civil penalties;
- Repair, replacement, refunds, recall or seizure of our products;

- Operating restrictions or partial suspension or total shutdown of production;
- Refusing our requests for 510(k) clearance or premarket approval of new products, new intended uses, or modifications to existing products;
- Withdrawing clearance or premarket approvals that have already been granted; and
- Criminal prosecution.

If any of these events were to occur, they could harm our business.

We must comply with facility registration and product listing requirements of the FDA and adhere to applicable Quality System regulations. The FDA enforces its Quality System regulations through periodic unannounced inspections. We have not yet been subject to an FDA inspection, and we cannot assure you we will successfully pass such an inspection in the future. Our failure to take satisfactory corrective action in response to an adverse inspection or our 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 the 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 affect of HIPAA and newly enacted 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. Additionally, the HIPAA Security Standard, which goes into effect in April 2005, requires that we implement safeguards that reasonably and appropriately protect the confidentiality, integrity and availability of the electronic protected health information that we create, receive, maintain or transmit pursuant to our Business Associate Agreements with healthcare professionals. Compliance with the Security Standard could require complex changes in our internal systems and services and could be costly.

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; and
- the marketing and advertising of our products.

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

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

We currently sell our products in Europe, Canada, the United Kingdom, Mexico, Brazil, Australia and Hong Kong, and may expand into other countries from time to time. We do not know whether orthodontists, dentists 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., if we fail to receive these approvals, we may be unable to market our products or enhancements in international markets in a timely manner, if at all.

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

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

In fiscal 2004, the market price for our common stock was volatile.

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

- quarterly variations in our results of operations and liquidity;

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

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

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

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

Changes in, or interpretations of, accounting rules and regulations, such as expensing of stock options, could result in unfavorable accounting charges.

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

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

In particular, the FASB recently enacted SFAS No. 123 (revised 2004), "Share-Based Payment" ("SFAS 123(R)") which we will adopt effective the third quarter fiscal 2005. As a result, we expect that SFAS 123R will have a significant adverse effect on our reported financial results and may impact the way in which we conduct our business.

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

Quantitative Disclosures

We are exposed to market risks inherent in our operations, primarily related to interest rate risk and currency risk. These risks arise from transactions and operations entered into in the normal course of business. We do not use derivatives to alter the interest characteristics of our marketable securities or our debt instruments. We have no holdings of derivative or commodity instruments.

Interest Rate Risk. We are subject to interest rate risks on cash and cash equivalents, available-for-sale marketable securities, existing long-term debts and any future financing requirements. Interest rate risks related to marketable securities are managed by monitoring maturities in our marketable securities portfolio. Our long-term debt at December 31, 2004 consists of outstanding balances on capital lease obligations of $0.2 million and a $1.7 million equipment-based term loan.

The fair value of our investment portfolio or related income would not be significantly impacted by changes in interest rates since the marketable securities maturities do not exceed fiscal year 2004 and the interest rates are primarily fixed. Our capital lease obligations of $0.2 million at December 31, 2004 carry fixed interest rates of 6.53% and 11.15% per annum, with principal payments due in 60 and 48 monthly installments, respectively, which began in 2000.

In December 2002, we obtained a $5.0 million equipment-based term loan which accrues interest at a rate of 2.25% above prime. In December 2002 we had drawn down $5.0 million from the equipment-based term loan. Principal payments are due in 36 monthly installments which began in January 2003.

The following table presents the future principal cash flows or amounts and related weighted average interest rates expected by year for our existing cash and cash equivalents, marketable securities and long-term debt instruments:

	Expected Maturity Date (as of December 31, 2004)						
	2005	2006	2007	2008	2009	Total	Fair Value
	(in thousands)						
ASSETS:							
Cash and cash equivalents	$69,659	$—	$—	$—	$—	$69,659	$69,659
Short-term marketable securities	—	—	—	—	—	—	—
Weighted average interest rate	—	—	—	—	—	—	—
LIABILITIES:							
Equipment-based term loan	$ 1,667	—	$—	$—	$—	$ 1,667	$ 1,667
Fixed rate debt lease obligation	182	—	—	—	—	182	182
Weighted average interest rate	6.5%	—	—	—	—	—	—

Qualitative Disclosures

Interest Rate Risk. Our primary interest rate risk exposures relate to:

- A decrease in the value of available-for-sale securities if market interest rates increase;
- Our ability to pay long-term debts at maturity; and
- The impact of interest rate movements on our ability to obtain adequate financing to fund future operations.

We have the ability to hold at least a portion of the fixed income investments until maturity. As a result, we would not expect our operating results or cash flows to be affected to any significant degree by a sudden change in market interest rates on our short- and long-term marketable securities portfolio.

We manage interest rate risk on our outstanding long-term debts through the use of fixed rate debt. Management evaluates our financial position on an ongoing basis.

Currency Rate Risk. Our primary currency rate risk exposures relate to our decentralized or outsourced operations, whereby approximately $15.6 million of our annual expenses are related to operations outside the United States, denominated in currencies other than the U.S. dollar.

We do not hedge any balance sheet exposures or intercompany balances against future movements in foreign exchange rates. The exposure related to currency rate movements would not likely have a material impact on future net income or cash flows for the foreseeable future.

ITEM 8. CONSOLIDATED FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

Quarterly Results of Operations

	Three Months Ended							
	2004				2003			
	Dec. 31 (1)	Sep. 30	June 30	March 31	Dec. 31	Sep. 30	June 30	March 31
	(in thousands, except per share data) (unaudited)							
Revenues	$43,655	$45,766	$44,204	$39,205	$36,502	$34,038	$29,225	$ 22,960
Gross profit	28,694	30,844	29,954	25,812	23,576	20,592	15,956	11,036
Operating profit (loss)	656	3,851	4,341	917	470	(1,748)	(8,186)	(10,473)
Net profit (loss)	1,121	3,318	3,772	557	452	(2,144)	(7,759)	(10,671)
Net profit (loss) available to common stockholders	$ 1,121	$ 3,318	$ 3,772	$ 557	$ 452	$ (2,144)	$ (7,759)	$(10,671)
Net profit (loss) per share available to common stock-holders, basic	$ 0.02	$ 0.06	$ 0.06	$ 0.01	$ 0.01	$ (0.04)	$ (0.13)	$ (0.19)
Shares used in computing per share amounts, basic	60,744	60,319	59,692	59,091	58,398	57,948	57,489	57,189
Net profit (loss) per share available to common stock-holders, diluted	$ 0.02	$ 0.05	$ 0.06	$ 0.01	$ 0.01	$ (0.04)	$ (0.13)	$ (0.19)
Shares used in computing per share amounts, diluted	63,560	64,055	64,461	64,559	63,704	57,948	57,489	57,189

(1) Reflects an increase to cost of revenues and a decrease to net profit of $383,000 as compared to the results for the fourth quarter and year ended December 31, 2004 that we announced on January 26, 2005 and included in our financial statements filed with our Form 8-K for the fourth quarter and year ended December 31, 2004. The $383,000 increase to cost of revenues reflects asset impairment charges identified by management against manufacturing fixed assets at our international manufacturing facility. See Item 7, Management's Discussion and Analysis of Financial Condition and Results of Operations—Overview.

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 in the United States of America. 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 in the United States of America, 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 consolidated 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, 2004. 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 concluded that Align maintained effective internal control over financial reporting as of December 31, 2004.

Our management's assessment of the effectiveness of Align's internal control over financial reporting as of December 31, 2004 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as indicated in their report which appears immediately after this report.

/s/ THOMAS M. PRESCOTT

Thomas M. Prescott
President and Chief Executive Officer

March 3, 2005

/s/ ELDON M. BULLINGTON

Eldon M. Bullington
Vice President, Finance and Chief Financial Officer

March 3, 2005

ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have completed an integrated audit of Align Technology, Inc.'s 2004 consolidated financial statements and of its internal control over financial reporting as of December 31, 2004 and audits of its 2003 and 2002 consolidated financial statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Our opinions, based on our audits, are presented below.

Consolidated financial statements and financial statement schedule

In our opinion, the consolidated financial statements listed in the index appearing under Item 15(a)1 present fairly, in all material respects, the financial position of Align Technology, Inc. and its subsidiaries at December 31, 2004 and 2003, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2004 in conformity with accounting principles generally accepted in the United States of America. In addition, in our opinion, the financial statement schedule listed in the index appearing under Item 15(a)2 presents fairly, in all material respects, the information set forth therein when read in conjunction with the related consolidated financial statements. These financial statements and financial statement schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and financial statement schedule based on our audits. We conducted our audits of these statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit of financial statements includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

Internal control over financial reporting

Also, in our opinion, management's assessment, included in 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, 2004 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, 2004, 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.

PRICEWATERHOUSECOOPERS LLP

San Jose, California
March 3, 2005

ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS
(in thousands, except per share data)

	December 31, 2004	December 31, 2003
ASSETS		
Current assets:		
Cash and cash equivalents	$ 69,659	$ 44,939
Restricted cash	303	439
Marketable securities, short-term	—	2,292
Accounts receivable, net of allowance for doubtful accounts of $1,493 and $1,259 at December 31, 2004 and 2003, respectively	28,809	21,265
Inventories, net	2,852	2,334
Prepaid expenses	4,219	4,097
Other current assets	992	1,748
Total current assets	106,834	77,114
Property and equipment, net	21,702	23,121
Other assets	2,176	1,967
Total assets	$ 130,712	$ 102,202
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 3,361	$ 3,095
Accrued liabilities	23,481	19,180
Deferred revenue	16,257	13,113
Current portion of equipment-based term loan	1,667	1,667
Capital lease obligations	182	322
Total current liabilities	44,948	37,377
Equipment-based term loan, net of current portion	—	1,667
Other long term liabilities	25	182
Total liabilities	44,973	39,226
Commitments and contingencies (Note 4)		
Stockholders' equity:		
Preferred stock, $0.0001 par value; Authorized: 5,000 shares at December 2004 and 2003; Issued and Outstanding: no shares at December 31, 2004 and 2003	—	—
Common stock, $0.0001 par value, Authorized: 200,000 shares at December 31, 2004 and 2003; Issued: 60,916 and 58,793 shares at December 31, 2004 and 2003, respectively; Outstanding: 60,876 and 58,753 shares at December 31, 2004 and 2003, respectively	6	6
Additional paid-in capital	377,559	368,796
Deferred stock-based compensation	—	(5,219)
Notes receivable from stockholders	—	(17)
Accumulated other comprehensive income (loss)	(2)	2
Accumulated deficit	(291,824)	(300,592)
Total stockholders' equity	85,739	62,976
Total liabilities and stockholders' equity	$ 130,712	$ 102,202

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

ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except per share data)

	Year Ended December 31,		
	2004	2003	2002
Revenues:			
Invisalign	$164,536	$115,278	$ 63,690
Ancillary products and other services	8,294	7,447	6,008
Total revenues	172,830	122,725	69,698
Cost of revenues:			
Invisalign	49,019	43,990	37,089
Ancillary products and other services	8,507	7,575	7,902
Total cost of revenues	57,526	51,565	44,991
Gross profit	115,304	71,160	24,707
Operating expenses:			
Sales and marketing	55,932	43,689	45,313
General and administrative	33,851	34,296	39,265
Research and development	15,756	13,112	13,064
Total operating expenses	105,539	91,097	97,642
Profit (loss) from operations	9,765	(19,937)	(72,935)
Interest income	713	531	979
Interest expense	(271)	(364)	(162)
Other expense	(445)	(268)	(701)
Net profit (loss) before provision for income taxes	9,762	(20,038)	(72,819)
Provision for income taxes	994	84	—
Net profit (loss)	$ 8,768	$ (20,122)	$(72,819)
Net profit (loss) per share available to common stockholders, basic	$ 0.15	$ (0.35)	$ (1.52)
Shares used in computing net profit (loss) per share, basic	59,963	57,758	47,878
Net profit (loss) per share, diluted	$ 0.14	$ (0.35)	$ (1.52)
Shares used in computing net profit (loss) per share, diluted	64,089	57,758	47,878

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, 2004, 2003 and 2002

(in thousands)

	Common Stock		Additional Paid-In Capital	Deferred Stock-Based Compensation	Notes Receivable from Stockholders	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total
	Shares	Amount						
Balances at December 31, 2001	47,771	5	355,055	(48,324)	(1,484)	226	(207,651)	97,827
Net loss	—	—	—	—	—	—	(72,819)	(72,819)
Net change in unrealized loss from available-for-sale securities	—	—	—	—	—	(209)	—	(209)
Comprehensive loss,								(73,028)
Sale of common stock upon the completion of private stock offering, net of issuance costs of $54	9,579	1	18,145	—	—	—	—	18,146
Issuance of common stock relating to employee stock purchase plan	163	—	480	—	—	—	—	480
Issuance of common stock upon exercise of stock options	670	—	625	—	(3)	—	—	622
Repurchase of common stock contributed to the treasury	(40)	—	(170)	—	—	—	—	(170)
Repurchase of common stock	(443)	—	(410)	—	263	—	—	(147)
Payments on stockholder notes receivable	—	—	—	—	401	—	—	401
Interest accrued on stockholder notes receivable	—	—	—	—	(69)	—	—	(69)
Cancellations, net of deferred stock compensation	—	—	(13,289)	12,735	—	—	—	(554)
Amortization of deferred stock compensation	—	—	—	16,584	—	—	—	16,584
Charge for compensation expense on non-employee stock options	—	—	2,010	—	—	—	—	2,010
Charge for accelerated vesting of employee stock options	—	—	2,245	—	—	—	—	2,245
Balances at December 31, 2002	57,700	6	364,691	(19,005)	(892)	17	(280,470)	64,347
Net loss	—	—	—	—	—	—	(20,122)	(20,122)
Net change in unrealized loss from available-for-sale securities	—	—	—	—	—	(15)	—	(15)
Comprehensive loss								(20,137)
Issuance of common stock relating to employee stock purchase plan	194	—	434	—	—	—	—	434
Issuance of common stock upon exercise of stock options	879	—	2,446	—	—	—	—	2,446
Repurchase of common stock	(20)	—	(20)	—	—	—	—	(20)
Payments on stockholder notes receivable	—	—	—	—	921	—	—	921
Interest accrued on stockholder notes receivable	—	—	—	—	(46)	—	—	(46)
Cancellations, net of deferred stock compensation	—	—	(990)	990	—	—	—	—
Amortization of deferred stock compensation	—	—	—	12,796	—	—	—	12,796
Charge for compensation expense on non-employee stock options	—	—	1,276	—	—	—	—	1,276
Charge for accelerated vesting of employee stock options	—	—	959	—	—	—	—	959
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

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

ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Year Ended December 31,		
	2004	2003	2002
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net profit (loss)	$ 8,768	$(20,122)	$(72,819)
Adjustments to reconcile net profit (loss) to net cash provided by (used in) operating activities:			
Depreciation and amortization	9,597	9,119	13,051
Amortization of deferred stock-based compensation	5,089	12,796	16,030
Compensation expense for accelerated vesting of stock options	350	959	2,245
Stock-based compensation	429	1,276	2,010
Loss on retirement, disposal and impairment of fixed assets	70	279	2,052
Provision for doubtful accounts	541	(86)	229
Non-cash interest income on notes receivable from stockholders	—	(46)	(69)
Non-cash accretion on marketable securities	(4)	1	98
Allowance for excess and obsolete inventory	(210)	(216)	(86)
Changes in operating assets and liabilities:			
Accounts receivable	(8,085)	(4,413)	(5,439)
Inventories	(308)	554	(323)
Prepaid expenses and other current assets	634	(940)	(891)
Accounts payable	221	(246)	(2,450)
Accrued and other long term liabilities	4,326	9,497	(313)
Deferred revenue	3,144	3,710	6,276
Net cash provided by (used in) operating activities	24,562	12,122	(40,399)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchase of property and equipment	(9,061)	(7,585)	(8,112)
Proceeds from sale of property and equipment	858	65	—
Restricted cash	136	2,822	(2,538)
Purchase of marketable securities	(519)	(7,684)	(1,972)
Maturities of marketable securities	2,811	8,069	14,093
Other assets	(209)	(21)	41
Net cash (used in) provided by investing activities	(5,984)	(4,334)	1,512
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from issuance of common stock	8,115	2,880	19,248
Proceeds from payment on stockholders' notes receivable	17	921	401
Repurchase of common stock	(1)	(20)	(317)
Proceeds from draw down of line of credit	—	—	5,000
Payments on line of credit	(1,667)	(1,666)	—
Payments on capital lease obligations	(322)	(516)	(443)
Net cash provided by financing activities	6,142	1,599	23,889
Net increase (decrease) in cash and cash equivalents	24,720	9,387	(14,998)
Cash and cash equivalents, beginning of year	44,939	35,552	50,550
Cash and cash equivalents, end of year	$69,659	$ 44,939	$ 35,552

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

Note 1 Organization

Formation and business of the Company

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. The Company began commercial operations in July 2000.

Note 2 Summary of Significant Accounting Policies

Basis of consolidation

The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. All intercompany transactions have been eliminated in consolidation.

Use of estimates

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 reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ materially and adversely from those estimates.

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 and cash equivalents

Cash equivalents are stated at cost, which approximates market value. The Company considers all highly liquid debt instruments purchased with an original maturity of three months or less to be cash equivalents. The Company invests primarily in money market funds and commercial paper, accordingly, these investments are subject to minimal credit and market risks.

Restricted cash

The Company's restricted cash as of December 31, 2004 of $303,000 and December 31, 2003 of $439,000 was primarily comprised of security against leasing arrangements in Europe.

Short- and long-term marketable securities

Marketable securities are classified as available-for-sale and are carried at fair value. Marketable securities classified as current assets have scheduled maturities of less than one year, while marketable securities classified as non-current assets have scheduled maturities of more than one year. Unrealized holding gains or losses on such securities are included in accumulated other comprehensive income 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.

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, 2004 and 2003, or net revenues in fiscal 2004, 2003 and 2002.

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 third party manufacturers in 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 stated at the lower of cost or market. Cost is computed on a first-in, first-out basis. The Company records provisions to write down its inventory and related purchase commitments for estimated obsolescence or unmarketable inventory equal to the difference between the cost of the inventory and the

estimated market value based upon assumptions about the future demand and market conditions. If actual future demand or market conditions are less favorable than the Company estimates, additional inventory provisions may be required.

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, which are: three years for computer software and hardware and five years for plant equipment, furniture, fixtures and equipment. Amortization of leasehold improvements is computed using the straight-line method over the estimated useful lives of the assets, or the remaining lease term, whichever is shorter. Upon sale or retirement, the asset's cost and related accumulated depreciation are removed from the accounts 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 $3,214,000 in related internal use software costs. As of December 31, 2004 and 2003, capitalized internal use software at cost was $4,416,000 and $1,202,000, respectively, and the associated accumulated amortization were $881,000 and $443,000 respectively. Capitalized software costs are amortized over the estimated useful lives of the software, which generally range from three to five years.

Impairment of long-lived assets

The Company identifies and records impairment losses on long-lived assets used in operations when events and circumstances indicate that the assets may not be recoverable. Recoverability is measured by comparison of the assets carrying amount to future net undiscounted cash flows the assets are expected to generate. 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

Aligners are subject to the Invisalign product warranty, which covers defects in materials and workmanship. The Company's materials and workmanship warranty is in force until the Invisalign case in completed. In the event the Aligners fall within the scope of the Invisalign product warranty, the Company will replace the Aligners at its expense. The Company's 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 for the additional expense. The Invisalign product warranty does not provide any assurances regarding the outcome of treatment using Invisalign.

The Company generally warrants its products for a specific period of time against material defects. The Company accrues for estimated warranty costs upon shipment of products. The Company provides for the estimated future costs of warranty obligations in costs of goods sold when the related revenue is recognized. The accrued warranty costs represent the best estimate at the time of sale of the total costs that the Company expects to incur to repair or replace product which fails while still under warranty. 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 based on historical warranty cost trends. Actual warranty costs incurred have not materially differed from those accrued. If the Company were to experience higher rates of warranty events, the Company would be required to accrue additional warranty costs, which would negatively affect its operating results.

The following table reflects the change in the Company's warranty accrual during the years ended December 31, 2004 and 2003.

	(in thousands)
Warranty accrual, December 31, 2002	$ 514
Charged to costs and expenses	2,004
Actual warranty expenditures	(1,656)
Warranty accrual, December 31, 2003	862
Charged to costs and expenses	2,651
Actual warranty expenditures	(1,897)
Warranty accrual, December 31, 2004	$ 1,616

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. If the financial condition of any of our customers were to deteriorate, resulting in their inability to make payments, an additional allowance may be required and would negatively impact the Company's operating results.

Revenue Recognition

The Company recognizes revenue in accordance with SEC Staff Accounting Bulletin, or SAB, No. 104, Revenue Recognition, and Emerging Issues Task Force 00-21, "Accounting for Revenue Arrangements with Multiple Deliverables" ("EITF 00-21"). EITF 00-21 addresses the issue of accounting for arrangements that involve the delivery of multiple products or services. Should changes in conditions cause management to determine these criteria are not met for certain future transactions, revenue recognized for any reporting period could be adversely affected. SAB No. 104 requires that four criteria must be met before revenue can be recognized: persuasive evidence of an arrangement exists; shipments have occurred; the fee is fixed and determinable; and collectibility is reasonably assured. Determination of whether persuasive evidence of an arrangement exists and whether delivery has occurred or services have been 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 the sale of Invisalign and ancillary products is recognized upon product shipment, provided that no significant obligations remain, transfer of title has occurred and collection of the receivable is deemed probable. The costs of producing the ClinCheck™ treatment plan, which are incurred prior to the production of Aligners, are deferred and recognized as related revenues are earned. In certain instances, adjustments to a patient's teeth are made in the final stages of orthodontic treatment. To make these final adjustments and move a patient's teeth to the final desired position, dental professionals may elect to use Invisalign as a finishing

treatment tool and order newly manufactured Aligners. These newly manufactured Aligners, or "case refinement", are not provided with the Aligners produced as part of the initial treatment plan and are manufactured only upon the request of the dental professional if final adjustments are desired. Align's case refinement policy allows doctors to order one case refinement as part of their original lab fee, provided they submit the order prior to the point in time when the case is deemed completed, or the "case expiration". Prior to the Company's policy change during the fourth quarter of fiscal 2004, Align deemed the case expiration date to occur on the 90th day after the expected end of treatment. Under the new policy, the case expiration date is deemed to occur on the 180th day after the expected end of treatment. In certain instances, adjustments to a patient's teeth are made in the final stages of orthodontic treatment. To make these final adjustments and move a patient's teeth to the final desired position, dental professionals may elect to use Invisalign as a finishing treatment tool and order newly manufactured Aligners. These newly manufactured Aligners, or "case refinement", are not provided with the Aligners produced as part of the initial treatment plan and are manufactured only upon the request of the dental professional if final adjustments are desired.

From June 2001 through April 2003, the Company offered its dental professionals the opportunity, at the time of the creation of the initial treatment plan, to purchase at a discount a one-time, non-refundable case refinement. Revenue, in the amount of the stand-alone sales price of the undelivered element, is deferred until the earlier of shipment of the case refinement or, if case refinement is never requested, the point in time when the case is deemed completed, or "case expiration". In cases where the dental professional did not purchase case refinement in advance, case refinement revenues, if any, are recognized when the new Aligners are shipped.

The Company updated its domestic and international pricing policies in May 2003 and January 2004, respectively, to include the future delivery of one case refinement in the price of each case and to offer additional case refinements at a price of $125 each and at a comparable price internationally, which the Company believes represents its fair value based on competitive product offerings. Revenue deferrals associated with future case refinement after May 1, 2003 are $125 per case and a comparable price internationally after January 2004. This revenue deferral amount represents the fair value of a case refinement as determined in accordance with EITF 00-21, which addresses the issue of accounting for arrangements that involve the delivery of multiple products or services. These revenue deferrals will be recognized when the case refinement has been shipped or upon case expiration, whichever is earliest.

Service revenues earned for training of dental professionals and staff for Invisalign are recorded as the services are performed. Service revenues earned under agreements with third parties are based on negotiated rates, which are intended to approximate a mark-up on the Company's anticipated costs.

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.

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, 2004, 2003 and 2002 advertising costs totaled $6,335,000, $5,003,000 and $5,993,000, respectively.

Foreign currency

The Company uses the U.S. dollar as its functional currency for its foreign subsidiaries. Foreign currency monetary assets and liabilities are re-measured into U.S. dollars at current exchange rates and non-monetary assets are re-measured at historical rates. Revenues and expenses are re-measured at average exchange rates in effect during each period. Gains or losses from foreign currency re-measurement are included in other income (expense).

Income taxes

Income taxes are recorded under the liability method, under which deferred tax assets and liabilities are determined based on the difference between the financial statement and tax bases of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to affect taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to the amount expected to be realized.

Stock-based compensation

The Company accounts 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 complies with the disclosure requirements of SFAS 148, "Accounting for Stock-Based Compensation Transition and Disclosure an amendment of FASB Statement No. 123." The following table illustrates the effect on net loss and net loss per common share if the Company had applied the fair value recognition provisions of SFAS 123 to stock-based employee compensation:

	Year Ended December 31,		
	2004	2003	2002
	(in thousands, except per share amounts)		
Net profit (loss), as reported	$ 8,768	$(20,122)	$(72,819)
Add: Stock-based employee compensation expense included in reported net profit (loss), net of related tax effects	5,956	13,378	18,784
Deduct: Total stock-based employee compensation determined under fair value based method for all awards, net of related tax effects	(17,933)	(26,742)	(29,350)
Pro forma net loss	$ (3,209)	$(33,486)	$(83,385)
Basic net profit (loss) per common share:			
As reported	$ 0.15	$ (0.35)	$ (1.52)
Pro forma	$ (0.05)	$ (0.58)	$ (1.74)
Diluted net profit (loss) per common share:			
As reported	$ 0.14	$ (0.35)	$ (1.52)
Pro forma	$ (0.05)	$ (0.58)	$ (1.74)

Such pro forma disclosure may not be representative of future compensation cost because options vest over several years and additional grants are anticipated to be made each year.

The value of options granted to employees is estimated on the date of grant using the minimum value method for shares issued prior to January 2001, the date of the Company's initial public offering (IPO), and using the Black-Scholes option valuation model subsequent to the IPO with the following weighted assumptions:

	Year Ended December 31,		
	2004	2003	2002
Risk-free interest rate	3.44%	3.02%	3.03%
Expected life	5 years	5 years	5 years
Volatility	55.9%	101.8%	119.8%

The fair value of the employees' purchase rights under the Employee Stock Purchase Plan was estimated using the Black-Scholes option pricing model with the following assumptions:

	Year Ended December 31,		
	2004	2003	2002
Risk free interest rate	1.79%	1.73%	3.03%
Expected life	2 years	2 years	2 Years
Expected volatility	55.3%	117.0%	119.8%

The Company accounts for equity instruments issued to non-employees in accordance with the provisions of SFAS 123 and Emerging Issues Task Force Issue No. 96-18, "*Accounting for Equity Instruments that are Issued to Other Than Employees, or in Conjunction with Selling Goods and Services*," and Financial Accounting Standards Board Interpretation No. 28, "*Accounting for Stock Appreciation Rights and Other Variable Stock Option or Award Plan*" ("FIN 28").

Segments and Geographical Information

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 in a single business segment. No single territory other than the United States of America and Canada, the Company's domestic market, accounted for 10% or more of assets or 10% or more of revenues in fiscal 2004, 2003 and 2002.

For fiscal 2004, 2003 and 2002, the Company's revenues and long-lived assets are presented below by geographic area.

	Year Ended December 31,		
(Amounts in thousands)	2004	2003	2002
Revenues			
Domestic	$155,683	$110,579	$63,460
International	17,147	12,146	6,238
Total revenues	$172,830	$122,725	$69,698

	As of December 31,		
	2004	2003	2002
Long-lived Assets			
Domestic	$ 20,627	$ 22,197	$23,871
International	3,251	2,891	3,153
Total long-lived assets	$ 23,878	$ 25,088	$27,024

Comprehensive Income (loss)

Comprehensive income, 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 investments, are reported, net of their related tax effect.

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):

	Year Ended December 31,		
	2004	2003	2002
Numerator:			
Net profit (loss)	$ 8,768	$(20,122)	$(72,819)
Denominator:			
Weighted-average common shares outstanding	60,036	58,166	49,112
Less: Unvested common shares subject to repurchase	(73)	(408)	(1,234)
Total shares, basic	59,963	57,758	47,878
Effect of dilutive securities:			
Add: Dilutive common stock equivalents	4,053	—	—
Unvested common shares subject to repurchase	73	—	—
Total shares, diluted	64,089	57,758	47,878
Net profit (loss) per share, basic	$ 0.15	$ (0.35)	$ (1.52)
Net profit (loss) per share, diluted	$ 0.14	$ (0.35)	$ (1.52)

The following table sets forth potential shares of common stock that are not included in the diluted net profit (loss) per share available to common stockholders because to do so would be anti-dilutive for the years indicated (in thousands):

	December 31,		
	2004	2003	2002
Options to purchase common stock	1,289	8,767	7,670
Common stock subject to repurchase	—	200	637
	1,289	8,967	8,307

Reclassifications

Certain prior year amounts have been reclassed to conform with current year presentation.

Recent Accounting Pronouncements

In December 2004, the FASB issued SFAS No. 123 (revised 2004), "Share-Based Payment" ("SFAS 123(R)") which requires the measurement of all employee share-based payments to employees, including grants of employee stock options, using a fair-value-based method and the recording of such expense in the Company's consolidated statements of income. The accounting provisions of SFAS 123(R) are effective for reporting periods beginning after June 15, 2005. The Company will adopt SFAS 123(R) effective as of the third quarter of fiscal 2005. The pro forma disclosures previously permitted under SFAS 123 no longer will be an alternative to financial statement recognition. See "Stock-based compensation" above for the pro forma net income and net income per share amounts, for fiscal 2002 through fiscal 2004, as if the Company had used a fair-value-based method similar to the methods required under SFAS 123(R) to measure compensation expense for employee stock incentive awards. Although the Company has not yet determined whether the adoption of SFAS 123(R) will result in amounts that are similar to the current pro forma disclosures under SFAS 123, the Company is evaluating the requirements under SFAS 123(R) and expects the adoption to have a significant adverse impact on its consolidated statements of income and net income per share.

Note 3 Balance Sheet Components

Inventories consist of the following (in thousands):

	December 31,	
	2004	2003
Raw materials	$ 953	$ 859
Work in progress	1,547	1,140
Finished goods	352	335
	$2,852	$2,334

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):

	December 31,	
	2004	2003
Clinical and manufacturing equipment	$ 26,999	$ 26,558
Computer hardware	8,503	6,891
Computer software	7,620	3,413
Furniture and fixtures	3,977	3,869
Leasehold improvements	6,030	5,217
Construction in progress	1,609	2,133
	54,738	48,081
Less: Accumulated depreciation and amortization	(33,036)	(24,960)
	$ 21,702	$ 23,121

Property and equipment includes approximately $1,477,000 and $2,223,000 of assets under capital leases at December 31, 2004 and 2003. Accumulated amortization of assets under capital leases totaled approximately $1,342,000 and $1,771,000 at December 31, 2004 and 2003, respectively.

Depreciation expense and amortization was $9,597,000, $9,119,000 and $13,051,000 for the years ended December 31, 2004, 2003 and 2002, respectively.

Accrued liabilities consist of the following (in thousands):

	December 31,	
	2004	2003
Accrued marketing expenses	$ 3,313	$ 2,391
Accrued payroll and benefits	9,276	7,348
Accrued loss	1,985	871
Warranty	1,616	862
Taxes	2,201	2,093
Litigation settlement	—	2,094
Other	5,090	3,521
	$23,481	$19,180

Note 4 Commitments and Contingencies

Operating leases

In June 2000, the Company entered into a non-cancelable operating lease to lease a manufacturing facility in Santa Clara, California. The lease term is for five years and commenced on July 1, 2000. The Company paid $1,269,000 security deposit upon execution of the lease. In August 2001, the Company entered into an agreement to sublease additional office space in Santa Clara, California. The Company exercised a renewal option on this lease that extended the term to June 30, 2005. In February 2005, the Company renewed its Santa Clara leases beginning in July 2005. See Note 10—Subsequent Events.

In February 2004, the Company entered into an agreement to lease an operating 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 $53,000. The lease for this facility expires at the end of 2008.

The Company's 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 $27,000. The lease for this facility expires in 2014.

The Company operates a facility in Moscow, Russia. The facility comprises approximately 6,000 square feet of office space where the Company conducts certain research and development activities. The monthly rent for the Russian facility is approximately $17,000. The lease for this facility expires on April 10, 2005 and the Company does not expect to purchase or lease property in Moscow, Russia after this time.

Total rent expense was $4,868,000, $3,504,000 and $4,355,000 for the years ended December 31, 2004, 2003 and 2002, respectively. The terms of the facility lease provide for rental payments on a graduated scale. The Company recognizes rent expense on a straight-line basis over the lease period, and has accrued for rent expense incurred but not paid.

The future minimum lease payments under operating leases as of December 31, 2004 are as follows (in thousands):

Year Ended December 31,	
2005	$2,736
2006	$1,268
2007	990
2008	834
2009	141
Thereafter	—
Total	$5,969

Capitalized lease obligations

In May and August 2000, the Company leased two stereolithography machines from 3D Capital Corporation ("3D") under a Master Lease Agreement entered into in March 2000 and assigned to DeLage Landen in July 2001 for a total value of $1,479,000 at a borrowing rate of 6.533% per annum for a period of 60 months.

Future minimum payments under capital lease obligations as of December 31, 2004 are as follows (in thousands):

Minimum lease payment for 2005	$ 187
Less: Amount representing interest	(5)
Present value of minimum lease payments	182
Amount due within one year	(182)
Amount due after one year	$ —

Contingencies

In October 2003, the Company entered into a Loan Agreement with General Orthodontics, LLC ("GO"), whereby the Company agreed to make loan advances to GO of amounts not to exceed an aggregate principle balance of $200,000. The commitment by the Company to make advances to GO shall expire upon GO obtaining alternative financing. Interest on the loans will accrue on the unpaid principal amount of the outstanding loans at an annual rate of 5%. All loan advances and accrued interest are due and payable no later than October 2006. No advances were made by the Company to GO as of December 31, 2004. In February 2005, the Company entered into an agreement to acquire GO. See Note 10—Subsequent Events.

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. Among other things, the complaint alleges tort, contract, statutory and common law causes of action arising from OrthoClear and the individual defendants' alleged plan to unlawfully utilize the Company's intellectual property, confidential information and employees. The complaint also alleges that OrthoClear, Chishti and other defendants are in breach of contractual obligations, statutory law and common law for attempting to intentionally interfere and disrupt our ongoing business operations and improperly gain access to our customer relationships and trade secrets. The complaint seeks injunctive relief and monetary damages in an amount to be determined.

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

On February 18, 2005, the Court granted the Company's request for and issued a Temporary Restraining Order ("TRO") prohibiting OrthoClear and the individual OrthoClear defendants from engaging, assisting, or participating, directly or indirectly, in soliciting, inducing to leave, recruiting, or encouraging any current Align employee or consultant to terminate or alter his or her employment or business relationship with the Company or attempting to do the same. The Court also granted the Company's request and issued a TRO prohibiting OrthoClear and the individual OrthoClear defendants from disclosing, using, lecturing upon or publishing any of the Company's proprietary information without the Company's express prior written permission. In addition, in response to a cross-application for TRO filed by certain OrthoClear defendants, the Court enjoined Chishti and the Align Parties from disparaging each other in such a manner as to violate the mutual non-disparagement clause contained in the Separation Agreement between the Company and Chishti dated as of March 27, 2002. The Court also enjoined the Align Parties from advising any Align employee or consultant that he or she will be subject to criminal charges or a civil lawsuit if that person elects to change his or her employment status with the Company, unless the Company has good cause to believe criminal conduct has been or will be committed or that a civil cause of action will lie against the employee or consultant. The Court also required the Align Parties to refrain from taking any actions inconsistent with Federal or State securities laws relating to the issuance or redemption of the common stock of the Company. The Court scheduled an Order to Show Cause hearing why a Preliminary Injunction should not be issued in accordance with the terms of the TRO for March 8, 2005. On March 1, 2005, the Court signed a Stipulated Preliminary Injunction Order, whereby the Court ordered that the March 8th hearing date be vacated and further ordered that the express terms of the TRO remain in place until the earlier of (i) trial, (ii) written agreement of the parties or further Court order setting an earlier termination, or (iii) as to the preliminary injunction regarding non-solicitation or recruiting of Align employees or consultants only, October 27, 2005. No trial date has been set in the case.

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 U.S. Patent Nos. 5,447,432, 5,683,243 and 6,244,861. The complaint seeks 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 its U.S. Patent No. 6,398,548, seeking unspecified monetary damages and injunctive relief. Ormco filed a reply to the Company's counterclaims on March 10, 2003 and asserted counterclaims against the Company seeking a declaration by the Court of invalidity and non-infringement of U.S. Patent No. 6,398,548. The Company responded to Ormco's counterclaims on April 2, 2003. The Company amended its counterclaim to add Allesee Orthodontic Appliances, Inc. ("AOA"), a wholly-owned subsidiary of Ormco, as a counterdefendant in regard to the Company's counterclaim of infringement of U.S. Patent No. 6,398,548. The Court then permitted Ormco to amend its Complaint and permitted the Company to amend its 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, the Company 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 the Company filed. First, on May 14, 2004, the Court granted our motion for summary judgment of non-infringement, finding that the Company's 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 the Company's motion for summary judgment of infringement, finding that Ormco and AOA infringe certain, but not all, claims of the Company's 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 the Company's 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 the Company does not infringe these patents. In addition, the Court also denied Ormco's motion for summary judgment seeking a finding of invalidity of the Company's asserted patent claims (6,398,548 and 6,554,611). Fourth, the Court granted the Company's summary judgment motion that the Company's asserted its 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 asserted. Fifth, the Court also granted the Company's summary judgment motion that its patents are not unenforceable and granted Ormco's summary judgment motion that Ormco did not willfully infringe the Company's patents.

On December 20, 2004, the Company filed a further summary judgment motion that the Company's asserted claims are not invalid based on Ormco's new evidence. Ormco filed a counter-summary judgment motion that the Company's 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 the Company's motion in part, confirming the validity of all of the asserted claims of the Company's 6,554,611 patent and two of the asserted claims of the Company's 6,398,548 patent. The Court also granted Ormco's motion in part, finding certain claims of the Company's 6,398,548 patent to be invalid in view of prior use evidence. At this stage, only the Company's remedies for Ormco's adjudged infringement remain at issue.

From time to time, the Company has received and may in the future receive letters from third parties drawing our attention to their patent rights. While the Company does not believe that it infringes upon any valid and enforceable rights that have been brought to its attention, there may be other more pertinent rights of which the Company is not presently unaware. The defense and prosecution of intellectual property suits, interference proceedings and related legal and administrative proceedings could result in substantial expense to the Company and significant diversion of effort by the Company's technical and management personnel. An adverse determination in a patent suit by Ormco or in any other litigation or interference proceeding to which the Company may become a party could subject it to significant liabilities. An adverse determination of this nature could also put the Company's patents at risk of being invalidated or interpreted narrowly or require the Company 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.

Note 5 Credit Facilities

In December 2003, the Company negotiated a $15.0 million revolving line of credit based on domestic accounts receivable which accrues interest at a rate of 0.5% above prime. Accessing the accounts receivable based revolving line of credit is restricted based on qualifying accounts receivable and compliance with certain loan covenants. As of December 31, 2004 the Company had not drawn down the revolving line of credit.

In December 2002, the Company obtained and accessed a $5.0 million equipment-based term loan, which accrues interest at a rate of 2.25% above prime. The Company had not drawn down on any new funds in fiscal 2004. As of December 31, 2004, the equipment-based term loan had an outstanding balance of $1.7 million. Principal payments are due in 36 monthly installments and the remaining $1.7 million of principal payments are due by December 2005.

During the quarter ended December 31, 2004, the Company determined that it was out of compliance with its loan covenants for the accounts receivable-based revolving line of credit and equipment-based term loan requiring certain financial ratios and measurements to be maintained. The loan covenant requirements were amended as of January 28, 2005. As a result of the amendment, the Company is in full compliance with its loan covenants for the quarter ended December 31, 2004.

Note 6 Stockholders Equity

Preferred Stock

As of December 31, 2004, the Company has authorized 5,000,000 shares of preferred stock, $0.0001 par value, none of which was issued and outstanding. The Company's Board of Directors is authorized to determine the designation, powers, preferences and rights of preferred stock.

Common Stock

The holders of common stock are entitled to receive dividends whenever funds are legally available and when declared by the Board of Directors, subject to the prior rights of holders of all classes of stock having priority rights as to dividends. The Company has not declared or paid any dividends as of December 31, 2004.

In November 2002, the Company completed a private placement of 9,578,944 shares of common stock to a group of institutional investors led by existing shareholders, at $1.90 per share. Net proceeds to the Company were approximately $18,146,000.

Stock Option Plans

In April 1997, the Company adopted the 1997 Equity Incentive Plan ("1997 Plan") which provided for the grant of incentive stock options and non-statutory stock options to employees, non-employee directors, and consultants. In January 2001, the Board of Directors adopted and the stockholders approved the 2001 Stock Incentive Plan ("2001 Plan"). The 2001 Plan succeeded the 1997 Plan, and all outstanding options under the 1997 Plan were transferred to the 2001 Plan. No further grants have been made under the 1997 Plan. All transferred options are governed by their original terms which are substantially similar to options granted under the 2001 Plan. Under the terms of the 1997 Plan, the Company has the right to repurchase any unvested shares after termination of service with the Company. At December 31, 2004 and 2003, there were 570 and 200,298 shares of common stock subject to repurchase, respectively, relating to unvested options that were granted and exercised under the 1997 Plan.

The 2001 Plan, which expires in 2011, provides for the granting of incentive stock options, non-statutory stock options and restricted stock purchase rights and stock bonuses to employees, non-employee directors and consultants. The options are granted for periods not exceeding ten years and generally vest 25% one year from the date of grant and 1/48th each month thereafter. Options are to be granted at an exercise price not less than fair market value at the date of grant. The authorized shares under the 2001 Plan automatically increase each January 1 by an amount equal to the lesser of 3,000,000 shares or 5.0% of the Company's outstanding shares as of the prior fiscal year end. A total of 16,211,001 shares of the Company's common stock have been reserved for issuance under the 2001 Plan as of December 31, 2004.

Executive Grants

In January 2001, the stockholders approved two option grants to purchase 1,000,000 shares of the Company's common stock to purchase shares 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 Plan and prior to the adoption of the 2001 Plan. As of December 31, 2004, an aggregate of 1,500,000 options to purchase shares of common stock remained outstanding under these two option grants.

Activity under the stock option plans are set forth below (in thousands, except per share data):

		Options Outstanding		
	Shares Available for Grant	Shares	Weighted Average Exercise Price	Aggregate Price
Balances at December 31, 2001	8,743	5,489	$ 7.14	$39,193
Increase in pool	2,388	—	—	—
Options granted	(4,150)	4,150	4.22	17,513
Options exercised	—	(670)	0.93	(622)
Stock repurchased	443	—	0.96	—
Options cancelled	1,299	(1,299)	4.54	(5,902)
Balances at December 31, 2002	8,723	7,670	$ 6.54	$50,182
Increase in pool	2,885	—	—	—
Options granted	(2,720)	2,720	8.48	23,062
Options exercised	—	(879)	2.78	(2,446)
Stock repurchased	20	—	1.02	—
Options cancelled	244	(244)	6.88	(1,677)
Options expired	—	(500)	15.00	(7,500)
Balances at December 31, 2003	9,152	8,767	$ 7.03	$61,621
Increase in pool	2,937	—	—	—
Options granted	(2,446)	2,446	17.85	43,661
Options exercised	—	(1,695)	3.79	(6,424)
Stock repurchased	1	—	1.07	—
Options cancelled	468	(468)	11.13	(5,209)
Balances at December 31, 2004	10,112	9,050	$10.35	$93,649

The options outstanding and currently exercisable by exercise price at December 31, 2004 are as follows (in thousands, except per share data):

	Options Outstanding			Vested	
Range of Exercise Prices	Number of Outstanding and Exercisable	Weighted-Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Number of Shares	Weighted Average Exercise Price
$ 0.01 – 2.24	732	5.8	$ 1.07	577	$0.83
2.25 – 4.48	1,079	6.0	3.45	609	3.66
4.49 – 6.73	2,605	7.7	5.62	1,302	5.57
6.74 – 11.21	208	7.2	9.28	129	8.96
11.22 – 13.45	342	8.9	12.39	111	12.53
13.46 – 15.70	1,767	3.7	14.94	1,621	14.95
15.71 – 17.94	730	9.3	16.23	59	16.65
$17.95 – 22.43	1,587	9.2	18.95	73	18.63
	9,050	7.0	$10.35	4,481	$8.72

The weighted average per share fair values of options granted during the years ended December 31, 2004, 2003 and 2002 were $9.17, $6.03 and, $3.50, respectively.

Employee Stock Purchase Plan

In January 2001, the Board of Directors adopted and the stockholders approved the Employee Stock Purchase Plan ("the Purchase Plan"). The Purchase Plan is intended to qualify as an employee stock purchase plan within the meaning of Section 423 of the Internal Revenue Code of 1986, as amended. The Purchase Plan, which has 5,109,000 shares of common stock reserved for future issuance, enables eligible employees to purchase shares at 85% of the fair market value of the common stock at the beginning of the offering period or end of the purchase period, whichever is lower. Each offering period has a maximum duration of two years and consists of four six-month purchase periods. Offering periods and purchase periods generally begin on the first trading day on or after February 1 and August 1 of each year. Under the Purchase Plan, the Company sold approximately 429,000 and 194,000 shares of common stock during the years ended December 31, 2004 and 2003, respectively.

Stock-based compensation

In connection with the grant of stock options to employees prior to our initial public offering ("IPO") and certain grants subsequent to the IPO, the Company recorded deferred stock compensation representing the difference between the fair value of the common stock for accounting purposes and the exercise price of these options at the date of grant. Compensation expense is amortized over the option vesting period of four years using the straight-line method. For the years ended December 31, 2004, 2003, and 2002, Align recorded amortization of stock-based compensation of $5,089,000, $12,419,000 and $16,539,000, respectively. If the employee terminates employment and therefore cancels any unvested options, the Company will reverse the unamortized deferred stock-based compensation related to those options. During fiscal 2004, 2003, and 2002, Align reversed $147,000, $1,355,000 and $12,419,000, respectively, of unrecognized deferred compensation for terminated employees. As of December 31, 2004, the Company had fully amortized the deferred stock-based compensation balance related to employee options.

For options granted to non-employees in connection with the IPO, the Company initially recorded deferred stock-based compensation based on the fair value at the grant date using the Black-Scholes valuation model. The Company revalued the remaining unvested options at the end of each period and reflected the change in deferred stock based compensation as an additional deferral or reversal. During the fiscal years 2004, 2003, and 2002, Align recorded additional (reversals of) deferred stock-based compensation of $17,000, $365,000 and $(316,000) related to the revaluation of non-employee options. The compensation expense is recognized over the option vesting period of four years, using the method presented by FIN 28. For the years ended December 31, 2004, 2003 and 2002, the Company recorded amortization of deferred stock-based compensation expense of $24,000, $377,000, and $45,000, respectively, in connection with non-employee options. As of December 31, 2004, Align had fully amortized the deferred stock-based compensation balance related to non-employee options.

For options granted to non-employees, the Company measures the options' fair value using the Black-Scholes model at each reporting period and recognizes stock based compensation expense as the options vest. The vesting period is generally over four years from the date of grant. For the fiscal years 2004, 2003, and 2002 Align recorded stock-based compensation of $429,000, $1,276,000 and $2,010,000 related to stock options granted to non-employees.

The Company accelerated the vesting of options to several employees in connection with related severance packages. In accordance with FASB Interpretation No. 44 (FIN 44), the acceleration charges are 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 less any previously recognized expense. Acceleration charges for December 31, 2004, 2003 and 2002 were $350,000, $959,000 and $2,245,000, respectively.

Stock based compensation has been recorded as follows (in thousands):

	Year Ended December 31,		
	2004	2003	2002
Cost of revenues	$ 894	$ 2,560	$ 3,399
Sales and marketing	651	2,202	3,002
General and administrative	2,736	7,107	10,663
Research and development	1,586	3,162	3,221
	$5,867	$15,031	$20,285

Note 7 Income Taxes

The tax effects of temporary differences that give rise to significant portions of the deferred tax assets are presented below (in thousands):

	Year Ended December 31,	
	2004	2003
Deferred tax assets, net:		
Net operating loss carryforwards	$ 78,090	$ 63,986
Research and development credit carrryforwards	5,852	4,022
Deferred revenue	—	4,597
Accruals, allowances & other not currently deductible for tax purposes	4,597	2,323
Deferred tax assets	88,539	74,928
Less: Valuation allowance	(88,539)	(74,928)
Net deferred tax asset	$ —	$ —

Based on the available objective evidence, management believes it is more likely than not that the net deferred tax assets will not be fully realizable. Accordingly, the Company has provided a full valuation allowance against its net deferred tax assets at December 31, 2004.

The differences between the U.S. federal statutory income tax rate (benefit) and the Company's effective tax rate were as follows:

	Year Ended December 31,	
	2004	2003
U.S. federal statutory income tax rate	34.00%	(34.00)%
State income taxes, net of federal tax benefit	6.00%	(6.00)%
Deferred tax benefits utilized	(98.66)%	—
Foreign losses not benefited	11.24%	5.64%
Impact of differences in foreign tax rates	37.06%	—
Amortization of stock-based compensation	13.27%	30.00%
Other items not individually material	7.27%	4.78%
	10.18%	0.42%

As of December 31, 2004, the Company had a net operating loss carryforward of approximately $201.7 million for federal purposes and $122.5 million for state tax purposes. If not utilized, these carryforwards will begin to expire beginning in 2017 for federal purposes and 2005 for state purposes.

The Company has research credit carryforwards of approximately $3.8 million for federal purposes and $3.1 million for California state income tax purposes. If not utilized, the federal credit carryforward will begin to expire in various amounts beginning in 2017. The California state credit can be carried forward indefinitely.

The Tax Reform Act of 1986 limits the use of net operating loss and tax credit carryforwards in certain situations where stock ownership changes occur. In the event the Company has had a change in ownership, utilization of the carryforwards could be restricted.

The components of the provision for income taxes are as follows (in thousands):

	Year Ended December 31,		
	2004	2003	2002
Current:			
Federal	$282	$ 17	$—
State	197	67	—
Foreign	515	—	—
Total provision for income taxes	$994	$ 84	$—

Note 8 Supplemental Cash Flow Information

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

	Year Ended December 31,		
	2004	2003	2002
Taxes paid	$258	$222	$ 231
Interest paid	$190	$364	$ 143
Non-cash investing and financing activities:			
Repurchase of note receivable for common stock	$—	$—	$ (260)
Fixed assets acquired as exchange	$834	$—	$ —
Fixed assets acquired with accounts payable or accrued liabilities	$ 45	$—	$ 48
Deferred stock-based compensation	$130	$549	$13,289

Note 9 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 10 Subsequent Events

In February 2005, the Company entered into three new lease agreements for the Company's headquarters located in Santa Clara, California. The new lease agreements will be effective as of July 1, 2005 and expire in 2010. The Company will lease approximately 110,000 square feet of space and will house the Company's manufacturing, customer support, software engineering and administrative personnel. The combined monthly rent for the Santa Clara facilities will be approximately $61,000. Commencing July 1, 2005, however, and continuing on the first day of each calendar month thereafter, $10,575 will be deducted from the $1,269,000 security deposit previously paid by the Company to the lessor and such amount will be applied against the monthly base rent for the Santa Clara facilities. Upon the occurrence of certain events, the Company will lease an additional 15,704 square feet of space at the Santa Clara facilities for a monthly rent of $25,000. The future minimum operating lease payments under the new lease obligations commencing July 1, 2005 for the 110,000 square feet of space are approximately $366,000, $743,000, $765,000, $788,000, $812,000, $412,000 for the fiscal years 2005, 2006, 2007, 2008, 2009 and thereafter (excluding the $25,000 monthly lease payment for the additional 15,704 square feet of space the Company will rent upon the occurrence of certain events).

In February 2005, the Company entered into an agreement to acquire General Orthodontic LLC (GO), a privately-held company. Prior to the acquisition, GO had provided a range of Invisalign treatment planning consulting and support services to doctors since 2003. Under the terms of the agreement, the Company has agreed to purchase GO for approximately $2.4 million, which includes an initial payment of $1.4 million and up to $1.0 million for performance-based earnouts.

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) as of the end of the period covered by this report. Based upon that evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that our disclosure controls and procedures were effective as of December 31, 2004 to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act 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.

The information required to be furnished pursuant to this item is set forth under the caption "Management's Report on Internal Control over Financial Reporting" on page 46 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 48 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, 2004 that have materially affected or are reasonably likely to material affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION.

None.

PART III

Certain information required by Part III is omitted from this Form 10-K because we intend to file a definitive Proxy Statement for our 2005 Annual Meeting of Stockholders (the "Proxy Statement") not later than 120 days after the end of the fiscal year covered by this Form 10-K, and certain information to be included therein is incorporated herein by reference.

ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT.

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 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.

Audit Committee Financial Expert

Our Board of Directors has determined that Mr. Greg J. Santora is an audit committee financial expert. Mr. Santora is considered "independent" as the term is used in Item 7(d)(3)(iv) of Schedule 14A under the Exchange Act.

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 10 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 Stock 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.

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

Equity Compensation Plan Information

The following table provides information as of December 31, 2004 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, each as amended, and certain individual arrangements.

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted average exercise price of outstanding options, warrants and rights (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	9,050,000(1)(2)	$10.35	15,221,000(3)
Equity compensation plans not approved by security holders	—	—	—
Total	9,050,000	$10.35	15,221,000

(1) This number reflects the number of securities to be issued upon exercise of outstanding options under the 2001 Stock Incentive Plan and arrangements outside of this Plan between Align Technology, Inc. and two former employees. In January 2001, all outstanding options under the 1997 Equity Incentive Plan were subsumed under the 2001 Stock Incentive Plan. Currently there are no options outstanding under 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 2001 Stock Incentive Plan and the Employee Stock Purchase Plan. In January 2001, all of the options available for issuance under the 1997 Equity Incentive Plan were subsumed under the 2001 Stock Incentive Plan. Currently there are no options available for issuance under the 1997 Equity Incentive Plan. Additionally, no options are available for issuance under any arrangement between Align Technology, Inc. and any individual. The 2001 Stock Incentive 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 five percent (5%) 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 3,000,000 shares. 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, 2004, the total number of our Common Stock reserved for issuance under the Employee Stock Purchase Plan is 5,109,000. As of December 31, 2004, the number of options available for future issuance under the 2001 Stock Incentive Plan is 10,112,000.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS.

The information required by this Item is incorporated by reference to the Proxy Statement under the section captioned “Certain Relationships and Related Transactions.”

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this item is included under the captions “Ratification of Appointment of Independent Registered Public Accounting Firm” in our Proxy Statement and is incorporated herein by reference.

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:

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

   Schedule II—Valuation and Qualifying Accounts and Reserves

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

SCHEDULE II: VALUATION AND QUALIFYING ACCOUNTS AND RESERVES

	Balance at Beginning of Period	Additions (reductions) to Costs and Expenses	Write-offs	Reclasses from Other Accounts	Balance at End of Period
			(in thousands)		
Allowance for doubtful accounts:					
Year ended December 31, 2002	1,882	1,068	(821)	(18)	2,111
Year ended December 31, 2003	2,111	(86)	(753)	(13)	1,259
Year ended December 31, 2004	1,259	540	(311)	5	1,493
Allowance for deferred tax asset:					
Year ended December 31, 2002	63,140	21,842	—	—	84,982
Year ended December 31, 2003	84,982	(10,054)	—	—	74,928
Year ended December 31, 2004	74,928	13,611	—	—	88,539
Allowance for excess and obsolete inventory and abandoned product:					
Year ended December 31, 2002	555	51	(107)	(30)	469
Year ended December 31, 2003	469	18	(234)	—	253
Year ended December 31, 2004	253	(72)	(138)	—	43

3. Exhibits

Exhibit Number	Description	Incorporated by reference herein			Filed herewith
		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	
4.1	Form of Specimen Common Stock Certificate.	Form S-1, as amended (File No. 333-49932)	01/17/2001	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	
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 Services Agreement between registrant and ELAMEX, S.A. DE C.V. dated February 16, 2000.	Form S-1 as amended (File No. 333-49932)	11/14/2000	10.7	
10.8	Amendment dated June 3, 2003 to Shelter Services Agreement by ELAMEX, S.A. DE C.V. and registrant.	Form 10-K for fiscal year ended December 31, 2002	03/27/2003	10.7.1	

Exhibit Number	Description	Incorporated by reference herein			Filed herewith
		Form	Date	Number	
10.9	Assignment of Interest and Obligations dated July 4, 2003 by and between Elamex, S.A. de C.V. and International Manufacturing Solutions Operaciones, S.R.L.	Form 10-Q for quarter ended June 30, 2003	08/13/2003	10.7.2	
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	Agreement to confirm consulting and board duties, dated February 26, 2002, between Kelsey Wirth and registrant.	Form 10-Q for quarter ended March 31, 2002	05/15/2002	10.18	
10.15†	Employment Agreement dated March 27, 2002 between Thomas M. Prescott and registrant.	Form 10-Q for quarter ended March 31, 2002	05/15/2002	10.20	
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 July 15, 2002 for David S. Thrower, Vice-President of Global Marketing.	Form 10-Q for quarter ended September 30, 2002	11/14/2002	10.19	
10.18†	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	
10.19†	Form of Employment Agreement entered into by and between registrant and each of Eldon M. Bullington, Roger E. George, Len M. Hedge and David S. Thrower.	Form 10-K for fiscal year ended December 31, 2002	03/27/2003	10.25	
10.20	Stock Option Agreement dated January 4, 2001 by and between Kelsey Wirth and registrant.	Form 10-K for fiscal year ended December 31, 2002	03/27/2003	10.26	
10.21	Amendment to Master Professional Services Agreement dated May 20, 2003 by and between Invisible IT Inc. and registrant.	Form 10-K for fiscal year ended December 31, 2002	03/27/2003	10.29	

Exhibit Number	Description	Incorporated by reference herein			Filed herewith
		Form	Date	Number	
10.22	Settlement Agreement and Mutual Release dated February 6, 2004 by and among GW Com, Inc., now known as Byair, Inc., Intelecady, Inc., James S. Lindsey and registrant.	Form 10-K for fiscal year ended December 31, 2002	03/27/2003	10.30	
10.23	Director Offer Letter dated March 6, 2004 for David E. Collins.	Form 10-K for fiscal year ended December 31, 2002	03/27/2003	10.33	
10.24	Loan and Security Agreement dated December 20, 2002 by and between Comerica Bank-California and registrant.	Form 10-K for fiscal year ended December 31, 2002	03/27/2003	10.35	
10.25	Amendment No. 1 to Loan and Security Agreement with Limited Waiver dated as of August 4, 2003 by and between the registrant and Comerica Bank.	Form 10-Q for quarter ended June 30, 2003	08/13/2003	10.35.1	
10.26	Amendment No. 3 to Loan and Security Agreement dated as of December 17, 2003 by `and between registrant and Comerica Bank.	Form 10-K for fiscal year ended December 31, 2003	03/09/2004	10.35.2	
10.27	Amendment No. 4 to Loan and Security Agreement dated as of January 28, 2005 by and between registrant and Comerica Bank.	Form 8-K	02/02/2005	10.1	
10.28	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	
10.29	Director Offer Letter dated July 18, 2003 for Greg J. Santora.	Form 10-Q for quarter ended September 30, 2003	11/12/2003	10.37	
10.30	Director Offer Letter dated January 29, 2004 for C. Raymond Larkin.	Form 10-Q for quarter ended March 31, 2004	05/06/2004	10.39	
10.31†	Employment Agreement dated as of December 15, 2003 by and between registrant and Patricia Wadors.	Form 10-K for quarter ended December 31, 2003	03/09/2004	10.38	
10.32	Lease Agreement between Schootsepoort Onroerendgoed Beheer, for Stichting Philips Pensioenfonds and Align Technology, Inc.	Form 10-Q for quarter ended June 30, 2004	08/05/2004	10.41	
10.33†	Terms of employment between Align Technology, Inc. and Bob Mitchell dated June 15, 2004.	Form 10-Q for quarter ended June 30, 2004	08/05/2004	10.42	

Exhibit Number	Description	Incorporated by reference herein			Filed herewith
		Form	Date	Number	
10.34†	Employment Agreement between Robert D. Mitchell and Align dated July 12, 2004.	Form 10-Q for quarter ended September 30, 2004	11/05/2004	10.44	
10.35†	Employment Agreement between Cecilia Claudio and Align dated September 13, 2004.	Form 10-Q for quarter ended September 30, 2004	11/05/2004	10.45	
10.36†	Severance Agreement between Jon Fjeld and Align dated July 14, 2004.	Form 10-Q for quarter ended September 30, 2004	11/05/2004	10.46	
10.37†	Employment Agreement with Rok Sribar.	Form 8-K	02/07/2005	10.1	
10.38	Summary of standard director cash compensation arrangements for fiscal year ending December 31, 2005.	Form 8-K	02/16/2005	N/A	
10.39†	Summary of cash bonus awards for fiscal year ended December 31, 2004 for each of the registrant's named executive officers.				*
10.40†	Summary of certain stock option grants to the registrant's named executive officers.				*
21.1	Subsidiaries of the registrant.				*
23.1	Consent of PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firm.				*
24.1	Power of Attorney incorporated herein by reference to the signature page of this Annual Report on Form 10-K.				*
31.1	Certifications of Chief Executive Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2003.				*
31.2	Certifications of Chief Financial Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2003.				*
32	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2003.				*

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

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this amendment to be signed on its behalf by the undersigned, thereunto duly authorized, on March 3, 2005.

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 amendment has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ THOMAS M. PRESCOTT **Thomas M. Prescott**	President and Chief Executive Officer (Principal Executive Officer)	March 3, 2005
/s/ ELDON M. BULLINGTON **Eldon M. Bullington**	Chief Financial Officer and Vice President, Finance (Principal Financial Officer and Principal Accounting Officer)	March 3, 2005
/s/ KELSEY WIRTH **Kelsey Wirth**	Director	March 3, 2005
/s/ BRIAN DOVEY **Brian Dovey**	Director	March 3, 2005
/s/ JOSEPH LACOB **Joseph Lacob**	Director	March 3, 2005
/s/ H. KENT BOWEN **H. Kent Bowen**	Director	March 3, 2005
/s/ DAVID E. COLLINS **David E. Collins**	Director	March 3, 2005
/s/ GREG J. SANTORA **Greg J. Santora**	Director	March 3, 2005
/s/ WARREN S. THALER **Warren S. Thaler**	Director	March 3, 2005
/s/ C. RAYMOND LARKIN **C. Raymond Larkin**	Director	March 3, 2005

Officers and Directors

EXECUTIVE TEAM

Thomas M. Prescott
President and
Chief Executive Officer

Eldon M. Bullington
Vice President, Finance and
Chief Financial Officer

Cecilia Claudio
Vice President, Engineering and
Chief Information Officer

Roger E. George
Vice President, Legal Affairs and
General Counsel

Len Hedge
Vice President, Operations

Rok Sribar, Ph.D.
Vice President, Research
and Development

David S. Thrower
Vice President, Global Marketing

Patricia Wadors
Vice President, Human Resources

BOARD OF DIRECTORS

H. Kent Bowen
Bruce Rauner Professor of
Business Administration
Harvard University Graduate
School of Business Administration

David E. Collins
Former Vice Chairman
Johnson & Johnson

Brian H. Dovey
Managing Partner
Domain Associates, L.L.C.

Joseph S. Lacob
Partner
Kleiner Perkins Caufield & Byers

C. Raymond Larkin, Jr.
Chairman and
Chief Executive Officer
Eunoe, Inc.

Thomas M. Prescott
President and
Chief Executive Officer
Align Technology, Inc.

Greg J. Santora
Chief Financial Officer
Shopping.com

Warren S. Thaler
President
Gund Investment Corporation

Kelsey Wirth
Former President and Co-Founder
Align Technology, Inc.

Shareholder Information

CORPORATE HEADQUARTERS
Align Technology, Inc.
881 Martin Ave.
Santa Clara, CA 95050
408.470.1000

WEB SITES
www.aligntech.com
www.invisalign.com

INVESTOR RELATIONS
For additional information about Align, additional copies of this Annual Report and Align's Annual Report on Form 10-K as filed with the Securities and Exchange Commission, or other financial information, contact:

Investor Relations
Align Technology, Inc.
881 Martin Ave.
Santa Clara, CA 95050
Email: investorinfo@aligntech.com
408.470.1000

TRANSFER AGENT
EquiServe Trust Company, N.A.
P.O. Box 219045
Kansas City, MO 64121-9045
Shareholder Inquiries:
816.843.4299
Web site: www.EquiServe.com

INDEPENDENT AUDITORS
PricewaterhouseCoopers LLP
Ten Almaden Blvd., Suite 1600
San Jose, CA 95113

GENERAL COUNSEL
Wilson Sonsini Goodrich & Rosati
650 Page Mill Road
Palo Alto, CA 94304

designed and produced by see see eye / Atlanta, Georgia

Our vision is to provide people everywhere with a more attractive way to get beautiful, healthy smiles.

ALIGN

ALIGN TECHNOLOGY, INC.

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