ALIGN TECHNOLOGY INC
Form 10-K/A
August 13, 2003
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K/A

(Mark One)

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

For the fiscal year ended December 31, 2002

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 x 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/A or any amendment to this Form 10-K/A. x

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

As of June 28, 2002, the last business day of Registrant s most recently completed second fiscal quarter, there were 25,311,858 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 28, 2002) was approximately $99,222,483. Shares of Registrant s common stock held by each executive officer and director and by each entity that owns 5% or more of Registrant s outstanding common stock have been excluded in that such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

On March 18, 2003, 57,785,523 shares of Registrant s common stock were outstanding.

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EXPLANATORY NOTE

THIS ANNUAL REPORT ON FORM 10-K/A IS BEING FILED FOR THE PURPOSE OF AMENDING AND RESTATING ITEM 1 OF PART I, ITEMS 6, 7, AND 8 OF PART II, ITEM 14 OF PART III AND ITEM 15 OF PART IV OF FORM 10-K (EXCLUDING RISK FACTORS) SOLELY TO THE EXTENT NECESSARY (I) TO REFLECT THE RESTATEMENT OF OUR CONSOLIDATED FINANCIAL STATEMENTS AT DECEMBER 31, 2002 AND 2001, AND THE RESULTS OF OPERATIONS AND CASH FLOWS FOR EACH OF THE TWO YEARS IN THE PERIOD ENDED DECEMBER 31, 2002, AS DESCRIBED IN NOTE 1 TO THE CONSOLIDATED FINANCIAL STATEMENTS, (II) TO MAKE REVISIONS TO MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS , AS WARRANTED BY THE RESTATEMENT, (III) TO INCLUDE THE CERTIFICATIONS REQUIRED BY THE SARBANES-OXLEY ACT OF 2002 AND (IV) TO UPDATE THE EXHIBITS AND FINANCIAL STATEMENT SCHEDULES AND REPORTS IN ACCORDANCE WITH THE AMENDMENT. WE HAVE MADE NO FURTHER CHANGES TO THE PREVIOUSLY FILED FORM 10-K. ALL INFORMATION IN THIS ANNUAL REPORT ON FORM 10-K/A IS AS OF DECEMBER 31, 2002 AND DOES NOT REFLECT ANY SUBSEQUENT INFORMATION OR EVENTS OTHER THAN THOSE REFLECTED IN THE RESTATEMENT.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of Registrant s definitive Proxy Statement relating to its Annual Stockholders Meeting to be held on May 15, 2003 are incorporated by reference into Part III of this Annual Report on Form 10-K.

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ALIGN TECHNOLOGY, INC.

FORM 10-K/A

For the Year Ended December 31, 2002

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PART I

THIS ANNUAL REPORT ON FORM 10-K/A IS BEING FILED FOR THE PURPOSE OF AMENDING AND RESTATING ITEM 1 OF PART I, ITEMS 6, 7, AND 8 OF PART II, ITEM 14 OF PART III AND ITEM 15 OF PART IV OF FORM 10-K (EXCLUDING RISK FACTORS) SOLELY TO THE EXTENT NECESSARY (I) TO REFLECT THE RESTATEMENT OF OUR CONSOLIDATED FINANCIAL STATEMENTS AT DECEMBER 31, 2002 AND 2001, AND THE RESULTS OF OPERATIONS AND CASH FLOWS FOR EACH OF THE TWO YEARS IN THE PERIOD ENDED DECEMBER 31, 2002, AS DESCRIBED IN NOTE 1 TO THE CONSOLIDATED FINANCIAL STATEMENTS (II) TO MAKE REVISIONS TO MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS , AS WARRANTED BY THE RESTATEMENT, (III) TO INCLUDE THE CERTIFICATIONS REQUIRED BY THE SARBANES-OXLEY ACT OF 2002 AND (IV) TO UPDATE THE EXHIBITS AND FINANCIAL STATEMENT SCHEDULES AND REPORTS IN ACCORDANCE WITH THE AMENDMENT. WE HAVE MADE NO FURTHER CHANGES TO THE PREVIOUSLY FILED FORM 10-K. ALL INFORMATION IN THIS ANNUAL REPORT ON FORM 10-K/A IS AS OF DECEMBER 31, 2002 AND DOES NOT REFLECT ANY SUBSEQUENT INFORMATION OR EVENTS OTHER THAN THOSE REFLECTED IN THE RESTATEMENT.

Align Technology, Inc. (Align) has not amended its Annual Report on Form 10-K for the period ended December 31, 2001 or Quarterly Reports on Form 10-Q for the periods affected by the restatement during the years ended December 31, 2002 or 2001, therefore the consolidated financial statements and related financial information contained therein should no longer be relied upon. The restated consolidated financial statements for the year ended December 31, 2001 are included as part of the consolidated financial statements included in this Annual Report on Form 10-K/A. The restated quarterly results of operations for the years ended December 31, 2002 and 2001 are included in Item 8, Consolidated Financial Statements and Supplementary Data.

The statements contained below and elsewhere in this Annual Report on Form 10-K/A that are not purely historical are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and Section 21E of the Securities Exchange Act of 1934, including, without limitation, statements regarding our expectations, hopes, beliefs, anticipations, commitments, intentions and strategies regarding the future. Actual results could differ from those projected in any forward-looking statements for the reasons, among others, detailed below. The fact that some of the risk factors may be the same or similar to our past filings means only that the risks are present in multiple periods. We believe that many of the risks detailed here are part of doing business in the industry in which we compete and will likely be present in all periods reported. The fact that certain risks are characteristic to the industry does not lessen the significance of the risk. The forward-looking statements are made as of the date of this Annual Report on Form 10-K/A, and we assume no obligation to update the forward-looking statements or to update the reasons why actual results could differ from those projected in the forward-looking statements.

ITEM 1. BUSINESS.

Overview

Since the inception of Align in April 1997, we have been engaged in the design, manufacture and marketing of Invisalign, a proprietary system for treating malocclusion, or the misalignment of teeth. In July 1999, we commenced commercial sales of Invisalign. Prior to July 1999, we devoted nearly all our resources to developing our software and manufacturing processes, performing clinical trials of Invisalign and building our sales force, customer support and management teams. We exited the development stage in July 2000.

Invisalign has two components: ClinCheck and Aligners. ClinCheck is an Internet-based application that allows dental professionals to simulate treatment, in three dimensions, by modeling two-week stages of tooth movement. Aligners are thin, clear plastic, removable dental appliances

that are manufactured in a series to

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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.

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 contract 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.

In July 2002, we announced a plan to streamline worldwide operations. The plan included closing our facility in Pakistan and the United Arab Emirates, or the U.A.E. We transitioned the operations performed at these facilities to the United States and Costa Rica. For the period ending December 31, 2002, we recorded severance charges of $2.3 million, facility closure charges of $0.9 million, a loss on disposal of fixed assets of $1.1 million and an impairment charge of $0.9 million related to the land in Pakistan. The land was written down to a zero value to reflect its fair value as estimated by management. Approximately $0.1 million of accrued charges related to professional fees were included in accrued liabilities as of December 31, 2002. We discontinued operations at our facilities in Pakistan and the U.A.E in October and December 2002, respectively. We concluded the remainder of indirect operational activities related to the Costa Rica transition in January 2003. We will cease non-operational closing activities in Pakistan when the land is disposed of at that location and in the U.A.E when the necessary statutory filings have been completed.

Revenue from the sale of Invisalign and ancillary products is recognized upon product shipment, provided no significant obligations remain, transfer of title has occurred, and collection of the receivables 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, i.e. upon shipment of the Aligners.

From June 2001 until April 2003, Align offered customers the option to purchase a one-time, non-refundable case refinement at the time of the initial treatment plan purchase at a discounted price of $50. Customers not electing to purchase the upfront case refinement (or requiring additional refinements i.e. in addition to the one purchased in advance) could subsequently purchase a case refinement at a price of $250 (stand-alone value). Align deferred $50 of revenue and accrued the anticipated loss related to the cost of producing and delivering the related Aligners for discounted case refinements sold at the beginning of the treatment period. These deferred amounts were recognized when either the case refinement shipped or upon case expiration. Where the customer declined to purchase the $50 upfront case refinement but subsequently purchased the $250 stand-alone case refinement, Align recognized the revenue associated with the $250 stand-alone case refinement fee upon shipment of the new Aligners.

In May 2003, Align updated its domestic pricing policy 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, which Align believes represents its fair value based on competitive product offerings. Revenue deferrals associated with future case refinement sales will be at $125. This revenue deferral amount represents the fair value of a case refinement as determined in accordance with the newly adopted rules contained in Emerging Issues Task Force Issue No. 00-21 (EITF 00-21), Accounting for Revenue Arrangements with Multiple Deliverables, 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 utilized or upon case expiration.

During the quarter ended June 30, 2003, in conjunction with Align s adoption of EITF 00-21, Align re-evaluated its prior accounting treatment for case refinement revenues under the principles contained in Staff Accounting Bulletin No. 101, Revenue Recognition in Financial Statements, (SAB 101) and related guidance. Align determined that under SAB 101 the revenue amount deferred on advance sales of case refinement should be based on the stand-alone value of case refinement rather than the published discounted price for advance

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purchase. On July 24, 2003, Align announced that, as a result of its review, it would restate its financial statements for fiscal 2001, fiscal 2002 and the first three months of fiscal 2003. Refer to Item 6. Selected Consolidated Financial Data and Item 8, Note 1, Restatement of Previously Issued Financial Statements, for a detailed discussion of investigation results and related restatements.

Service revenues earned under agreements with third parties for training of dental professionals and staff for Invisalign are recorded as the services are performed. Charges to third parties are based on negotiated rates that 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.

Industry Background

Malocclusion

Malocclusion 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 orthodontic treatment 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, in an attempt to improve treatment aesthetics, dental professionals use ceramic, tooth-colored brackets or bond brackets on the inside, or lingual surfaces, of the patient s teeth. Dental professionals also augment braces with elastics, metal bands, headgear and other ancillary devices.

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

residual cement from the patient s teeth.

Fees for traditional orthodontic treatment typically range between U.S. $3,000 to $5,000 and 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.

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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 half of 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. Invisalign consists of two components: ClinCheck and Aligners.

ClinCheck. ClinCheck is an interactive Internet application 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

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simulation. Upon the dental professional s approval of the ClinCheck simulation, we use the data underlying the simulation to manufacture the patient s Aligners.

Aligners. Aligners are custom-manufactured, clear, removable dental appliances that, when worn in a prescribed series, provide orthodontic treatment. 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 discards the Aligners and 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 the last Aligner as a temporary retainer or go directly to a conventional retainer.

Benefits of Invisalign

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

Benefits to the Patient

Excellent aesthetics. Aligners are nearly invisible when worn, eliminating 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 series, minimizing inconvenience to both patient and dental professional.

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

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.

Minimal additional training. The biomechanical principles that underlie Invisalign are consistent with those of traditional orthodontics. Dental professionals can complete our initial training and certification program within two days.

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Ease of use. When treating patients with Invisalign, dental professionals do not spend their time manipulating wires and brackets. This allows them to spend proportionately more time diagnosing and interacting with their patients.

Expanded patient base. We believe that Invisalign has the potential to transform the practice of orthodontics. Currently, less than one percent of the over 200 million people with malocclusion in the U.S. enter treatment each year. We believe that Invisalign will allow dental professionals to attract patients who would not otherwise seek orthodontic treatment.

Decreased dental professional and staff time. We believe that Invisalign reduces both the frequency and length of patient visits. Invisalign eliminates the need for time-intensive processes such as bonding appliances to the patient s teeth, adjusting archwires during the course of treatment and removing the appliances at the conclusion of treatment. As such, use of Invisalign reduces dental professional and staff chair time and can increase practice throughput.

Practice productivity. We believe that as dental professionals move to a higher volume of Invisalign patients, 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.

We believe the combination of increased patient volume, reduced chair time and increased practice productivity has the potential to improve orthodontic practice profitability.

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. We believe that these limitations are outweighed by the many benefits of Invisalign to both patients and dental professionals.

Our Target Market

Commercial sales of Invisalign commenced in the U.S. in July 1999. As of December 31, 2002 approximately 80,000 patients worldwide had entered treatment using Invisalign.

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. We voluntarily restrict the use of Invisalign to adults and adolescents with mature dentition. Individuals with mature dentition have fully erupted second molars and substantially complete jaw growth. This group represents approximately 160 million people in the U.S. Typically, girls by the age of 13 years and boys by the age of 16

years will have developed mature dentition. Currently, 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.

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Approximately two million patients enter into traditional orthodontic treatment in the U.S. annually. These patients represent approximately one percent of the population of people with malocclusion. Of these, over 50%, or more than one million patients, have mature dentition and are therefore potential candidates for Invisalign.

In addition, we believe that we have an immediate and substantial market expansion opportunity. 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 significant market expansion opportunity.

In each of fiscal 2002, 2001 and 2000, no single customer accounted for 10% or more of our total revenues.

We continue to focus on the domestic market opportunity and on selected international markets.

Business Strategy

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

Educate dental professionals and 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, 2002, we had trained over 18,000 dental professionals worldwide on the use and benefits of Invisalign.

Communicate practice benefits of Invisalign to dental professionals. Invisalign provides substantial financial incentives to dental professionals by enabling them to increase patient volume, charge a premium price and reduce chair time per treatment. We intend to continue to emphasize these practice benefits to dental professionals through our sales and training efforts.

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 intend to maintain manufacturing capacity in excess of projected demand to reduce the risk that manufacturing capacity may place on our ability to grow. 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. We believe that our issued patents, multiple pending patents and other intellectual property provide us with a substantial lead over potential competitors. One of our issued U.S. patents is written broadly to cover any algorithmic method of segmenting orthodontic treatment into a sequence of three or more steps, based on calculated initial and final digital representations of a patient s dentition. 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.

Expand our target patient base. Invisalign can provide complete treatment for patients with mature dentition and a broad range of malocclusion. In addition, we believe that Invisalign can provide partial treatment

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of severe malocclusion. In an effort to demonstrate Invisalign s ability to comprehensively treat such cases, we initiated the publication of a series of clinical case studies and articles that highlight the applicability of Invisalign to malocclusion cases of severe complexity. We are also undertaking post-marketing studies and making additional improvements to the product.

Build an international presence. While we focus primarily on the domestic market, we continue to introduce Invisalign in selected international markets on a limited basis.

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 believe the complexity inherent in producing such highly customized devices in high volumes is a barrier to potential competitors. Furthermore, we believe the sophisticated software we use to guide a custom manufacturing process on a high volume was not available until we developed it. 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.

Manufacturing is coordinated in Santa Clara, California. As of December 31, 2002, we employed a manufacturing staff in the U.S. and Costa Rica of approximately 340 people. In addition, in the U.S. we employed a software development team comprised of approximately 26 software engineers with experience in computational geometry, animation, computer-aided design and various manufacturing industries. We also contracted with approximately 20 software engineers in Pakistan and Russia, who were part of the team responsible for the creation of treatment simulation software. The operations team in Costa Rica creates treatment simulations using ClinCheck. We outsource the fabrication and packaging of Aligners to a contract manufacturer based in Juarez, Mexico.

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 wax bite 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 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

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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 delivered to the prescribing dental professional via ClinCheck, which is available on our website at www.invisalign.com and www.aligntech.com. The dental professional then reviews the ClinCheck simulation and, on occasion, asks 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 custom manufacturing techniques, including 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 aide the placement of bonding attachments to the patient s teeth. These attachments are used to optimize the force applied to a tooth or teeth in circumstances where the Aligners alone may have difficulty in effecting the desired movements. Also, in cases where intraproximal reduction, or IDR, is requested by the dental professional, we provide an IDR prescription form, quantifying the amount of space to be created through enamel reduction, location, and timing of IDR.

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 currently conducted in Mexico. In order to scale our manufacturing capacity, we continue to invest in facilities and capital equipment.

Quality Assurance

Our quality assurance system is compliant with FDA Medical Device regulations 21CFR Part 820, and we are ISO 9001:1994 certified, an internationally recognized quality system. Our system defines processes and procedures to ensure product and service quality, and includes

methods to monitor levels of quality, based on internal data and direct customer feedback. We utilize this data to continuously improve our systems and processes, taking corrective action as required.

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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. However, if actual treatment results deviate significantly from the approved ClinCheck treatment plan, the dental professional may request a mid-course correction under the Invisalign product warranty. These deviations have typically been the result of unpredictable biological factors, such as variations in bone density or tooth topography and abnormal jaw growth. A mid-course correction 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. However, in these cases, the case refinement Aligners are provided 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 consumers and dental professionals 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 worldwide demand, we are training a broad base of dental professionals.

Consumer Marketing

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

Our experience indicates that prospective patients exposed to our advertising seek information from four primary sources:

- an orthodontist;
- a general practice dentist;

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, importantly, also allow us to channel consumer interest to dental professionals. We have outsourced the telephone support function to a national call center operator.

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Professional Marketing

Professional marketing consists of training dental professionals and assisting them in building their practices. As of December 31, 2002, our domestic sales team consisted of 32 salespeople supporting the orthodontic market, and 2 area managers and 17 contract salespeople supporting the general practitioner dentist market. Our international sales team consisted of 33 salespeople supporting the orthodontic market and the general practitioner dentist market. Approximately 30 customer support staff, together with the marketing department and our in-house orthodontic staff, support the domestic sales team. 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, 2002, we had trained over 18,000 dental professionals worldwide to use Invisalign. Of those dental professionals trained, approximately 67% are dental professionals in our domestic market. Within our domestic market, we have trained approximately 7,000 orthodontists, representing approximately 80% of all practicing orthodontists in the U.S. and Canada, and approximately 5,300 general practitioner dentists. As of December 31, 2002, approximately 8,500 of the worldwide dental professionals we have trained had submitted one or more cases to us, and over 80,000 patients have commenced treatment with Invisalign. 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.

General practitioner dentists play an important role in informing their patients about orthodontics and are a key source of both referrals to orthodontists and Invisalign case submissions. There are over 120,000 active general practice dentists in the U.S. and Canada.

Research and Development

As of December 31, 2002, our research and development team consisted of 15 individuals with medical device development, orthodontic and other relevant backgrounds. In addition, we employed a software development team comprised of approximately 26 software engineers in the U.S. with experience in computational geometry, animation, computer-aided design and various manufacturing industries. We also contracted with approximately 20 software engineers in Pakistan and Russia, who were part of the team responsible for the creation of treatment simulation software. Prior to commercial launch in July 1999, our research and development strategy had three primary objectives: developing Invisalign, establishing the ability of Invisalign to treat malocclusion and developing software and processes to enable the manufacture 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

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line of products. Our research and development expenses were $13.1 million, $15.6 million and $9.4 million in fiscal 2002, 2001 and 2000, respectively.

In an effort to demonstrate Invisalign s broad treatment capabilities, we initiated the publication of a series of clinical case studies and articles 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.

In fiscal 2002, we continued to enhance our proprietary, three-dimensional treatment-planning software primarily to increase our manufacturing capacity and efficiency.

Intellectual Property

We believe our intellectual property position represents a substantial business advantage. As of December 31, 2002, we had 29 issued U.S. patents, 20 issued foreign patents, 69 pending U.S. patent applications, and numerous 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.

Competition

We compete directly with companies such as Ormco Orthodontics, a wholly owned subsidiary of Sybron Dental Specialties, which manufactures and distributes a product called Red, White & Blue, a product that is similar in use to Invisalign, but different in features, manufacturing process and delivery. We compete for the attention of dental professionals with manufacturers of other orthodontic products. These manufacturers of traditional orthodontic appliances include 3M Company, Ormco Orthodontics and Dentsply International, Inc.

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 Regulation of Medical Devices. Invisalign is regulated as a medical device. Accordingly, our product development, labeling, manufacturing processes and promotional activities are subject to extensive review and rigorous regulation by government agencies in those countries in which we sell our products.

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In the U.S., the FDA regulates the design, manufacture, distribution, preclinical and clinical study, clearance, and approval of medical devices. Medical devices are classified in one of three classes on the basis of the controls necessary to reasonably assure their safety and effectiveness. Class I or II devices require the manufacturer to submit a pre-market notification requesting permission for commercial distribution, which is known as 510(k) clearance. Class III devices, which are deemed by the FDA to pose greater risk than Class I and II devices, require FDA approval of a pre-market approval application which includes, among other things, extensive preclinical and clinical trial data and information about the devices and components design, manufacturing and labeling.

Invisalign is a Class I device, the least stringent class, which only requires general controls, including labeling, pre-market notification and adherence to the FDA s Quality System regulations. In addition, because Invisalign is a Class I device, we are required to register contract manufacturers located outside the U.S. with the FDA. Accordingly, we have registered Elamex, our Mexico-based contract manufacturer, with the FDA. Elamex is certified under ISO, an internationally recognized quality standard, and also performs subcontractor manufacturing for other U.S.-based medical device companies. Our quality system and procedures are set up to comply with all FDA regulations. Elamex has dedicated an area in its facilities and certain personnel for our exclusive use. We have supplied Elamex with procedures to manufacture and ship our products and have trained Elamex s personnel, thus ensuring compliance with FDA regulations as long as the procedures are followed. We conduct frequent visits to the Mexico facility to monitor Elamex s performance and its compliance with our procedures.

In November 1998, Invisalign received 510(k) Pre-Market Notification by the FDA, allowing us to market Invisalign in the U.S. The manufacture and distribution of Invisalign are subject to continuing regulation by the FDA. We are subject to routine inspections by the FDA to determine compliance with facility registration, product listing requirements, medical device reporting regulations and Quality System requirements. The Quality System regulation is similar to good manufacturing practices and relates to product testing and quality assurance, as well as the maintenance of records and documentation.

If the FDA finds that we have failed to comply with the applicable FDA regulations, it can institute a wide variety of enforcement actions against us, ranging from a public Warning Letter to more severe sanctions, including but not limited to financial penalties, withdrawal of 510(k) pre-market notification clearances already granted, and criminal prosecution.

In Europe, Invisalign is regulated as a custom device. As such, we are not subject to regulations promulgated by the European Union, although we have the option to CE mark our product. We are ISO 9001:1994 certified, which facilitates the commercialization of Invisalign outside the U.S.

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

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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 similar other federal or state health care programs. Most states have also enacted illegal remuneration laws that are similar to the federal laws. These laws are applicable to our financial relationships with, and any marketing or other promotional activities involving, our dental professional customers. Finally, various states regulate the operation of an advertising and referral service for dentists, and may require registration of such services with a state agency as well as compliance with various requirements and restrictions on how they conduct business and structure their relationships with participating dentists. Violations of any of these laws or regulations could subject us to a variety of civil and criminal sanctions.

Employees

As of December 31, 2002, we had approximately 608 employees, approximately 282 of whom were employed in the U.S., 251 in Costa Rica, 46 in Europe, 12 in Latin America, 10 in Asia/Pacific and 7 in the U.A.E. As of December 31, 2002, of our U.S. employees, approximately 91 were employed in manufacturing, 67 were employed in various management, administrative and support positions, 49 were marketing and customer support staff, 34 were sales representatives, 26 were software engineers and 15 were employed in research and development.

Web Site Postings

We make our annual report on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K, and amendments to such reports, available free of charge through our web site as soon as reasonably practicable after we electronically file such material with, or furnish it to, the United States Securities and Exchange Commission, at the following addresses: www.aligntech.com and www.invisalign.com. The information in, or that can be accessed through, our web site is not part of this report.

ITEM 2. PROPERTIES.

Our headquarters are located in Santa Clara, California. We lease approximately 90,000 square feet of space where we house our manufacturing, customer support, software engineering and administrative personnel. We lease our Santa Clara facilities under two leases, both of which expire at the end of 2005. The combined monthly rent for the Santa Clara facilities is approximately $270,000.

We also operate a facility in San Jose, Costa Rica. The main facility comprises approximately 25,000 square feet of manufacturing and office space. The monthly rent for the Costa Rica facility is approximately $14,000. The lease for this facility expires at the end of 2006.

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.

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ITEM 3. LEGAL PROCEEDINGS.

In January 2003, Ormco Corporation filed suit against Align Technology, Inc., 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. In February 2003, Align answered the complaint and asserted counterclaims seeking a declaration by the Court of invalidity and non-infringement of the asserted patents. In addition, Align counterclaimed for infringement of its U.S. Patent No. 6,398,548, seeking unspecified monetary damages and injunctive relief. Ormco filed a reply to Align s counterclaims on March 10, 2003 and asserted counterclaims against Align seeking a declaration by the Court of invalidity and non-infringement of U.S. Patent No. 6, 398, 548. Align s response to Ormco s counterclaims is due in early April 2003. No trial or other dates have yet been set by the Court.

Three years ago, Ormco filed suit against Align asserting infringement of U.S. Patent Nos. 5,447,432 and 5,683,243. In June 2000, the parties entered into a Stipulation of Dismissal with Ormco. Ormco agreed for a period of at least two years not to pursue litigation with respect to these patents, except as set forth below. Further, Ormco agreed that it would not bring any patent action against Align for at least a period of one year with respect to any as yet unissued patents. If Ormco were to bring such an action concerning as yet unissued patents after one year, the Stipulation of Dismissal would allow Ormco to include in such an action claims involving U.S. Patent Nos. 5,447,432 and 5,683,243. In August 2001, Ormco notified Align of the issuance of U.S. Patent No. 6,244,861 and offered a license for this patent. Align did not take a license to this patent. Five months after Ormco s notification, it filed the lawsuit that is currently pending.

The claims in U.S. Patent Nos. 5,447,432 and 5,683,243 relate to methods and systems for forming and manufacturing custom orthodontic appliances. The relevant claims are limited to computerized methods and algorithms for determining the final positioning of a patient s teeth based upon a derived or ideal dental archform of the patient. The claims in U.S. Patent No. 6,244,861 are more generic claims relating to the methods and systems for forming and manufacturing custom orthodontic appliances. Based on the disclosure in the patent, however, the relevant claims also appear to be limited to computerized methods and algorithms for determining the final positioning of a patient s teeth based upon a derived or ideal dental archform of the patient. The treatment plan simulation developed in Align s facilities determines the final positioning of a patient s teeth but is not based on a derived or ideal dental archform of the patient.

The claims in Align s U.S. Patent No. 6,398,548 relate to methods and systems for incrementally moving teeth using a series of appliances designed to be placed successively on the patient s teeth.

Align strongly believes that Ormco s claims of infringement lack merit and that Align s counterclaim of infringement will be successful. However, the outcome of a lawsuit is inherently unpredictable. Should Align s technology be found to infringe any one of Ormco s asserted patents, Align would have to seek a license from Ormco, which license might not be available on commercially reasonable terms or at all. In that event, Align could be subject to damages or an injunction which could materially adversely affect its business.

On May 1, 2002, GW Com, Inc. filed a complaint in Santa Clara Superior Court against us and James Lindsey, the owner of the premises located at 851 Martin Avenue, Santa Clara, California. We were parties with GW Com to a sub-sublease for such premises, the term of which expired on August 14, 2002. In early 2001, we engaged in negotiations with GW Com to amend the sub-sublease to add additional space and to extend the term through November 30, 2004. The proposed amendment, however, required the consent of the owner of the subject property, Mr. Lindsey. We withdrew from the negotiations of the amendment, after, among other things, Mr. Lindsey s consent could not be obtained. GW Com s complaint alleged breach of contract against us and breach of contract and intentional interference with contract against Mr. Lindsey. In the complaint, GW Com sought damages of more than $4 million. In February 2002 we entered into a written settlement agreement pursuant to which GW Com paid us an aggregate of $188,000 and Mr. Lindsey paid us an aggregate of $10,000.

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On April 9, 2002, we exercised our right to terminate an Exclusive Marketing Agreement dated October 18, 2001 with Discus Dental Impressions, Inc. pursuant to the express terms of the Agreement and we issued a press release reporting this termination. On or about May 14, 2002, we received a demand for arbitration submitted by Discus Dental with the American Arbitration Association in San Jose, California. In its arbitration demand, Discus Dental seeks damages of approximately $30 million, including commissions and bonus payments it claims it would have received under the Agreement as well as other expenses, attorneys fees and injunctive relief to prevent us from selling Invisalign to dentists in the U.S. and Canada. However, prior to terminating the Agreement, we conducted a thorough review of the Agreement and each party s performance thereunder. Based upon that review of the factual and legal issues, we deny all claims made by Discus Dental in its demand and contend that such claims are entirely without merit. In addition, on or about June 13, 2002 we submitted a counterclaim against Discus Dental in the arbitration seeking damages of approximately $40 million arising out of our claims for misrepresentation, breach of confidentiality provisions and unfair competition, among others. The three arbitrators have been selected, and the parties are exchanging and reviewing documents in response to document demands. The matter is currently set for arbitration on August 18, 2003.

In February 2001, Align Technology was named in a class action lawsuit filed on behalf of all licensed dentists (excluding orthodontists) in the U.S. The complaint alleged that Align Technology s policy of selling Invisalign exclusively to orthodontists violated the U.S. antitrust laws. Without admitting any wrongdoing, the company entered into a Stipulation and Agreement of Settlement with the plaintiffs to settle the lawsuit. The total legal and other settlement costs that Align has agreed to pay are approximately $400,000 in legal fees. In November 2001, the Court approved the Stipulation and Agreement of Settlement. Pursuant to the settlement, we trained and certified approximately 5,000 in fiscal 2002, and have undertaken to certify 5,000 general practitioner dentists each year over the next three years.

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 2002.

ITEM 4A. EXECUTIVE OFFICERS OF THE REGISTRANT.

The following table sets forth certain information regarding our executive officers as of March 18, 2003.

Name	Age	Position
Thomas M. Prescott	47	President and Chief Executive Officer
Eldon M. Bullington	51	Chief Financial Officer and Vice President, Finance
Amir Abolfathi	38	Vice President, Research and Development
Jon Fjeld	51	Vice President, Technology
Roger E. George	37	Vice President, Legal Affairs, and General Counsel
Len M. Hedge	45	Vice President, Operations
David S. Thrower	38	Vice President, Global Marketing

Thomas M. Prescott has served as our President and Chief Executive Officer since March 27, 2002, at which time he was also appointed as a director by our Board of Directors to fill a vacancy on the Board. Prior to joining us, Mr. Prescott was President and Chief Executive Officer of Cardiac Pathways, Inc. from May 1999 to August 2001 and a consultant for Boston Scientific Corporation from August 2001 to January 2002 after its purchase of Cardiac Pathways in August 2001. Prior to Cardiac Pathways, Mr. Prescott held various sales, general management and executive roles at Nellcor Puritan Bennett, Inc. from April 1994 to May 1999, and various management positions at GE Medical Systems from October 1987 to April 1994. In addition,

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Mr. Prescott served in sales, marketing and management roles at Siemens from December 1980 to July 1986. Mr. Prescott serves as a director of R2 Technologies, Inc., a privately held company. He earned his Masters degree from Kellogg Graduate School of Management, Northwestern University and his Bachelors degree in Civil Engineering from Arizona State University.

Eldon M. Bullington has served as our Vice President and Chief Financial Officer since October 2002. Mr. Bullington was previously Vice President, Finance and CFO of Milpitas, CA-based Verplex Systems, Inc. where he established financial controls and policies, software revenue recognition disciplines, business plans and cultivated investment banking relationships for the early stage electronic design and automation company. Prior to that, Mr. Bullington spent two years as the Vice President and CFO at Cardiac Pathways, Inc., where he helped lead the successful financial turnaround and sale of Cardiac Pathways to Boston Scientific. Prior to Cardiac Pathways, Mr. Bullington was Vice President and CFO at Saraide, Inc. He also served in executive financial management roles at Verifone, Inc. and Radius, Inc., both Bay Area technology companies and prior to that spent five years with IBM providing business and financial planning leadership at IBM North American Operations and its System Technology Division. Mr. Bullington began his financial career with Arthur Andersen, and graduated Cum Laude from California State University, Long Beach with a B.S. degree in Business Administration and Accounting.

Amir Abolfathi has served as our Vice President of Research and Development since March 2000. From November 1999 to March 2000, Mr. Abolfathi served as our Senior Director of Planning. Prior to joining Align Technology, Mr. Abolfathi served as a consultant for a number of newly venture funded medical device companies from February 1999 through November 1999, including Embolic Protection, Inc. and Novasys Medical, Inc. From April 1995 through January 1999, Mr. Abolfathi served as Senior Director of Research and Development and Vice President of Research and Development for EndoTex Interventional Systems, Inc., a company focused on the treatment of neurovascular diseases that he co-founded. From 1988 to 1995, he held a variety of management and engineering positions at Pfizer, Inc., Guidant Corporation and Baxter, Inc. Mr. Abolfathi received his M.S. in engineering management from the University of Southern California and his B.S. in biomedical engineering from the University of California at San Diego.

Jon Fjeld has served as our Vice President of Technology since December 2000. Prior to joining us, Mr. Fjeld was the President and Chief Executive Officer of Raindrop Geomagic, Inc., a software company. From January 1998 through June 1998, Mr. Fjeld served as Vice President of Larscom, Inc., a networking company. From August 1995 through December 1997, Mr. Fjeld served in various positions at Netedge Systems, Inc., a networking company, including Vice President of Marketing and later as President and Chief Executive Officer. From 1982 to 1995 he held several management and executive positions in the networking and software business units at IBM. Mr. Fjeld received his M.B.A. from Duke University and his PhD and M.A. from the University of Toronto, his M.S. from the University of North Carolina and his B.A. from Bishop s University.

Roger E. George has served as the Vice President, Legal Affairs, and General Counsel at Align 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, in Sunnyvale, Ca. Prior to SkyStream, Mr. George was a partner at Wilson Sonsini Goodrich & Rosati, P.C. in Palo Alto, California. He is a Certified Public Accountant. Mr. George attended the University of Virginia where he earned the degrees of B.S. in Commerce and Juris Doctor.

Len M. Hedge has served as our Vice President, Operations since March 2002, having served as our Vice President of Manufacturing from January 1999 to March 2002. Mr. Hedge served as Vice President of Operations for Plynetics Express Corporation, a rapid-prototyping and stereolithography services supplier, from December 1996 to December 1998. From October 1991 to December 1996, Mr. Hedge worked at Beckman Instruments Corporation as Manager for Prototype Manufacturing and Process Development. Prior to joining Beckman, Mr. Hedge spent 13 years with General Dynamics Corporation, holding positions of increasing responsibility from Machinist to Manager of Mechanical Fabrication. Mr. Hedge received his B.S. from La Verne University.

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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 of Camarillo, CA-based BioSource International, a publicly held life science reagent company. At BioSource, Mr. Thrower was responsible for sales, marketing, business development and R&D for signal transduction products. Prior to that, he served as Senior Vice President, Global Marketing at GN ReSound, Inc. a Redwood City, CA-based hearing and communications device company where he led strategic marketing and managed a joint partnership effort in a significant corporate turnaround and launched the company s first digital product line. Mr. Thrower also has previous experience in large and small independent management consulting firms, including five years with Boston-based Bain & Company where he specialized in assisting corporate clients in the development and execution of strategy, marketing and customer loyalty initiatives. Mr. Thrower holds a B.S. in Math and Computational Sciences from Stanford University and a MBA from Harvard Graduate School of Business.

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

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PART II

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

(a) Price Range of Common Stock

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

	High	Low
Year Ended December 31, 2002:		
Fourth quarter	$ 3.59	$ 1.30
Third quarter	$ 3.50	$ 1.70
Second quarter	$ 5.48	$ 3.32
First quarter	$ 5.98	$ 4.05
Year Ended December 31, 2001:		
Fourth quarter	$ 5.59	$ 2.87
Third quarter	$ 8.00	$ 2.18
Second quarter	$ 12.07	$ 5.45
First quarter (from January 30, 2001)	$ 16.88	$ 6.69

On March 18, 2003, the last reported sale price of our common stock on the NASDAQ National Market was $5.48 per share. As of March 18, 2003 there were approximately 57,785,523 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.

(b) Sales of Unregistered Securities

In November 2002, we completed a financing deal for a private placement of 9,578,944 shares of common stock to a group of institutional investors led by existing shareholders, raising $18.1 million, net of issuance costs. The investors include Dionis Trust, Gordon Gund-Grant Gund Generation Skipping Trust, Gordon Gund-G. Zachary Gund Generation Skipping Trust, Kleiner Perkins Caulfield Byers VIII, L.P., KPCB VIII Founders Fund, L.P., Carlyle Partners III, L.P., CP III Coinvestment, L.P., Warren Thaler, Thomas M. Prescott, Oak Hill Capital Partners, L.P. and Oak Hill Capital Management Partners, L.P. The shares sold are unregistered and were issued pursuant to the private placement exemption from the registration requirements of Section 5 of the Securities Act of 1933. We are obligated to file an S-3 Registration Statement registering the shares for resale at least 30 days prior to November 26, 2003, and to use our reasonable best efforts to cause the S-3 Registration Statement to become effective as soon thereafter as practicable but not prior to November 26, 2003.

(c) Use of Proceeds from Sales of Registered Securities

We did not issue any registered securities during the fiscal year ended December 31, 2002.

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

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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/A.

During the quarter ended June 30, 2003, in conjunction with our adoption of EITF 00-21, Align re-evaluated its prior accounting treatment for case refinement revenues under the principles contained in SAB 101 and related guidance. Align determined that under SAB 101 the revenue amount deferred on advance sales of case refinement should be based on the stand-alone value of case refinement rather than the published discounted price for advance purchase. On July 24, 2003, Align announced that, as a result of its review, it would restate its financial statements for fiscal 2001, fiscal 2002 and the first three months of fiscal 2003.

From June 2001 until April 2003, Align offered customers the option to purchase a one-time, non-refundable case refinement at the time of the initial treatment plan purchase at a discounted price of $50. Customers not electing to purchase the upfront case refinement (or requiring additional refinements i.e. in addition to the one purchased in advance) could subsequently purchase a case refinement at a price of $250 (stand-alone value). Align deferred $50 of revenue and accrued the anticipated loss related to the cost of producing and delivering the related Aligners for discounted case refinements sold at the beginning of the treatment period. These deferred amounts were recognized when either the case refinement shipped or upon case expiration. Where the customer declined to purchase the $50 upfront case refinement but subsequently purchased the $250 stand-alone case refinement, Align recognized the revenue associated with the $250 stand-alone case refinement fee upon shipment of the new Aligners.

The following tables set forth the selected consolidated financial data for each of the years in the five-year period ended December 31, 2002. The selected consolidated financial data is qualified in its entirety and should be read in conjunction with our restated consolidated financial statements as of December 31, 2002 and notes thereto set forth on pages 48 to 76 and Management s Discussion and Analysis of Financial Condition and Results of Operations beginning on page 26.

Align did not amended its Annual Report on Form 10-K for the period ended December 31, 2001 and the consolidated financial statements and related financial information contained therein should no longer be relied upon. The historical results presented below are not necessarily indicative of future results.

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SELECTED CONSOLIDATED FINANCIAL DATA

(in thousands, except per share data)

(unaudited)

	Year Ended December 31,				
	Restated 2002	Restated 2001	2000	1999	1998
Consolidated Statement of Operations Data (1)(2):					
Total revenues	$ 69,698	$ 44,808	$ 6,741	$ 411	$
Cost of revenues	44,991	46,830	20,251	1,754	
Loss from operations	(72,935)	(100,769)	(81,115)	(14,705)	(3,951)
Other income (expense), net	116	1,730	(7,633)	(710)	176
Net loss before provision for income taxes	(72,819)	(99,039)	(88,748)	(15,415)	(3,775)
Provision for income taxes		10			
Net loss	(72,819)	(99,049)	(88,748)	(15,415)	(3,775)
Dividend related to beneficial conversion feature of preferred stock		(11,191)	(53,516)		
Net loss available to common stockholders	$ (72,819)	$ (110,240)	$ (142,264)	$ (15,415)	$ (3,775)
Net loss per share available to common stockholders, basic and diluted	$ (1.52)	$ (2.61)	$ (25.64)	$ (3.65)	$ (1.33)
Shares used in computing net loss per share available to common stockholders, basic and diluted	47,878	42,247	5,548	4,218	2,842

	December 31,				
	Restated 2002	Restated 2001	2000	1999	1998
Consolidated Balance Sheet Data (2):					
Working capital	$ 41,160	$ 62,172	$ 18,273	$ 10,027	$ 6,815
Total assets	92,856	118,218	70,561	17,091	8,117
Total long-term liabilities	3,837	980	1,455	3	10
Convertible preferred stock and preferred stock warrants			130,691	32,755	12,147
Stockholders equity (deficit)	64,347	97,827	(84,674)	(19,414)	(4,433)

(1) Certain reclassifications of prior period amounts have been made to conform to current year presentation.

(2) The effect of the restatement adjustments on the previously reported amounts for the years ended December 31, 2002 and 2001 are set forth in the following table.

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The following tables present amounts from operations as previously reported and as restated (in thousands, except per share data):

	Year Ended December 31,			
	2002		2001	
	As Previously Reported	As Restated	As Previously Reported	As Restated
Consolidated Statement of Operations Data (1):				
Total revenues (2)	$ 75,395	$ 69,698	$ 46,384	$ 44,808
Cost of revenues (3)	45,990	44,991	46,831	46,830
Loss from operations (4)	(68,237)	(72,935)	(99,194)	(100,769)
Other income (expense), net	116	116	1,730	1,730
Net loss before provision for income taxes (4)	(68,121)	(72,819)	(97,464)	(99,039)
Provision for income taxes			10	10
Net loss (4)	(68,121)	(72,819)	(97,474)	(99,049)
Dividend related to beneficial conversion feature of preferred stock			(11,191)	(11,191)
Net loss available to common stockholders (4)	$ (68,121)	$ (72,819)	$ (108,665)	$ (110,240)
Net loss per share available to common stockholders, basic and diluted (5)	$ (1.42)	$ (1.52)	$ (2.57)	$ (2.61)
Shares used in computing net loss per share available to common stockholders, basic and diluted	47,878	47,878	42,247	42,247

	December 31,			
	2002		2001	
	As Previously Reported	As Restated	As Previously Reported	As Restated
Consolidated Balance Sheet Data:				
Working capital (6)	$ 47,433	$ 41,160	$ 63,747	$ 62,172
Total assets	92,856	92,856	118,218	118,218
Total long-term liabilities	3,837	3,837	980	980
Stockholders equity (6)	70,620	64,347	99,402	97,827

(1) Certain reclassifications of prior period amounts have been made to conform with current year presentation.

(2) Revenues include a reduction of $5,697 and $1,576 for the years ended December 31, 2002 and 2001, respectively, due to an increase in deferred revenue as a result of the restatement.

(3) Cost of revenues include a reduction of $999 and $1 for the years ended December 31, 2002 and 2001, respectively, due to a decrease in accrued loss as a result of the restatement.

(4) The years ended December 31, 2002 and 2001 include an increase in net loss from operations of $4,698 and $1,575 respectively, as a result of the restatement.

(5) The years ended December 31, 2002 and 2001 include an increase in net loss per share of $(0.10) and $(0.04), respectively.
(6) Working capital and shareholders equity includes a reduction of $6,273 and $1,575 for the years ended December 31, 2002 and 2001, respectively, as a result of the restatement.

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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/A.

In addition to historical information, this Annual Report on Form 10-K/A 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 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 sections entitled Risk Factors and Management s Discussion and Analysis of Financial Condition and Results of Operations. We undertake no obligation to revise or publicly release the results of any revision to these forward-looking statements. Given these risks and uncertainties, readers are cautioned not to place undue reliance on such forward-looking statements.

During the quarter ended June 30, 2003, in conjunction with Align s adoption of EITF 00-21, Align re-evaluated its prior accounting treatment for case refinement revenues under the principles contained in SAB 101 and related guidance. Align determined that under SAB 101 the revenue amount deferred on advance sales of case refinement should be based on the stand-alone value of case refinement rather than the published discounted price for advance purchase. On July 24, 2003, Align announced that, as a result of its review, it would restate its financial statements for fiscal 2001, fiscal 2002 and the first three months of fiscal 2003.

Overview

Since our inception in April 1997, we have been engaged in the design, manufacture and marketing of Invisalign, a proprietary system for treating malocclusion, or the misalignment of teeth.

The Invisalign product has two components: ClinCheck and Aligners. ClinCheck is an Internet-based application that allows dental professionals to simulate treatment, in three dimensions, by modeling two-week stages of tooth movement. 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.

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.

In July 2002, we announced a plan to streamline worldwide operations. The plan included closing our facilities in Pakistan and the U.A.E. We transitioned the operations performed at these facilities to the United States and Costa Rica. For the period ending December 31, 2002, we recorded severance charges of $2.3 million, facility closure charges of $0.9 million, a loss on disposal of fixed assets of $1.1 million and an impairment charge of $0.9 million related to the land in Pakistan. The land was written down to a zero value to reflect its fair value as estimated

by management. Approximately $0.1 million of accrued charges related to professional fees were included in accrued liabilities as of December 31, 2002. We discontinued operations at our facilities in Pakistan and the U.A.E in October and December 2002, respectively. We concluded the remainder of indirect

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operational activities related to the Costa Rica transition in January 2003. We will cease non-operational closing activities in Pakistan when the land is disposed of at that location and in the U.A.E. when the necessary statutory filings have been completed.

Revenue from the sale of Invisalign and ancillary products is recognized upon product shipment, provided no significant obligations remain, transfer of title has occurred, and collection of the receivables 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, i.e. upon shipment of the Aligners.

From June 2001 until April 2003, Align offered customers the option to purchase a one-time, non-refundable case refinement at the time of the initial treatment plan purchase at a discounted price of $50. Customers not electing to purchase the upfront case refinement (or requiring additional refinements i.e. in addition to the one purchased in advance) could subsequently purchase a case refinement at a price of $250 (stand-alone value). Align deferred $50 of revenue and accrued the anticipated loss related to the cost of producing and delivering the related Aligners for discounted case refinements sold at the beginning of the treatment period. These deferred amounts were recognized when either the case refinement shipped or upon case expiration. Where the customer declined to purchase the $50 upfront case refinement but subsequently purchased the $250 stand-alone case refinement, Align recognized the revenue associated with the $250 stand-alone case refinement fee upon shipment of the new Aligners.

In May 2003, Align updated its domestic pricing policy 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, which Align believes represents its fair value based on competitive product offerings. Revenue deferrals associated with future case refinement sales will be at $125. This revenue deferral amount represents the fair value of a case refinement as determined in accordance with the newly adopted rules contained in 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 utilized or upon case expiration.

Service revenues earned under agreements with third parties for training of dental professionals and staff for Invisalign are recorded as the services are performed. Charges to 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.

We have incurred significant operating losses and negative operating cash flows since inception and have not yet achieved profitability. As of December 31, 2002, we had a restated accumulated deficit of approximately $280.5 million.

We expect to expend significant capital to continue to build our national brand, expand our dental professional channel, automate our manufacturing processes and develop both product and process technology. In November 2002, we completed a private placement of common stock to a group of investors led by existing shareholders, raising $18.1 million, net of issuance costs. In December 2002, we secured an accounts receivable-based revolving line of credit of up to $10 million and an equipment-based term loan of $5 million, which was accessed in December 2002. As of December 31, 2002 and March 18, 2003, we had not utilized the accounts receivable-based revolving line of credit.

Accessing the accounts receivable-based revolving line of credit is restricted based on qualifying accounts receivable and compliance with certain loan covenants. However, there can be no assurance that such financing will be adequate for us to avoid reducing operating expenses by, including but not limited to, reducing planned capital expenditures relating to enhancing our manufacturing process and reducing worldwide staff.

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Results of Operations, as Restated

Comparison of Years Ended December 31, 2002 and 2001:

Revenues. Revenues for the restated year ended December 31, 2002 increased 56% to $69.7 million compared to $44.8 million for the restated year ended December 31, 2001. Revenues of $63.7 million were derived from the sale of Invisalign compared to revenues of $43.4 million for the years ended December 31, 2002 and 2001, respectively. The increase in Invisalign revenues was primarily due to an increase in the domestic orthodontic channel of $6.2 million, the domestic general practitioner channel of $9.5 million and the international channel of $4.6 million for the year ended December 31, 2002 over the year ended December 31, 2001. The balance of our revenues represented sales of ancillary products and other services of $6.0 million for the year ended December 31, 2002 and $1.4 million for the year ended December 31, 2001, with the increase primarily attributable to training.

Cost of revenues. Cost of revenues for the restated year ended December 31, 2002 was $45.0 million compared to $46.8 million for the restated year ended December 31, 2001. 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. Also included in cost of revenues are stock based compensation expenses of $3.4 million and $4.6 million in 2002 and 2001, respectively, and $0.6 million of restructuring charges incurred as part of our July 2002 plan to streamline worldwide operations. Restated gross margin for the year ended December 31, 2002 was $24.7 million or 35% of revenue, compared with a negative restated gross margin of $2.0 million for the year ended December 31, 2001. We achieved positive gross margins in 2002 and the second half of 2001 mainly due to efficiencies in manufacturing as well as increased production volumes. Our gross margin is affected by changes in manufacturing volume, manufacturing capacity and changes in our average selling price.

Sales and marketing. Sales and marketing expenses for the year ended December 31, 2002 were $45.3 million compared to $51.9 million for the year ended December 31, 2001. Sales and marketing expenses include sales force compensation together with expenses for professional marketing, conducting training workshops and market surveys, advertising and attending dental professional trade shows. The decrease in sales and marketing expenses for the year ended December 31, 2002 resulted primarily from reduced spending in North America for media and advertising by approximately $13.2 million and reduced spending of direct mail advertising by approximately $1.6 million, partially offset by an increase in spending of $1.6 million related to incremental headcount in our North American sales force. Also offsetting spending reductions was an increase in spending at our international locations by approximately $5.7 million primarily in the first two quarters of fiscal 2002. Also included in sales and marketing expenses are stock based compensation expenses of $2.9 million and $3.9 million in 2002 and 2001, respectively, and $1.2 million of restructuring charges related to severance incurred as part of our July 2002 plan to streamline worldwide operations.

General and administrative. General and administrative expenses for the year ended December 31, 2002 were $39.3 million compared to $30.8 million for the year ended December 31, 2001. General and administrative expenses include salaries for administrative personnel, outside consulting services, facilities, legal expenses and general corporate expenses. The increase in general and administrative expenses for the year ended December 31, 2002 resulted primarily from expanded support infrastructure at our international locations primarily in the first two quarters of fiscal 2002. Included in general and administrative expenses in 2002 were $3.4 million of restructuring charges for severance charges of $0.5 million, facility closure charges of $0.9 million, a loss on disposal of fixed assets of $1.1 million and an impairment charge of $0.9 million related to the land in Pakistan, incurred as part of our July 2002 plan to streamline worldwide operations.

Research and development. Research and development expenses for the year ended December 31, 2002 were $13.1 million compared to $15.6 million for the year ended December 31, 2001. Research and development expenses include the costs associated with software engineering, the cost of designing, developing and testing our products and the conducting of both clinical and post-marketing trials. We expense our research

and development costs as they are incurred. The decrease in research and development expenses for the year ended December 31,

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2002 was primarily due to a decrease in outside consulting services of approximately $1.2 million and a decrease in headcount expense related to product development activities of approximately $1.5 million. Research and development expenses for 2002 also included $0.1 million of restructuring charges incurred as part of our July 2002 plan to streamline worldwide operations, and $3.2 million and $4.1 million of stock based compensation expense for 2002 and 2001, respectively.

Litigation settlement expenses. In February 2001 Align was named in a class action lawsuit filed on behalf of all licensed dentists (excluding orthodontists) in the U.S. The complaint alleged that Align s policy of selling Invisalign exclusively to orthodontists violated the U.S. antitrust laws. Without admitting any wrongdoing, we entered into a Stipulation and Agreement of Settlement with the plaintiffs to settle the lawsuit. The total legal and other settlement costs that Align has agreed to pay are approximately $0.4 million in legal fees. In November 2001, the Court approved the Stipulation and Agreement of Settlement. Pursuant to the settlement, we trained and certified approximately 5,000 in fiscal 2002, and have undertaken to certify 5,000 general practitioner dentists each year over the next three years.

Interest and other income (expense), net. Interest and other income was $0.1 million for the year ended December 31, 2002 compared to $1.7 million for the year ended December 31, 2001. Interest income decreased in 2002 by $4.0 million primarily due to the decrease in our cash, cash equivalent and marketable securities balances. Interest income for the year ended December 31, 2001 was primarily generated from our cash and cash equivalents balance and investments in short-term marketable securities. Offsetting this income in the first quarter of 2001 was non-cash interest expense of $1.8 million, related to the beneficial conversion feature embedded in convertible subordinated notes.

Dividend related to beneficial conversion feature of preferred stock. In 2000 we issued 9,535,052 shares of Series D preferred stock which were subject to an antidilution conversion price adjustment feature. We triggered this antidilution conversion price adjustment feature when we granted options to purchase our common stock beyond the number of options that were authorized under our 1997 Plan at the time we commenced our Series D preferred stock offering in May 2000. The conversion feature provided that if, during the period between May 12, 2000 (the commitment date for our Series D preferred stock offering) and the earlier of the closing of an initial public offering or January 31, 2001, we had granted more than an aggregate of 3,331,978 options to purchase our common stock, then the conversion price of our Series D preferred stock would be adjusted downward from its original conversion price of $10.625 per share. As of the end of January 2001, we had granted an aggregate of 3,591,458 options to purchase shares of our common stock in excess of the 3,331,978 options permitted. As a result we were required to issue an additional 790,342 shares of common stock upon the conversion of the Series D preferred stock. These shares were in addition to the 419,700 additional shares of common stock that we were required to issue upon conversion of the Series D preferred stock as of December 31, 2000. As a result, we recorded a deemed dividend for the year ended December 31, 2001 based on the fair value of the common stock. We also recorded at the commitment date of the Series D preferred stock offering $11.2 million related to the preferred stock sold and a charge to interest expense of $1.8 million for the beneficial conversion feature embedded in convertible subordinated notes that were previously converted. In 2002, we had no issued and outstanding preferred stock, and in 2002 we did not record any deemed dividends related to preferred stock.

Stock-based compensation. In connection with the grant of stock options to employees and non-employees, 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 become exercisable, we revalue the remaining unvested options, with the change in fair value from period to period represented as a change in the deferred compensation charge. This stock-based compensation is amortized as charges to operations over the vesting periods of the options. For the years ended December 31, 2002 and 2001, we recorded amortization of deferred compensation

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of $16.0 million and $22.2 million, respectively. Additionally, we recorded expenses of $2.0 million for the year ended December 31, 2002, related to options granted to non-employees.

We 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. The charge for the years ended December 31, 2002 and 2001 were recorded as $2.2 million and $0.2 million, respectively. The 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.

Comparison of Years Ended December 31, 2001 and 2000:

Revenues. Restated revenues for the year ended December 31, 2001 increased to $44.8 million as compared to $6.7 million for the year ended December 31, 2000. Increases in revenues in fiscal 2001 over fiscal 2000 were driven by increases to the U.S. orthodontic channel as we commercialized the Invisalign product. For the year ended December 31, 2001, restated revenues of $43.4 million were derived from the sale of Invisalign compared to revenues of $5.4 million for the year ended December 31, 2000. The balance of our revenues for year ended December 31, 2001 and 2000 represented sales of dental impression machines, other products and training.

Cost of revenues. Cost of revenues includes the compensation of staff involved in production, the cost of materials and packaging used in production and shipping, together with an allocation of the cost of facilities and depreciation on the capital equipment used in the production process. Restated cost of revenues for the year ended December 31, 2001 increased to $46.8 million as compared to $20.3 million for the year ended December 31, 2000. Cost of revenues for the years ended December 31, 2001 and 2000 includes $10.6 and $11.2 million, respectively, of unabsorbed manufacturing costs due to an increase in our manufacturing capacity in 2001 and 2000. For the third and fourth quarters of fiscal 2001, we achieved positive gross margins mainly due to efficiencies achieved in manufacturing as well as reducing over capacity in many areas. Our gross loss is affected by changes in manufacturing volume, manufacturing capacity and changes in our pricing policies.

Sales and marketing. Sales and marketing expenses include sales force compensation together with the expense of professional marketing principally, conducting training workshops and market surveys, advertising and attending orthodontic trade shows. Sales and marketing expenses for the year ended December 31, 2001 increased to $51.9 million as compared to $40.7 million for the year ended December 31, 2000. This increase resulted primarily from increases in headcount and related expenses of approximately $4.6 million, expenses relating to increased direct mailings of $1.4 million and expenses related to the expansion of our international sales and marketing offices of $5.7 million. Partially offsetting the increase was a $2.4 million decrease in advertising expenses.

General and administrative. General and administrative expenses include costs for the compensation of administrative personnel, outside consulting services, facilities, legal expenses and general corporate expenses. General and administrative expenses for the year ended December 31, 2001 increased to $30.8 million as compared to $17.5 million for the year ended December 31, 2000, primarily due to increased headcount and related expenses.

Research and development. Research and development expenses include the cost for the compensation of staff, the costs associated with software engineering, the costs of designing, developing and testing our products and the conduct of both clinical and post-marketing trials. Research and development is expensed as incurred. Research and development expenses for the year ended December 31, 2001 increased to $15.6 million as compared to $9.4 million for the year ended December 31, 2000. This increase resulted primarily from increases in headcount and related expenses of approximately $3.3 million.

Litigation settlement expenses. In February 2001 Align was named in a class action lawsuit filed on behalf of all licensed dentists (excluding orthodontists) in the U.S. The complaint alleged that Align s policy of selling Invisalign exclusively to orthodontists violated the U.S. antitrust laws. Without admitting any wrongdoing, we

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entered into a Stipulation and Agreement of Settlement with the plaintiffs to settle the lawsuit. The total legal and other settlement costs that Align has agreed to pay are approximately $0.4 million in legal fees. In November 2001, the Court approved the Stipulation and Agreement of Settlement.

Other income (expense), net. Other income was $1.7 million for the year ended December 31, 2001 as compared to expense of $7.6 million for the year ended December 31, 2000. The interest income in fiscal 2001 was generated from higher average cash and cash equivalents balance and investments in short-term and long-term securities in fiscal 2001, which included the proceeds from our initial public offering completed in January 2001. Partially offsetting the interest income was a non-cash interest expense of $1.8 million, recorded in January 2001, related to the beneficial conversion feature embedded in convertible subordinated notes. The other expense balance of $7.6 million as of December 31, 2000 was primarily the result of non-cash interest expense related to the beneficial conversion feature of a bridge loan financing.

Dividend related to beneficial conversion feature of preferred stock. In 2000 we issued 9,535,052 shares of Series D preferred stock which were subject to an antidilution conversion price adjustment feature. We triggered this antidilution conversion price adjustment feature when we granted options to purchase our common stock beyond the number of options that were authorized under our 1997 Plan at the time we commenced our Series D preferred stock offering in May 2000. The conversion feature provided that if, during the period between May 12, 2000 (the commitment date for our Series D preferred stock offering) and the earlier of the closing of an initial public offering or January 31, 2001, we had granted more than an aggregate of 3,331,978 options to purchase our common stock, then the conversion price of our Series D preferred stock would be adjusted downward from its original conversion price of $10.625 per share. As of the end of January 2001, we had granted an aggregate of 3,591,458 options to purchase shares of our common stock in excess of the 3,331,978 options permitted. As a result, we were required to issue an additional 790,342 shares of common stock upon the conversion of the Series D preferred stock. These shares were in addition to the 419,700 additional shares of common stock that we were required to issue upon conversion of the Series D preferred stock as of December 31, 2000. As a result, we recorded a deemed dividend for the year ended December 31, 2001 based on the fair value of the common stock. We also recorded at the commitment date of the Series D preferred stock offering $11.2 million related to the preferred stock sold and a charge to interest expense of $1.8 million for the beneficial conversion feature embedded in convertible subordinated notes that were previously converted.

Stock based compensation. In connection with the grant of stock options to employees and non-employees, we recorded deferred stock-based compensation as a component of stockholders equity (deficit). 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 become exercisable, we revalue the remaining unvested options, with the change in fair value from period to period represented as a change in the deferred compensation charge. This stock-based compensation is amortized as charges to operations over the vesting periods of the options. We recorded amortization of deferred compensation of $22.2 million for the year ended December 31, 2001 and $13.4 million for the year ended December 31, 2000.

Income Taxes

We have incurred immaterial amounts of income tax expense to date since we have not been profitable in either our domestic or international operations. As of December 31, 2002, we have aggregate federal and state net operating loss carryforwards of $268.1 million. As of December 31, 2002 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 $5.2 million as of December 31, 2002. The federal research credit carryforwards expire beginning in the year 2017, if not utilized. The state research credit carryforward does not expire. The federal and state net operating loss carryforwards expire beginning in the year

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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.

Liquidity and Capital Resources, as Restated

Historically, we have funded our operations with the proceeds from the sale of our common and preferred stock, equipment leases and bridge loans. As of December 31, 2002, we had $35.6 million of cash and cash equivalents, marketable securities of $2.7 million and an accumulated deficit of $280.5 million, as restated. In addition, we had $3.3 million of restricted cash.

Net cash used in operating activities, as restated, totaled $40.4 million and $77.9 million for the years ended December 31, 2002 and 2001, respectively. For the year ended December 31, 2002, net cash used by operating activities consisted primarily of operating losses and increases in accounts receivable balances, partially offset by increases in depreciation and amortization, amortization of deferred stock-based compensation, and deferred revenue. For the year ended December 31, 2001, net cash used by operating activities consisted primarily of operating losses and increases in accounts receivable balances, partially offset by increases in depreciation and amortization and amortization of deferred stock-based compensation.

Net cash provided by investing activities totaled $1.5 million for the years ended December 31, 2002 and net cash used in investing activities totaled $2.0 million for the year ended December 31, 2001. For the year ended December 31, 2002, net cash provided by investing activities consisted primarily of maturities of marketable securities, which was partially offset by purchases of property and equipment. For the year ended December 31, 2001, net cash used in investing activities consisted primarily of proceeds from the sales and maturities of marketable securities and a decrease in restricted cash, partially offset by purchases of marketable securities and purchases of property and equipment.

Net cash provided by financing activities was $23.9 million and $127.5 million for the year ended December 31, 2002 and 2001, respectively. For the year ended December 31, 2002, net cash provided by financing activities consisted primarily of proceeds from the issuance of common stock. In November 2002, we completed a private placement of 9,578,944 shares common stock to a group of investors led by existing shareholders, raising $18.1 million, net of issuance costs. In December 2002, we obtained an accounts receivable-based revolving line of credit of up to $10.0 million and a $5.0 million equipment-based term loan. Accessing the accounts receivable based revolving line of credit is restricted based on qualifying accounts receivable and compliance with customary loan covenants. The $10.0 million revolving line of credit is based on domestic accounts receivable accrues interest at a rate of 1.75% above prime, and the $5.0 million equipment-based term loan accrues interest at 2.25% above prime. As of December 31, 2002, Align had not used any of the $10.0 million revolving line of credit and had drawn down the $5.0 million from the equipment-based term loan.

For the year ended December 31, 2001, net cash provided by financing activities consisted primarily of proceeds from the issuance of common stock. In January 2001, we completed our initial public offering of 10 million shares of common stock. In March 2001, the underwriters exercised an overallotment option for 628,706 shares. Net proceeds to us were approximately $126.0 million.

We expect that our operating expenses will increase with an overall increase in the level of our business activity, including increased sales and the related costs of products sold, our consumer advertising campaign and dental professional marketing efforts, continuing efforts to automate our manufacturing processes, increases in the size of our sales force and dental professional training staff, continued international sales and marketing efforts, and development and improvements to our product. In addition, we may use cash to fund acquisitions of complementary businesses or technologies. Our capital requirements depend on market acceptance of our products and our ability to market, sell and support our products on a worldwide basis. We believe that our current cash and cash equivalents, short-term and long-term investment balances will be

sufficient to fund our

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operations for at least the next 12 months. If we are unable to generate adequate operating cash flows, we may need to seek additional sources of capital through equity or debt financing, collaborative or other arrangements with other companies, bank financing and other sources in order to realize our objectives and to continue our operations. There can be no assurance that we will be able to obtain additional debt or equity financing on terms acceptable to us, or at all. If adequate funds are not available, we could be required to delay establishing a national brand, building manufacturing infrastructure and developing our product and process technology, or to 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

Revenue from the sale of Invisalign and ancillary products is recognized upon product shipment, provided no significant obligations remain, transfer of title has occurred, and collection of the receivables 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, i.e. upon shipment of the Aligners. Beginning July 2002, ClinCheck fees are no longer received up-front, but are billed together with the Aligner fees at the time the Aligners are shipped and are recognized at that time. We offer our dental professionals an opportunity to purchase case refinement in advance at a discount. The advance purchase price is non-refundable once Aligners are shipped. Revenue, in the amount of the stand-alone sales price of the undelivered element, is deferred until either upon shipment of the case refinement or upon case expiration. In cases where the dental professional does not purchase the case refinements in advance, case refinement revenues are recognized when the new Aligners are shipped. 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. Ancillary product sales and services consist primarily of training.

In May 2003, Align updated its domestic pricing policy 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, which Align believes represents its fair value based on competitive product offerings. Revenue deferrals associated with future case refinement sales will be at $125. This revenue deferral amount represents the fair value of a case refinement as determined in accordance with the newly adopted rules contained in 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 utilized or upon case expiration.

Service revenues earned under agreements with third parties for training of dental professionals and staff for Invisalign are recorded as the services are performed. Charges to 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.

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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

We accrue for estimated warranty costs upon shipment of products. Actual warranty costs incurred have not materially differed from those accrued. Our warranty policy is effective for shipped products which are considered defective or fail to meet the product specifications.

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 known to us. 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.

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 considered important which 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.

Legal contingencies

We are currently involved in certain legal proceedings as discussed in Note 5 of 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 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.

Recent Accounting Pronouncements

In April 2002, the Financial Accounting Standards Board (FASB) issued SFAS No. 145, Rescission of FASB Statement No. 4, 44, and 64, Amendment of FASB Statement No. 13, and Technical Corrections (SFAS No. 145) which eliminates inconsistencies between the required accounting for sale-leaseback transactions and the required accounting for certain lease modifications that have economic effects that are similar to sale-leaseback transactions. SFAS No. 145 also amends other existing authoritative pronouncements to make various technical corrections, clarify meanings, or describe their applicability under changed conditions. The provisions

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of SFAS No. 145 are effective for fiscal years beginning after May 15, 2002 and for transactions occurring after May 15, 2002. Align does not expect SFAS No. 145 to have a material impact on its consolidated financial position or on its consolidated results of operations.

In June 2002, the FASB issued SFAS No. 146, Accounting for Exit or Disposal Activities (SFAS No. 146) which addresses the recognition, measurement, and reporting of costs that are associated with exit and disposal activities, including restructuring activities that are currently accounted for pursuant to the guidance that the EITF has set forth in EITF Issue No. 94-3, Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (including Certain Costs Incurred in a Restructuring) . SFAS No. 146 is effective for exit or disposal activities that are initiated after December 31, 2002. The adoption of SFAS No. 146 did not have a material impact on Align s consolidated financial statements.

In November 2002, the FASB issued FASB Interpretation No. 45 (FIN 45), Guarantor s Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others. FIN 45 requires that a liability be recorded in the guarantor s balance sheet upon issuance of a guarantee. In addition, FIN 45 requires disclosures about the guarantees that an entity has issued, including a reconciliation of changes in the entity s product warranty liabilities. The initial recognition and initial measurement provisions of FIN 45 are applicable on a prospective basis to guarantees issued or modified after December 31, 2002, irrespective of the guarantor s fiscal year-end. The disclosure requirements of FIN 45 are effective for financial statements for interim or annual periods ending after December 15, 2002. In accordance with the provisions of FIN 45, Align has adopted the disclosure requirements. The adoption of FIN 45 did not have a material impact on Align s consolidated financial position and its consolidated statements of operations.

In November 2002, the Emerging Issues Task Force (EITF) reached consensus on EITF 00-21, which addresses how to account for arrangements that may involve the delivery or performance of multiple products, services, and/or rights to use assets. The final consensus of EITF 00-21 is be applicable to agreements entered into in fiscal periods beginning after June 15, 2003, with early adoption permitted. Additionally, companies are permitted to apply the consensus guidance to all existing arrangements as the cumulative effect of a change in accounting principle in accordance with APB Opinion No. 20, Accounting Changes. The Company adopted EITF 00-21 in the second quarter of 2003. The adoption did not have a material impact on the Company s consolidated financial statements.

In December 2002, the FASB issued SFAS No. 148, Accounting for Stock-Based Compensation Transition and Disclosure an amendment of FASB Statement No. 123. SFAS No. 148 provides alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation. SFAS No. 148 also requires prominent disclosures of the pro forma effect of using the fair value method of accounting for stock-based employee compensation in both annual and interim financial statements. The transition and annual disclosure requirements of SFAS No. 148 are effective for fiscal years ending after December 15, 2002. The interim disclosure requirements are effective for interim periods beginning after December 15, 2002. In accordance with the provisions of SFAS No. 148, Align has adopted the disclosure requirements. The adoption of SFAS No. 148 did not have a material impact on its consolidated financial position or on its consolidated results of operations.

In January 2003, the FASB issued FASB Interpretation No. 46 (FIN 46), Consolidation of Variable Interest Entities, an Interpretation of ARB No. 51. FIN 46 requires certain variable interest entities to be consolidated by the primary beneficiary of the entity if the equity investors in the entity do not have the characteristics of a controlling financial interest or do not have sufficient equity at risk for the entity to finance its activities without additional subordinated financial support from other parties. FIN 46 is effective immediately for all new variable interest entities created or acquired after January 31, 2003. For variable interest entities created or acquired prior to February 1, 2003, the provisions of FIN 46 must be applied for the first interim or annual period beginning after June 15, 2003. The Company does not expect the adoption of FIN 46 to have a material impact on its consolidated financial statements.

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RISK FACTORS

The statements contained below and elsewhere in this Annual Report on Form 10-K/A that are not purely historical are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and Section 21E of the Securities Exchange Act of 1934, including, without limitation, statements regarding our expectations, hopes, beliefs, anticipations, commitments, intentions and strategies regarding the future. Actual results could differ from those projected in any forward-looking statements for the reasons, among others, detailed below. The fact that some of the risk factors may be the same or similar to our past filings means only that the risks are present in multiple periods. We believe that many of the risks detailed here are part of doing business in the industry in which we compete and will likely be present in all periods reported. The fact that certain risks are characteristic to the industry does not lessen the significance of the risk. The forward-looking statements are made as of the date of this Annual Report on Form 10-K/A, and we assume no obligation to update the forward-looking statements or to update the reasons why actual results could differ from those projected in the forward-looking statements.

Since we have a history of losses and negative operating cash flows, and because we expect our operating losses to continue throughout all or a portion of fiscal 2003, we may not achieve or maintain profitability in the future.

We have incurred significant operating losses, negative operating cash flows and have not yet achieved profitability. 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.

Since July 2000 we have continued 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 dental professional training staff;
- execute clinical research and education plans;
- develop technological improvements to our products;
- continue our international sales and marketing efforts; and
- undertake quality assurance and improvement initiatives.

As a result, we will need to increase our revenue significantly, while controlling our expenses, to achieve profitability. It is possible that we will not achieve profitability in the near future, if at all, and even if we do achieve profitability, we may not sustain or increase profitability in the future.

We may be unable to raise additional capital if it should be necessary, which could harm our ability to compete.

We have incurred significant operating losses and negative operating cash flows since inception and have not yet achieved profitability. As of December 31, 2002, we had an accumulated deficit of approximately $280.5 million, as restated.

We expect to expend significant capital to continue to build our national brand, expand our dental professional channels, automate our manufacturing processes and develop both product and process technology. In November 2002, we completed a private placement of common stock to a group of investors led by existing shareholders, raising $18.1 million, net of issuance costs. In December 2002, we secured an accounts receivable-

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based revolving line of credit of up to $10.0 million and a equipment-based term loan of $5.0 million, which was accessed in December 2002. As of March 26, 2003, we had not utilized the accounts receivable-based revolving line of credit. Accessing the accounts receivable based-revolving line of credit is restricted based on qualifying accounts receivable and compliance with customary loan covenants. There can be no assurance that such financing will be adequate for us to avoid reducing operating expenses by, including but not limited to, reducing planned capital expenditures relating to enhancing our manufacturing process and reducing worldwide staff.

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

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

- changes in the timing of 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; and
- the development and marketing of competitive products by potential competitors.

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 have limited product offerings, and if demand for Invisalign declines or fails to develop 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. Continued and widespread market acceptance of Invisalign is critical to our future success. Invisalign may not achieve market acceptance at the rate at which we expect, or at all, which could reduce our revenue and results of operations.

If dental professionals do not adopt Invisalign in sufficient numbers or as rapidly as we anticipate, our operating results will be harmed.

As of December 31, 2002, approximately 8,500 of the worldwide dental professionals we have trained had submitted one or more cases to us. 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 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

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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 dental communities, our operating results will be harmed.

If consumers do not adopt Invisalign in sufficient numbers or as rapidly as we anticipate, our operating results will be harmed.

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. Our success will depend upon the acceptance of Invisalign by the substantially larger number of dental professionals and potential patients to which we are now actively marketing. We have had a limited number of complaints from patients and prospective patients generally related to shipping delays and minor manufacturing irregularities. 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, levels of consumer confidence and consumer spending, all of which could be affected by unstable global economic, political or other conditions. If consumers prove unwilling to adopt Invisalign as rapidly as we anticipate or in the volume that we anticipate, our operating results will 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.

In July 2002, we announced a plan to streamline worldwide operations. The plan included closing our facilities in Pakistan and the U.A.E. We transitioned the operations performed at these facilities to the United States and Costa Rica. For the period ending December 31, 2002, we recorded severance charges of $2.3 million, facility closure charges of $0.9 million, a loss on disposal of fixed assets of $1.1 million and an impairment charge of $0.9 million related to the land in Pakistan. The land was written down to a zero value to reflect its fair value as estimated by management. Approximately $0.1 million of accrued charges related to professional fees were included in accrued liabilities as of December 31, 2002. We discontinued operations at our Pakistan and U.A.E. facilities in October and December 2002, respectively. we concluded the remainder of indirect operational activities related to the Costa Rica transition in January 2003. We will cease non-operational closing activities in Pakistan when the land is disposed of at that location and in the U.A.E., when the necessary statutory filings have been completed.

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, particularly in light of the terrorist attacks of September 11, 2001;

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difficulties in staffing and managing international operations;

controlling quality of manufacture;

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;

import and export license requirements and restrictions;

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. We believe our intellectual property position represents a substantial business advantage. As of December 31, 2002, we had 29 issued U.S. patents, 20 issued foreign patents, 69 pending U.S. patent applications, and numerous 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 issue as 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. 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 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 another party s patent in the past and, while that action has been dismissed, we may be the subject of patent or other litigation in the future.

In January 2003, Ormco Corporation filed suit against Align Technology, Inc., 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. In February 2003, Align answered the complaint and asserted counterclaims seeking a declaration by the Court of invalidity

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and non-infringement of the asserted patents. In addition, Align counterclaimed for infringement of its U.S. Patent No. 6,398,548, seeking unspecified monetary damages and injunctive relief. Ormco filed a reply to Align s counterclaims on March 10, 2003 and asserted counterclaims against Align seeking a declaration by the Court of invalidity and non-infringement of U.S. Patent No. 6, 398, 548. Align s response to Ormco s counterclaims is due in early April 2003. No trial or other dates have yet been set by the Court.

Three years ago, Ormco filed suit against Align asserting infringement of U.S. Patent Nos. 5,447,432 and 5,683,243. In June 2000, the parties entered into a Stipulation of Dismissal with Ormco. Ormco agreed for a period of at least two years not to pursue litigation with respect to these patents, except as set forth below. Further, Ormco agreed that it would not bring any patent action against Align for at least a period of one year with respect to any as yet unissued patents. If Ormco were to bring such an action concerning as yet unissued patents after one year, the Stipulation of Dismissal would allow Ormco to include in such an action claims involving U.S. Patent Nos. 5,447,432 and 5,683,243. In August 2001, Ormco notified Align of the issuance of U.S. Patent No. 6,244,861 and offered a license for this patent. Align did not take a license to this patent. Five months after Ormco s notification, it filed the lawsuit that is currently pending.

The claims in U.S. Patent Nos. 5,447,432 and 5,683,243 relate to methods and systems for forming and manufacturing custom orthodontic appliances. The relevant claims are limited to computerized methods and algorithms for determining the final positioning of a patient s teeth based upon a derived or ideal dental archform of the patient. The claims in U.S. Patent No. 6,244,861 are more generic claims relating to the methods and systems for forming and manufacturing custom orthodontic appliances. Based on the disclosure in the patent, however, the relevant claims also appear to be limited to computerized methods and algorithms for determining the final positioning of a patient s teeth based upon a derived or ideal dental archform of the patient. The treatment plan simulation developed in Align s facilities determines the final positioning of a patient s teeth but is not based on a derived or ideal dental archform of the patient.

The claims in Align s U.S. Patent No. 6,398,548 relate to methods and systems for incrementally moving teeth using a series of appliances designed to be placed successively on the patient s teeth.

Align strongly believes that Ormco s claims of infringement lack merit and that Align s counterclaim of infringement will be successful. However, the outcome of a lawsuit is inherently unpredictable. Should Align s technology be found to infringe any one of Ormco s asserted patents, Align would have to seek a license from Ormco, which license might not be available on commercially reasonable terms or at all. In that event, Align could be subject to damages or an injunction which could materially adversely affect its business.

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 which 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 in a patent suit by Ormco or in any other litigation or interference proceeding to which we may become a party could subject us to significant liabilities. An adverse determination of this nature could also put our patents at risk of being invalidated or interpreted narrowly or require us to seek licenses from third parties. Licenses may not be available on commercially reasonable terms or at all, in which event, our business would be materially adversely affected.

We 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

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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. 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 September 30, 1999 to approximately 608 employees as of December 31, 2002. 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. Also, recent reductions in our workforce, although designed to not affect service levels and demand generation, may adversely affect these areas of our business. 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 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. In addition, 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 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 Specialities. In addition, manufacturers of traditional braces, such as 3M Company, Sybron Dental Specialities and Dentsply International, Inc. 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 our competitors, our business could be harmed.

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Complying with the Food and Drug Administration (FDA) and other regulations 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.

Noncompliance with applicable regulatory requirements can result in enforcement action which may include recalling products, ceasing product marketing, and paying significant fines and penalties. One or more of these enforcement actions could limit product sales, delay product shipment and adversely affect our profitability.

In the U.S., 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, which we have yet to undergo. If we or any third party manufacturer of our products do not conform to applicable Quality System regulations, 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., we must obtain FDA clearance or approval, which can be a lengthy and time-consuming process. Even though the devices we market have obtained the necessary clearances from the FDA through the pre-market notification provisions of Section 510(k) of the federal Food, Drug, and Cosmetic Act, we may be unable to maintain the necessary clearances in the future. Furthermore, we may be unable to obtain the necessary clearances for new devices that we 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, 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, 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 government regulations of healthcare 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 service provider, payor and plan customers are also subject to a wide variety of laws and regulations that could affect the nature and scope of their relationships with us.

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The healthcare market itself is highly regulated and subject to changing political, economic and regulatory influences. Regulations implemented pursuant to HIPAA may require us to make 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 on our business is difficult to predict, and there can be no assurance that we will adequately address the business risks created by HIPAA and its implementation or that we will be able to take advantage of any resulting business opportunities.

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

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

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

Sales of our products outside the U.S. are subject to foreign regulatory requirements that vary widely from country to country. The time required to obtain clearances or approvals required by other countries may be longer than that required for FDA clearance or approval, and requirements for such approvals may differ from FDA requirements. We may be unable to obtain regulatory approvals in one or more of the other countries in which we do business or in which we may do business in the future. We may also incur significant costs in attempting to obtain and maintain foreign regulatory approvals. If we experience delays in receipt of approvals to market our products outside of the U.S., or if we fail to receive these approvals, we may be unable to market our products or enhancements in international markets in a timely manner, if at all. We currently sell our product in Europe, 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.

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 2002, the market price for our common stock has declined significantly and was highly volatile.

In fiscal 2002, the trading price of our common stock declined, was highly volatile and could be subject to wide price fluctuations in response to various factors, many of which are beyond our control, including:

quarterly variations in our results of operations and liquidity;

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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, following periods of volatility in the market price of a company s securities, class action litigation has often been brought against the issuing company. 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.

Concentrations of ownership and agreements among our existing executive officers, directors and principal stockholders may prevent other stockholders from influencing significant corporate transactions.

The interests of our management could conflict with those of our other stockholders. As of December 31, 2002, our executive officers, directors and principal stockholders beneficially owned an aggregate of approximately 60.2% of our outstanding common stock. These stockholders, if acting together, would be able to influence significantly all matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. This could have the effect of delaying or preventing a change of control of us, which in turn could reduce the market price of our stock.

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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, 2002 consists of outstanding balances on lease obligations of $1.0 million and a $5.0 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 2003 and the interest rates are primarily fixed. Our capital lease obligations of $1.0 million at December 31, 2002 carry fixed interest rates of 6.53% and 11.15% per annum, with principal payments due in 60 and 48 monthly installments, respectively, beginning 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. As of December 31, 2002 we had drawn down $5.0 million from the equipment-based term loan. Principal payments are due in 36 monthly installments beginning 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, 2002)						
	2003	2004	2005	2006	2007	Total	Fair Value
	(in thousands)						
ASSETS:							
Cash and cash equivalents	$ 35,552	$	$	$	$	$ 35,552	$ 35,552
Short-term marketable securities	2,693					2,693	2,693
Weighted average interest rate	5.54%						
LIABILITIES:							
Equipment-based term loan	$ 1,667	$ 1,667	$ 1,666	$	$	$ 5,000	$ 5,000
Fixed rate debt lease obligation	516	320	184			1,020	1,020
Weighted average interest rate	8.30%	6.5%	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, 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.

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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 $18.2 million of our 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.

The consolidated financial statements and supplementary data, including notes to the consolidated financial statements, set forth in Item 8 have been revised to reflect the restatement of revenues and cost of revenues resulting from the historical revaluation of the revenue value associated with advance sales of case refinement. Refer to Note 1 of Notes to Consolidated Financial Statements, Restatement of Previously Issued Financial Statements, for discussion of restatement.

Quarterly Results of Operations

	Three Months Ended (1)(2)							
	2002				2001			
	Restated Dec. 31	Restated Sep. 30	Restated June 30	Restated March 31	Restated Dec. 31	Restated Sep. 30	Restated June 30	March 31
	(in thousands, except per share data) (unaudited)							
Revenues	$ 20,751	$ 17,375	$ 15,714	$ 15,858	$ 11,356	$ 12,381	$ 13,382	$ 7,689
Gross profit (loss)	9,112	6,777	4,984	3,834	1,185	1,105	(447)	(3,865)
Operating loss	(15,194)	(17,789)	(20,242)	(19,710)	(21,864)	(23,697)	(23,743)	(31,465)
Net loss	(15,396)	(17,806)	(20,313)	(19,304)	(21,652)	(23,045)	(22,394)	(31,958)
Net loss available to common stockholders	$ (15,396)	$ (17,806)	$ (20,313)	$ (19,304)	$ (21,652)	$ (23,045)	$ (22,394)	$ (43,149)
Net loss per share available to common stock-holders, basic an diluted	$ (0.30)	$ (0.38)	$ (0.44)	$ (0.42)	$ (0.47)	$ (0.51)	$ (0.50)	$ (1.29)
Shares used in computing per share amounts, basic and diluted	51,796	46,934	46,576	46,152	45,660	45,035	44,518	33,574

(1) Certain reclassifications of prior period amounts have been made to conform to current year presentation.

(2) The effect of the restatement adjustments on the previously reported amounts for the years ended December 31, 2002 and 2001 are set forth in the following table.

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The following tables present amounts from operations as previously reported and as restated for the years ended December 31, 2002 and 2001 (in thousands, except per share data):

	Three Months Ended 2002							
	As Previously Reported Dec. 31	Restated Dec. 31	As Previously Reported Sep. 30	Restated Sep. 30	As Previously Reported June 30	Restated June 30	As Previously Reported March 31	Restated March 31
Revenues	$ 22,426	$ 20,751	$ 18,573	$ 17,375	$ 17,255	$ 15,714	$ 17,141	$ 15,858
Gross profit	10,595	9,112	7,693	6,777	6,481	4,984	4,636	3,834
Operating loss	(13,711)	(15,194)	(16,873)	(17,789)	(18,745)	(20,242)	(18,908)	(19,710)
Net loss	(13,913)	(15,396)	(16,890)	(17,806)	(18,816)	(20,313)	(18,502)	(19,304)
Net loss available to common stockholders	$ (13,913)	$ (15,396)	$ (16,890)	$ (17,806)	$ (18,816)	$ (20,313)	$ (18,502)	$ (19,304)
Net loss per share available to common stock-holders, basic and diluted	$ (0.27)	$ (0.30)	$ (0.36)	$ (0.38)	$ (0.40)	$ (0.44)	$ (0.40)	$ (0.42)
Shares used in computing per share amounts, basic and diluted	51,796	51,796	46,934	46,934	46,576	46,576	46,152	46,152

	Three Months Ended 2001							
	As Previously Reported Dec. 31	Restated Dec. 31	As Previously Reported Sep. 30	Restated Sep. 30	As Previously Reported June 30	Restated June 30	As Previously Reported March 31	As Previously Reported March 31
Revenues	$ 12,300	$ 11,356	$ 12,912	$ 12,381	$ 13,483	$ 13,382	$ 7,689	$ 7,689
Gross profit (loss)	2,118	1,185	1,647	1,105	(347)	(447)	(3,865)	(3,865)
Operating loss	(20,931)	(21,864)	(23,155)	(23,697)	(23,643)	(23,743)	(31,465)	(31,465)
Net loss	(20,719)	(21,652)	(22,503)	(23,045)	(22,294)	(22,394)	(31,958)	(31,958)
Net loss available to common stockholders	$ (20,719)	$ (21,652)	$ (22,503)	$ (23,045)	$ (22,294)	$ (22,394)	$ (43,149)	$ (43,149)
Net loss per share available to common stock-holders, basic and diluted	$ (0.45)	$ (0.47)	$ (0.50)	$ (0.51)	$ (0.50)	$ (0.50)	$ (1.29)	$ (1.29)
Shares used in computing per share amounts, basic and diluted	45,660	45,660	45,035	45,035	44,518	44,518	33,574	33,574

The restatement adjustments affecting the years ended December 31, 2002 and 2001, are adjustments for the additional revenue deferral associated with the advance sales of case refinement and the corresponding reduction in the provision for estimated losses on advanced sales of case refinement.

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ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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REPORT OF INDEPENDENT ACCOUNTANTS

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

In our opinion, the consolidated financial statements listed in the accompanying index present fairly, in all material respects, the financial position of Align Technology, Inc. and its subsidiaries at December 31, 2002 and 2001, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2002 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 auditing standards generally accepted in the United States of America, which require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

As described in Note 1, the Company restated its financial statements for the years ended December 31, 2002 and 2001.

/s/ PricewaterhouseCoopers LLP

San Jose, California

February 7, 2003, except for Note 1 as to which the date is July 16, 2003

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ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

(in thousands, except per share data)

	December 31,	
	2002	2001
	Restated	Restated
ASSETS		
Current assets:		
Cash and cash equivalents	$ 35,552	$ 50,550
Restricted cash	3,261	723
Marketable securities, short-term	2,693	12,494
Accounts receivable, net of allowance for doubtful accounts of $2,111 and $1,882 at December 31, 2002 and 2001, respectively	16,766	11,556
Inventories, net	1,533	1,549
Deferred costs	1,139	714
Prepaid expenses	2,352	3,029
Other current assets	2,536	968
Total current assets	65,832	81,583
Property and equipment, net	25,078	32,021
Marketable securities, long-term		2,627
Other assets	1,946	1,987
Total assets	$ 92,856	$ 118,218
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 1,974	$ 4,376
Accrued liabilities	11,112	11,425
Deferred revenue	9,403	3,127
Current portion of equipment-based term loan	1,667	
Current portion of capital lease obligations	516	483
Total current liabilities	24,672	19,411
Equipment-based term loan, net of current portion	3,333	
Capital lease obligations, net of current portion	504	980
Total liabilities	28,509	20,391
Commitments and contingencies (Note 6)		
Stockholders equity:		
Preferred stock, $0.0001 par value; Authorized: 5,000 shares at December 2002 and 2001; Issued and Outstanding: no shares at December 31, 2002 and 2001		
	6	5

Common stock, $0.0001 par value, Authorized: 200,000 shares at December 31, 2002 and 2001; Issued: 57,740 and 47,771 shares at December 31, 2002 and 2001, respectively; Outstanding: 57,700 and 47,771 shares at December 31, 2002 and 2001, respectively		
Additional paid-in capital	364,691	355,055
Deferred stock-based compensation	(19,005)	(48,324)
Notes receivable from stockholders	(892)	(1,484)
Accumulated other comprehensive income	17	226
Accumulated deficit	(280,470)	(207,651)
Total stockholders equity	64,347	97,827
Total liabilities and stockholders equity	$ 92,856	$ 118,218

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

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ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per share data)

	Year Ended December 31,		
	2002 Restated	2001 Restated	2000
Revenues:			
Invisalign	$ 63,690	$ 43,379	$ 5,436
Ancillary products and other services	6,008	1,429	1,305
Total revenues	69,698	44,808	6,741
Cost of revenues:			
Invisalign	37,089	45,039	19,031
Ancillary products and other services	7,902	1,791	1,220
Total cost of revenues	44,991	46,830	20,251
Gross profit (loss)	24,707	(2,022)	(13,510)
Operating expenses:			
Sales and marketing	45,313	51,929	40,704
General and administrative	39,265	30,774	17,549
Research and development	13,064	15,644	9,352
Litigation settlement		400	
Total operating expenses	97,642	98,747	67,605
Loss from operations	(72,935)	(100,769)	(81,115)
Interest income	979	4,261	2,306
Interest expense	(162)	(1,999)	(9,807)
Other expense	(701)	(532)	(132)
Net loss before provision for income taxes	(72,819)	(99,039)	(88,748)
Provision for income taxes		10	
Net loss	(72,819)	(99,049)	(88,748)
Dividend related to beneficial conversion feature of preferred stock		(11,191)	(53,516)
Net loss available to common stockholders	$ (72,819)	$ (110,240)	$ (142,264)
Net loss per share available to common stockholders, basic and diluted	$ (1.52)	$ (2.61)	$ (25.64)
Shares used in computing net loss per share available to common stockholders, basic and diluted	47,878	42,247	5,548

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

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ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY (DEFICIT)

For the years ended December 31, 2002, 2001 and 2000

(in thousands)

	Common Stock		Additional Paid-In	Deferred Stock-Based	Notes Receivable from	Accumulated Other Comprehensive	Accumulated Deficit	Total
	Shares	Amount	Capital	Compensation	Stockholders	Income	Restated	Restated
Balances at December 31, 1999	5,664	$ 1	$ 2,219	$ (1,780)	$	$	$ (19,854)	$ (19,414)
Net loss							(88,748)	(88,748)
Net change in unrealized gain from available-for-sale securities						73		73
Comprehensive loss								(88,675)
Issuance of common stock upon exercise of stock options	4,121		2,828		(1,814)			1,014
Repurchase of common stock	(143)		(48)					(48)
Deferred stock compensation, net of cancellations			91,752	(91,752)				
Amortization of deferred stock compensation				13,372				13,372
Charge for accelerated vesting of employee stock options			429					429
Beneficial conversion feature embedded in convertible subordinated notes			8,648					8,648
Beneficial conversion feature embedded in preferred stock sold			53,516					53,516
Deemed dividend on preferred stock			(53,516)					(53,516)
Balances at December 31, 2000	9,622	1	105,828	(80,160)	(1,814)	73	(108,602)	(84,674)
Net loss, as restated (Note 1)							(99,049)	(99,049)
Net change in unrealized gain from available-for-sale securities						153		153
Comprehensive loss, as restated								(98,896)
Issuance of common stock to preferred stockholders upon conversion	26,998	3	128,870					128,873
Sale of common stock upon the completion of initial public offering, net of issuance costs of $12,200	10,629	1	125,976					125,977
Issuance of common stock upon exercise of stock options	260		184					184
Issuance of common stock relating to employee stock purchase plan	39		245					245
Issuance of common stock upon the conversion and the exercise of warrants	529		1,818					1,818
Repurchase of common stock	(306)		(266)		213			(53)
Cancellations, net of deferred stock compensation			(9,627)	9,627				
			224					224

Charge for accelerated vesting of common stock options								
Payments on stockholders notes receivable					287			287
Interest accrued on stockholders notes receivable					(170)			(170)
Amortization of deferred stock compensation				22,209				22,209
Beneficial conversion feature embedded in convertible subordinated notes			1,803					1,803
Beneficial conversion feature embedded in preferred stock sold			11,191					11,191
Deemed dividend on preferred stock			(11,191)					(11,191)
Balances at December 31, 2001, as restated	47,771	5	355,055	(48,324)	(1,484)	226	(207,651)	97,827

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	Common Stock		Additional Paid-In	Deferred Stock-Based	Notes Receivable from	Accumulated Other Comprehensive	Accumulated Deficit	Total
	Shares	Amount	Capital	Compensation	Stockholders	Income	Restated	Restated
Net loss, as restated (Note 1)							(72,819)	(72,819)
Net change in unrealized gain from available-for-sale securities						(209)		(209)
Comprehensive loss, as restated								(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, as restated	57,700	$ 6	$ 364,691	$ (19,005)	$ (892)	$ 17	$ (280,470)	$ 64,347

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

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ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

	Year Ended December 31,		
	2002 Restated	2001 Restated	2000
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net loss	$ (72,819)	$ (99,049)	$ (88,748)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	13,051	7,592	2,513
Amortization of deferred stock-based compensation	16,030	22,209	13,372
Compensation expense for accelerated vesting of stock options	2,245	224	429
Stock-based compensation	2,010		
Loss on retirement, disposal and impairment of fixed assets	2,052	35	98
Realized loss on marketable securities			10
Provision for doubtful accounts	229	1,388	461
Amortization of capitalized financing costs and debt discount			834
Non-cash interest income on notes receivable from stockholders	(69)	(170)	(23)
Non-cash interest expense on convertible subordinated notes		1,803	8,648
Non-cash accretion on marketable securities	98	(1,174)	
Provision for excess and obsolete inventory	(86)	555	
Changes in operating assets and liabilities:			
Accounts receivable	(5,439)	(8,479)	(4,612)
Deferred costs	(425)	1,717	(2,431)
Inventories	102	(80)	(1,658)
Other current assets	(891)	(1,886)	(1,425)
Accounts payable	(2,450)	(450)	4,401
Accrued liabilities	(313)	(2,867)	7,100
Deferred revenue	6,276	777	2,231
Net cash used in operating activities	(40,399)	(77,855)	(58,800)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchase of property and equipment	(8,112)	(19,175)	(13,571)
Restricted cash	(2,538)	15,263	(15,646)
Purchase of marketable securities	(1,972)	(72,219)	(19,645)
Maturities of marketable securities	14,093	54,412	1,250
Proceeds from sale of marketable securities		19,898	7,827
Other assets	41	(139)	(1,848)
Net cash provided by (used in) investing activities	1,512	(1,960)	(41,633)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from issuance of common stock	19,248	138,606	1,037
Proceeds from issuance of convertible preferred stock, net of issuance costs			83,085
Proceeds from payment on stockholders notes receivable	401	287	
Repurchase of common stock	(317)	(53)	(48)
Proceeds from convertible subordinated notes			14,000

Payments for incurred IPO costs		(10,853)	(1,327)
Proceeds from draw down of line of credit	5,000		5,000
Repayment of line of credit			(5,000)
Payments on capital lease obligations	(443)	(450)	(318)
Net cash provided by financing activities	23,889	127,537	96,429
Net increase (decrease) in cash and cash equivalents	(14,998)	47,722	(4,004)
Cash and cash equivalents, beginning of year	50,550	2,828	6,832
Cash and cash equivalents, end of year	$ 35,552	$ 50,550	$ 2,828

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

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ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Throughout these notes to the consolidated financial statements all referenced amounts reflect the balances and amounts on a restated basis.

Note 1 Restatement of Previously Issued Financial Statements

During the quarter ended June 30, 2003, in conjunction with Align Technology, Inc. s (the Company) adoption of Emerging Issues Task Force Issue No. 00-21, Accounting for Revenue Arrangements with Multiple Deliverables (EITF 00-21), which addresses the issue of accounting for arrangements that involve the delivery of multiple products or services, the Company re-evaluated its prior accounting treatment for case refinement revenues under the principles contained in Staff Accounting Bulletin No. 101, Revenue Recognition in Financial Statements, (SAB 101) and related guidance. The Company determined that under SAB 101 the revenue amount deferred on advance sales of case refinement should be based on the stand-alone value of case refinement rather than the published discounted price for advance purchase. On July 24, 2003, the Company announced that, as a result of its review, it would restate its financial statements for fiscal 2001, fiscal 2002 and the first three months of fiscal 2003.

From June 2001 until April 2003, the Company offered customers the option to purchase a one-time, non-refundable case refinement at the time of the initial treatment plan purchase at a discounted price of $50. Customers not electing to purchase the upfront case refinement (or requiring additional refinements i.e. in addition to the one purchased in advance) could subsequently purchase a case refinement at a price of $250 (stand-alone value). The Company deferred $50 of revenue and accrued the anticipated loss related to the cost of producing and delivering the related Aligners for discounted case refinements sold at the beginning of the treatment period. These deferred amounts were recognized when either the case refinement shipped or upon case expiration. Where the customer declined to purchase the $50 upfront case refinement but subsequently purchased the $250 stand-alone case refinement, the Company recognized the revenue associated with the $250 stand-alone case refinement fee upon shipment of the new Aligners.

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ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The following tables present amounts from operations as previously reported and as restated:

	Year ended December 31,			
	2002		2001	
	As Previously Reported	As Restated	As Previously Reported	As Restated
	(in thousands, except per share amounts)			
Revenues:				
Invisalign (1)	$ 69,387	$ 63,690	$ 44,955	$ 43,379
Ancillary products and other services	6,008	6,008	1,429	1,429
Total revenues (1)	75,395	69,698	46,384	44,808
Cost of revenues:				
Invisalign (1)	38,088	37,089	45,040	45,039
Ancillary products and other services	7,902	7,902	1,791	1,791
Total cost of revenues (1)	45,990	44,991	46,831	46,830
Gross profit (loss) (2)	29,405	24,707	(447)	(2,022)
Operating expenses	97,642	97,642	98,747	98,747
Loss from operations (2)	$ (68,237)	$ (72,935)	$ (99,194)	$ (100,769)
Net loss (2)	$ (68,121)	$ (72,819)	$ (97,474)	$ (99,049)
Net loss available to common stockholders (2)	$ (68,121)	$ (72,819)	$ (108,665)	$ (110,240)
Net loss per share available to common stockholders, basic and diluted (2)	$ (1.42)	$ (1.52)	$ (2.57)	$ (2.61)
Shares used in computing net loss per share available to common stockholders, basic and diluted	47,878	47,878	42,247	42,247

(1) Revenue and Cost of Revenue Adjustments:

The restatement of revenue from the additional deferral of case refinement revenue of $200 per discounted case refinement purchased, due to the re-evaluation of the fair value of case refinement, resulted in a decrease of revenue related to these advance sales. Revenue decreased $5,697,000

and $1,576,000 compared to the previously reported amounts for the year ended December 31, 2002 and 2001, respectively.

The restatement of revenue resulted in a corresponding adjustment to the cost of revenues due to the effect of the increased valuation of advance case refinement sales on the provision for estimated loss on sales i.e. no accrual for loss was required. Cost of revenues decreased by $ 999,000 and $1,000 compared to the amounts previously reported for the year ended December 31, 2002 and 2001, respectively.

(2) Net Loss and Related Per Share Adjustments:

The adjustments in revenues and cost of revenue resulted in a net increase in net loss available to stockholders of $4,698,000 and $1,575,000 over the amounts previously reported for the year ended December 31, 2002 and 2001, respectively. Restated net loss per share increased $(0.10) and $(0.04) for the year ended December 31, 2002 and 2001, respectively.

(3) Liabilities and Stockholders Equity Adjustments:

Deferred revenue increased $7,273,000 and $1,576,000 over the amounts previously reported as of December 31, 2002 and 2001, respectively, due to the deferral of additional case refinement revenue discussed above.

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ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The restated accrued loss decreased by $ 1,000,000 and $1,000 over previously reported amounts as of December 31, 2002 and 2001, respectively.

The restated increase in deferred revenue and related decrease in accrued loss resulted in a net increase in accumulated deficit of $6,273,000 and $1,575,000 over amounts previously reported as of December 31, 2002 and 2001, respectively.

Note 2 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 exited the development stage in July 2000.

The Company expects to expend significant capital to continue to build its national brand, expand its dental professional channel, automate its manufacturing processes and develop both product and process technology. In November 2002, the Company completed a private placement of common stock to a group of investors led by existing shareholders, raising approximately $18,146,000, net of issuance costs. In December 2002, the Company secured an accounts receivable-based revolving line of credit of up to $10,000,000 and an equipment-based term loan of $5,000,000, which was accessed in December 2002. As of March 26, 2003, the Company had not utilized the accounts-receivable based revolving line of credit. Accessing the accounts receivable-based revolving line of credit is restricted based on qualifying accounts receivable and compliance with certain loan covenants. Management believes that current cash and cash equivalents and marketable securities balances will be sufficient to fund operations for at least the next twelve months. However, there can be no assurance that such financing will be adequate for the Company to avoid reducing operating expenses by, including but not limited to, reducing planned capital expenditures relating to enhancing the Company s manufacturing process and reducing worldwide staff.

Note 3 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 our 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.

Reclassification of certain expenses

In 2002, the Company made the decision to reclassify certain costs and expenses within the consolidated statements of operations. These reclassifications do not change net loss. The nature of the change centers around the classification of order administration expenses, bank processing fees and information technology costs

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ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

between cost categories. The Company has historically expensed these costs in general and administrative expenses and other expense in the consolidated statements of operations. Current and future presentation of these expenses will be to allocate them to the functions utilizing the services.

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, 2002 is primarily comprised of $3,000,000, representing the minimum deposit requirement in connection with the Company s revolving line of credit and equipment loan facility with Comerica Bank (see note 8). The Company s restricted cash as of December 31, 2001 is primarily comprised of $723,000 for security deposits on customer credit card transactions and leases of administrative offices.

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

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ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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, 2002 and 2001, or net revenues in fiscal 2002, 2001 and 2000.

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: 3 years for computer software and hardware and 5 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 and web-site development

Website development and related costs consist of external and internal costs incurred to purchase and implement the website software and significant enhancements used in the Company s business. Costs incurred in

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ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

the development of application and infrastructure of the website are capitalized and amortized over the estimated useful life of the website. During fiscal 2002, the Company re-engineered its website, and previously capitalized costs of $392,000 were written off. Website development costs of $103,000 and $495,000 had been capitalized as of December 31, 2002 and 2001, respectively. Amortization of website development costs commenced upon launch of the website. Accumulated amortization as of December 31, 2002 and 2001 amounted to $40,000 and $201,000, respectively.

Internal and external costs of designing, creating and maintaining website content, graphics and user interface on the web site are expensed as incurred.

There was other software developed for internal use and capitalized as of December 31, 2002 and 2001 in the amount of $1,124,000 and $544,000, respectively. Accumulated amortization as of December 31, 2002 and 2001 amounted to $192,000 and $37,000, respectively.

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

The Company generally warrants its products for a specific period of time against material defects. 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 represents 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. On a quarterly basis, the Company reviews the accrued balances and updates the historical warranty cost trends. Actual warranty costs incurred have not materially differed from those accrued.

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.

The following table reflects the change in the Company s warranty accrual during the year ended December 31, 2002.

	(in thousands)
Warranty accrual, December 31, 2001	$ 870
Charged to costs and expenses	614
Actual warranty expenditures	(970)
Warranty accrual, December 31, 2002	$ 514

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ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Revenue Recognition

Revenue from the sale of Invisalign and ancillary products is recognized upon product shipment, provided no significant obligations remain, transfer of title has occurred, and collection of the receivables 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, i.e. upon shipment of the Aligners. The Company offers its dental professionals an opportunity to purchase case refinement in advance at a discount. The advance purchase price is non-refundable once Aligners are shipped. 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 case expiration. In cases where the dental professional does not purchase the case refinements in advance, case refinement revenues are recognized when the new Aligners are shipped.

In May 2003, the Company updated its domestic pricing policy 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, which the Company believes represents its fair value based on competitive product offerings. Revenue deferrals associated with future case refinement sales will be at $125. This revenue deferral amount represents the fair value of a case refinement as determined in accordance with the newly adopted rules contained in 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 utilized or upon case expiration.

Service revenues earned under agreements with third parties for training of dental professionals and staff for Invisalign are recorded as the services are performed. Charges to third parties are based on negotiated rates which are intended to approximate a mark-up on 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, 2002, 2001 and 2000 advertising costs totaled $5,993,000, $17,466,000 and $20,804,000, respectively.

Foreign currency

The Company uses the U.S. dollar as its functional currency. Foreign currency assets and liabilities are re-measured into U.S. dollars at current exchange 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.

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ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Stock-based compensation

The Company accounts for stock-based employee compensation arrangements in accordance with provisions of Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees (APB 25) and complies with the disclosure provisions of Statement of Financial Accounting Standards No. 123, Accounting for Stock-Based Compensation (SFAS 123).

Under APB 25, compensation expense for grants to employees is based on the difference, if any, on the date of the grant, between the fair value of the Company s stock and the option s exercise price. SFAS 123 defines a fair value based method of accounting for an employee stock option or similar equity investment.

During the year ended December 31, 2002, the Company adopted Statement of Financial Accounting Standards No. 148, Accounting for Stock-Based Compensation, Transition and Disclosure an Amendment of FASB Statement No. 123. The Company accounts for stock-based employee compensation using the intrinsic value method under APB 25 and related interpretations and complies with the disclosure provisions of SFAS 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,		
	2002 Restated	2001 Restated	2000
	(in thousands, except per share amounts)		
Net loss available to common stockholders, as reported	$ (72,819)	$ (110,240)	$ (142,264)
Add: Total stock-based employee compensation expense included in reported net earnings	18,784	22,571	11,252
Deduct: Total stock-based employee compensation determined under fair value based method for all awards	(29,350)	(28,271)	(11,351)
Pro forma net loss available to common stockholders	$ (83,385)	$ (115,940)	$ (142,363)
Basic and diluted net loss per common share available to common stockholders:			
As reported	$ (1.52)	$ (2.61)	$ (25.64)
Pro forma	$ (1.74)	$ (2.74)	$ (25.66)

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 25, 2001, the date of the IPO, and using the Black-Scholes option valuation model subsequent to the IPO with the following weighted assumptions:

	Year Ended December 31,		
	2002	**2001**	**2000**
Risk-free interest rate	3.03%	4.36%	5.17-6.71%
Expected life	5 years	5 years	5 years
Expected dividends			
Volatility	119.8%	117%	N/A

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ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

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 country, other than the United States of America, accounted for 10% or more of assets or 10% or more of revenues in fiscal 2002, 2001 and 2000.

Comprehensive Income

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

Net loss per share

Basic and diluted net loss per share is computed by dividing the net loss available to common stockholders for the period by the weighted average number of shares of common stock outstanding during the period, less the weighted average number of shares of common stock that are subject to repurchase. The calculation of diluted net loss per share excludes potential common stock if the effect would be anti-dilutive. Potential common stock consists of common stock subject to repurchase, incremental common shares issuable upon the exercise of stock options, warrants and shares issuable upon conversion of the preferred stock.

The following is a reconciliation of the numerator (net loss available to common stockholders) and the denominator (number of shares) used in the basic and diluted net loss per share calculations (in thousands, except per share data):

	Year Ended December 31,

	2002 Restated	2001 Restated	2000
Net loss available to common stockholders	$ (72,819)	$ (110,240)	$ (142,264)
Basic and diluted:			
Weight-average common shares outstanding	49,112	45,189	6,861
Less: Weighted-average shares subject to repurchase	1,234	2,942	1,313
Weighted-average shares used in basic and diluted net loss per share	47,878	42,247	5,548
Net loss per share available to common stockholders	$ (1.52)	$ (2.61)	$ (25.64)

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ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

	Year Ended December 31,		
	2002	2001	2000
Preferred stock (as if converted)			26,209
Options to purchase common stock	7,670	5,489	2,862
Common stock subject to repurchase	637	1,969	3,608
Warrants			646
	8,307	7,458	33,325

Recent Accounting Pronouncements

In April 2002, the Financial Accounting Standards Board (FASB) issued SFAS No. 145, Rescission of FASB Statement No. 4, 44, and 64, Amendment of FASB Statement No. 13, and Technical Corrections (SFAS No. 145) which eliminates inconsistencies between the required accounting for sale-leaseback transactions and the required accounting for certain lease modifications that have economic effects that are similar to sale-leaseback transactions. SFAS No. 145 also amends other existing authoritative pronouncements to make various technical corrections, clarify meanings, or describe their applicability under changed conditions. The provisions of SFAS No. 145 are effective for fiscal years beginning after May 15, 2002 and for transactions occurring after May 15, 2002. The Company does not expect SFAS No. 145 to have a material impact on the Company s consolidated financial position or on its consolidated results of operations.

In June 2002, the FASB issued SFAS No. 146, Accounting for Exit or Disposal Activities (SFAS No. 146) which addresses the recognition, measurement, and reporting of costs that are associated with exit and disposal activities, including restructuring activities that are currently accounted for pursuant to the guidance that the EITF has set forth in EITF Issue No. 94-3, Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (including Certain Costs Incurred in a Restructuring) . SFAS No. 146 is effective for exit or disposal activities that are initiated after December 31, 2002. The adoption of SFAS No. 146 did not have a material impact on the Company s consolidated financial statements.

In November 2002, the FASB issued FASB Interpretation No. 45 (FIN 45), Guarantor s Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others. FIN 45 requires that a liability be recorded in the guarantor s balance sheet upon issuance of a guarantee. In addition, FIN 45 requires disclosures about the guarantees that an entity has issued, including a reconciliation of changes in the entity s product warranty liabilities. The initial recognition and initial measurement provisions of FIN 45 are applicable on a prospective basis to guarantees issued or modified after December 31, 2002, irrespective of the guarantor s fiscal year-end. The disclosure requirements of FIN 45 are effective for financial statements for interim or annual periods ending after December 15, 2002. In accordance with

the provisions of FIN 45, the Company has adopted the disclosure requirements. The adoption of FIN 45 did not have a material impact on the Company s consolidated financial position or on its consolidated statements of operations.

In November 2002, the Emerging Issues Task Force (EITF) reached consensus on EITF 00-21, which addresses how to account for arrangements that may involve the delivery or performance of multiple products, services, and/or rights to use assets. The final consensus of EITF 00-21 is applicable to agreements entered into in fiscal periods beginning after June 15, 2003, with early adoption permitted. Additionally, companies are permitted to apply the consensus guidance to all existing arrangements as the cumulative effect of a change in

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ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

accounting principle in accordance with APB Opinion No. 20, Accounting Changes. The Company adopted EITF 00-21 in the second quarter of 2003. The adoption did not have a material impact on the Company s consolidated financial statements.

In December 2002, the FASB issued SFAS No. 148, Accounting for Stock-Based Compensation Transition and Disclosure an amendment of FASB Statement No. 123. SFAS No. 148 provides alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation. SFAS No. 148 also requires prominent disclosures of the pro forma effect of using the fair value method of accounting for stock-based employee compensation in both annual and interim financial statements. The transition and annual disclosure requirements of SFAS No. 148 are effective for fiscal years ending after December 15, 2002. The interim disclosure requirements are effective for interim periods beginning after December 15, 2002. In accordance with the provisions of SFAS No. 148, the Company has adopted the disclosure requirements. The adoption of SFAS No. 148 did not have a material impact on the Company s consolidated financial position or on its consolidated results of operations.

In January 2003, the FASB issued FASB Interpretation No. 46 (FIN 46), Consolidation of Variable Interest Entities, an Interpretation of ARB No. 51. FIN 46 requires certain variable interest entities to be consolidated by the primary beneficiary of the entity if the equity investors in the entity do not have the characteristics of a controlling financial interest or do not have sufficient equity at risk for the entity to finance its activities without additional subordinated financial support from other parties. FIN 46 is effective immediately for all new variable interest entities created or acquired after January 31, 2003. For variable interest entities created or acquired prior to February 1, 2003, the provisions of FIN 46 must be applied for the first interim or annual period beginning after June 15, 2003. The Company does not expect the adoption of FIN 46 to have a material impact on its consolidated financial statements.

Note 4 Short- and long-term marketable securities

The amortized cost and fair value of available-for-sale securities at December 31, 2002 are as follows (in thousands):

	Amortized Cost	Unrealized Gain	Fair Value	Maturity Date
Short-term marketable securities				
Corporate notes	$ 2,676	$ 17	$ 2,693	March 2003

The amortized cost and fair value of available-for-sale securities at December 31, 2001 are as follows (in thousands):

				Maturity Date

	Amortized Cost	Unrealized Gain	Fair Value	
Short-term marketable securities				
U.S. government agencies and asset-backed securities	$ 5,999	$ 68	$ 6,067	June 2002
Medium term notes	2,903	72	2,975	July 2002
Corporate notes	3,415	37	3,452	March-December 2002
	$ 12,317	$ 177	$ 12,494	
Long-term marketable securities				
Corporate notes	$ 2,578	$ 49	$ 2,627	March 2003

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ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 5 Balance Sheet Components

Inventories consist of the following (in thousands):

	December 31,	
	2002	2001
Raw materials	$ 931	$ 1,122
Work in progress	285	182
Finished goods	317	245
	$ 1,533	$ 1,549

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

	December 31,	
	2002	2001
Clinical and manufacturing equipment	$ 24,662	$ 20,277
Computer hardware	7,130	7,267
Computer software	3,350	3,561
Furniture and fixtures	3,813	3,471
Land		458
Leasehold improvements	5,321	4,134
Construction in progress	191	3,470
	44,467	42,638
Less: Accumulated depreciation and amortization	(19,389)	(10,617)
	$ 25,078	$ 32,021

During fiscal 2002, the Company recorded an impairment charge for the land in Pakistan of $0.9 million (See note 6).

Property and equipment includes approximately $2,223,000 of assets under capital leases at December 31, 2002 and 2001. Accumulated amortization of assets under capital leases totaled approximately $1,264,000 and $749,000 at December 31, 2002 and 2001, respectively.

Depreciation expense and amortization was $13,051,000, $7,592,000 and $2,513,000 for the years ended December 31, 2002, 2001 and 2000, respectively.

Accrued liabilities, as restated (see Note 1), consist of the following (in thousands):

	December 31,	
	2002	2001
	Restated	Restated
Accrued marketing expenses	$ 1,828	$ 1,830
Accrued payroll and benefits	4,231	3,621
Sales and franchise taxes	1,055	570
Other	3,998	5,404
	$ 11,112	$ 11,425

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ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 6 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, commencing July 1, 2000. The Company paid $1,175,000 security deposit upon execution of the lease.

In July 2000, the Company entered into an agreement to sublease additional office space in Santa Clara, California. The lease term began on July 14, 2000 and expired on August 14, 2002. A security deposit of $184,448 was paid by the Company upon execution of the lease.

In August 2001, the Company entered into an agreement to sublease additional office space in Santa Clara, California. The lease term began on October 1, 2001 and expired on September 30, 2002. The Company exercised a renewal option on this lease that extended the term to June 30, 2005.

Total rent expense was $4,355,000, $3,349,000 and $2,146,000 for the years ended December 31, 2002, 2001 and 2000, 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, 2002 are $3,390,000, $3,439,000, $2,065,000, $405,000 and $0 for the years ended December 31, 2003, 2004, 2005, 2006 and 2007 and thereafter, respectively.

Capitalized lease obligations

In February 2000, the Company leased a stereolithography apparatus from Leasing Technologies International, Inc. (LTI) under a master lease agreement entered into between the Company and LTI in August 1999. Under the terms of the lease, the value of the leased equipment is $729,000 at a borrowing rate of 11.154% per annum. The term of the lease is for 48 months with a bargain purchase option at the end of the lease to purchase the equipment at 15% of the purchase price.

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 for a total value of $1,479,000 at a borrowing rate of 6.533% per annum for a period of 60 months. In July 2001 this lease was assigned to DeLage Landen.

Future minimum payments under capital lease obligations are as follows (in thousands):

Year Ended December 31,	
2003	$ 578
2004	348
2005	187
2006	
Minimum lease payments	1,113
Less: Amount representing interest	(93)
Present value of minimum lease payments	1,020
Amount due within one year	(516)
Amount due after one year	$ 504

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ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Contingencies

In January 2003, Ormco Corporation 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. In February 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 Align seeking a declaration by the Court of invalidity and non-infringement of U.S. Patent No. 6,398,548. The Company s response to Ormco s counterclaims is due in early April 2003. No trial or other dates have yet been set by the Court.

Three years ago, Ormco filed suit against the Company asserting infringement of U.S. Patent Nos. 5,447,432 and 5,683,243. In June 2000, the parties entered into a Stipulation of Dismissal with Ormco. Ormco agreed for a period of at least two years not to pursue litigation with respect to these patents, except as set forth below. Further, Ormco agreed that it would not bring any patent action against the Company for at least a period of one year with respect to any as yet unissued patents. If Ormco were to bring such an action concerning as yet unissued patents after one year, the Stipulation of Dismissal would allow Ormco to include in such an action claims involving U.S. Patent Nos. 5,447,432 and 5,683,243. In August 2001, Ormco notified the Company of the issuance of U.S. Patent No. 6,244,861 and offered a license for this patent. The Company did not take a license to this patent. Five months after Ormco s notification, it filed the lawsuit that is currently pending.

The claims in U.S. Patent Nos. 5,447,432 and 5,683,243 relate to methods and systems for forming and manufacturing custom orthodontic appliances. The relevant claims are limited to computerized methods and algorithms for determining the final positioning of a patient s teeth based upon a derived or ideal dental archform of the patient. The claims in U.S. Patent No. 6,244,861 are more generic claims relating to the methods and systems for forming and manufacturing custom orthodontic appliances. Based on the disclosure in the patent, however, the relevant claims also appear to be limited to computerized methods and algorithms for determining the final positioning of a patient s teeth based upon a derived or ideal dental archform of the patient. The treatment plan simulation developed in the Company s facilities determines the final positioning of a patient s teeth but is not based on a derived or ideal dental archform of the patient.

The claims in the Company s U.S. Patent No. 6,398,548 relate to methods and systems for incrementally moving teeth using a series of appliances designed to be placed successively on the patient s teeth.

The Company strongly believes that Ormco s claims of infringement lack merit and that the Company s counterclaim of infringement will be successful. However, the outcome of a lawsuit is inherently unpredictable. Should the Company s technology be found to infringe any one of Ormco s asserted patents, the Company would have to seek a license from Ormco, which license might not be available on commercially reasonable terms or at all. In that event, the Company could be subject to damages or an injunction which could materially adversely affect its business.

On May 1, 2002, GW Com, Inc. filed a complaint in Santa Clara Superior Court against the Company and James Lindsey, the owner of the premises located at 851 Martin Avenue, Santa Clara, California. The Company was a party with GW Com to a sub-sublease for such premises, the term of which expired on August 14, 2002. In early 2001, the Company engaged in negotiations with GW Com to amend the sub-sublease to add additional space and to extend the term through November 30, 2004. The proposed amendment, however, required the consent of the owner of the subject property, Mr. Lindsey. The Company withdrew from the negotiations of the

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ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

amendment, after, among other things, Mr. Lindsey s consent could not be obtained. GW Com s complaint alleged breach of contract against the Company and breach of contract and intentional interference with contract against Mr. Lindsey. In the complaint, GW Com sought damages of more than $4 million. In February 2002 the Company entered into a written settlement agreement pursuant to which GW Com paid the Company an aggregate of $188,000 and Mr. Lindsey paid the Company an aggregate of $10,000.

On April 9, 2002, the Company exercised its right to terminate an Exclusive Marketing Agreement dated October 18, 2001 with Discus Dental Impressions, Inc. pursuant to the express terms of the Agreement and the Company issued a press release reporting this termination. On or about May 14, 2002, the Company received a demand for arbitration submitted by Discus Dental with the American Arbitration Association in San Jose, California. In its arbitration demand, Discus Dental seeks damages of approximately $30 million, including commissions and bonus payments it claims it would have received under the Agreement as well as other expenses, attorneys fees and injunctive relief to prevent the Company from selling Invisalign to dentists in the U.S. and Canada. However, prior to terminating the Agreement, the Company conducted a thorough review of the Agreement and each party s performance thereunder. Based upon that review of the factual and legal issues, the Company denies all claims made by Discus Dental in its demand and contend that such claims are entirely without merit. In addition, on or about June 13, 2002 the Company submitted a counter-claim against Discus Dental in the arbitration seeking damages of approximately $40 million arising out of our claims for misrepresentation, breach of confidentiality provisions and unfair competition, among others. The three arbitrators have been selected, and the parties are exchanging and reviewing documents in response to document demands. The matter is currently set for arbitration on August 18, 2003.

In February 2001, the Company was named in a class action lawsuit filed on behalf of all licensed dentists (excluding orthodontists) in the U.S. The complaint alleged that the Company s policy of selling Invisalign exclusively to orthodontists violated the U.S. antitrust laws. Without admitting any wrongdoing, the company entered into a Stipulation and Agreement of Settlement with the plaintiffs to settle the lawsuit. The total legal and other settlement costs that the Company has agreed to pay are approximately $400,000 in legal fees. In November 2001, the Court approved the Stipulation and Agreement of Settlement. Pursuant to the settlement, the Company trained and certified approximately 5,000 in fiscal 2002, and have undertaken to certify 5,000 general practitioner dentists each year over the next three years.

The Company is subject to claims and assessments from time to time in the ordinary course of business. Management does not believe that any such matters, individually or in the aggregate, will have a material adverse effect on the Company s financial condition, results of operations or cash flows.

Note 7 Restructuring and Land and Impairment

In July 2002, the Company announced a plan to streamline worldwide operations. The plan included closing the Company s facilities in Pakistan and the U.A.E. The Company transitioned operations performed at these facilities to the United States and Costa Rica. For the period ending December 31, 2002, the Company recorded severance charges of $2.3 million, facility closure charges of $0.9 million, a loss on disposal of fixed assets of $1.1 million and an impairment charge of $0.9 million related to the land in Pakistan. The land was written down to a zero value to reflect its fair value as estimated by management. Approximately $0.1 million of accrued charges related to professional fees were included in accrued liabilities as of December 31, 2002. We discontinued operations at our facilities in Pakistan and the U.A.E. in October and December 2002, respectively. We concluded the remainder of our indirect operational activities related to the Costa Rica transition in January 2003. The

Company will cease non-operational closing activities in Pakistan when the land is disposed of at that location and in the U.A.E. when the necessary statutory filings have been completed.

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ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 8 Credit Facilities

In December 2002, the Company obtained a $10.0 million revolving line of credit based on domestic accounts receivable which accrues interest at a rate of 1.75% above prime and a $5.0 million equipment-based term loan which accrues interest at a rate of 2.25% above prime. As of December 31, 2002 the Company had not drawn down the revolving line of credit and had drawn down $5.0 million from the equipment-based term loan. Accessing the accounts receivable based revolving line of credit is restricted based on qualifying accounts receivable and compliance with certain loan covenants. Principal payments are due in 36 monthly installments beginning in January 2003. Annual principal payments of $1.7 million are due for each of the years 2003 through 2005.

Note 9 Stockholders Equity

Preferred Stock

As of December 31, 2002, 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 and dividends as of December 31, 2002.

On January 4, 2001, the Company s Board of Directors approved a 2 for 1 stock split. All common and preferred stock and per share amounts for all periods presented in the accompanying consolidated financial statements have been restated to reflect the stock split.

In January 2001, the Company completed an initial public offering or IPO, of 10 million shares of common stock at $13.00 per share. In March 2001, the underwriters exercised an over allotment option for 628,706 shares. Net proceeds to the Company were approximately $125,976,000.

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.

Restricted stock purchase agreement

The Company has sold shares of its common stock to founders of the Company under agreements which provide for repurchase of the stock by the Company at the stock s original purchase price upon termination of employment. The Company s right to repurchase lapses at any time prior to the earlier of: (i) three years from date of agreement; (ii) the closing of an Asset Transfer or an Acquisition ; or (iii) the voluntary liquidation, dissolution, or winding up of the Company. The Company has also sold shares of its common stock to employees, directors and consultants under the terms of the 1997 Equity Incentive Plan that includes an early exercise feature. The Company s right to repurchase under those terms lapses over the vesting period of the underlying option exercised. At December 31, 2002 and 2001, 636,809 and 1,969,488 shares of common stock, respectively, were subject to repurchase.

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ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

1997 Equity Incentive Plan

In April 1997, the Company adopted the 1997 Equity Incentive Plan (the 1997 Plan) under which the Board of Directors may issue incentive and non-qualified stock options to employees, directors and consultants. The Company has reserved 9,709,092 shares of common stock for issuance under the Plan. The Board of Directors has the authority to determine to whom options will be granted, the number of shares, the term and exercise price. Options are to be granted at an exercise price not less than fair market value for incentive stock options or 85% of fair market value for non-qualified stock options. For individuals holding more than 10% of the voting rights of all classes of stock, the exercise price of incentive stock options will not be less than 110% of fair market value. Options become exercisable and vest on a cumulative basis at the discretion of the Board of Directors but at a rate not less than 20% per year over five years from the date of grant and generally vest at a rate of 25% on the first anniversary and 1/48th each month thereafter. The term of the options is no longer than five years for incentive stock options for which the grantee owns greater than 10% of the voting power of all classes of stock and no longer than ten years for all other options.

Executive Grants

In January 2001 the Company granted options (Executive Grants) to purchase 1,000,000 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 2001 Stock Incentive Plan (the 2001 Plan) becoming effective and represent options for an aggregate of 2,000,000 shares of common stock in addition to the shares of common stock reserved for issuance under the 2001 Plan. The Executive Grant was approved by the stockholders in January 2001.

2001 Stock Incentive Plan

On January 4, 2001, the Board of Directors adopted the 2001 Plan, which will terminate no later than 2011, provides for the granting of incentive stock options, non statutory stock options and restricted stock purchase frights and stock bonuses to employees, and consultants. As of December 31, 2002, a total of 10,388,436 shares of common stock have been authorized for issuance under the 2001 Plan. The 2001 Plan was approved by the Stockholders prior to the IPO.

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ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Activity under the 1997 Plan, the Executive Grants and the 2001 Plan 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, 1999	1,422	1,285	$ 0.15	$ 193
Increase in pool	5,600			
Options granted	(5,890)	5,890	0.86	5,044
Options exercised		(4,121)	0.69	(2,828)
Options cancelled	192	(192)	0.33	(64)
Balances at December 31, 2000	1,324	2,862	0.82	2,345
Increase in pool	10,000			
Options granted	(3,423)	3,423	11.11	38,038
Options exercised		(260)	0.71	(184)
Stock repurchased	306		0.87	
Options cancelled	536	(536)	1.88	(1,006)
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

The options outstanding and currently exercisable by exercise price at December 31, 2002 are as follows (in thousands, except per share data):

	Options Outstanding			Vested	
Range of Exercise Prices	Number Outstanding and Exercisable	Weighted-Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Number of Shares	Weighted Average Exercise Price

$ 0.01	1.50	1,375	7.4	$ 0.79	1,277	$ 0.78
1.51	3.00	980	9.5	2.28	79	2.13
3.01	4.50	954	9.3	4.05	292	4.26
4.51	6.00	2,014	9.1	5.09	190	5.29
6.01	7.50	161	8.3	6.61	69	6.61
7.51	9.00	109	6.8	8.21	53	8.15
9.01	10.50	72	8.4	9.93	43	9.89
12.01	13.50	5	8.1	13.06	2	13.06
$13.51	15.00	2,000	8.0	$ 15.00	958	$ 15.00
		7,670			2,964	

The weighted average per share fair values of options granted during the years ended December 31, 2002, 2001 and 2000 were $3.50, $9.25 and, $16.878, respectively.

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ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Employee Stock Purchase Plan

On January 4, 2001, the Board of Directors adopted the Employee Stock Purchase Plan, authorizing the issuance of 1,500,000 shares of common stock pursuant to purchase rights granted to United States employees. The Employee Stock 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 Employee Stock Purchase Plan was approved by the Stockholders prior to the Initial Public Offering.

The Employee Stock Purchase Plan permits eligible employees to purchase common stock at a discount through payroll deductions during defined offering periods. The price at which stock is purchased under the Purchase Plan is equal to 85% of the fair market value of the common stock on the first day of the offering period or 85% of the fair market value on the subsequent designated purchase dates, whichever is lower. The initial offering period commenced on January 25, 2001.

Under the Employee Stock Purchase Plan, the Company sold approximately 163,000 and 39,000 shares of common stock during the years ended December 31, 2002 and 2001, respectively. The fair value of the employees purchase rights was estimated using the Black-Scholes option pricing model with the following assumptions:

	Year Ended December 31,	
	2002	2001
Risk free interest rate	3.03	3.47
Expected life	.05 years	.05 years
Expected volatility	119.8%	117.0%

Stock-based compensation

The Company records deferred stock-based compensation for the excess of the deemed fair market value over the exercise price at the date of grant related to options granted to employees. The Company has recorded deferred stock-based compensation of $0, $3,530,000 and $87,687,000 related to options issued to employees to purchase common stock issued in fiscal 2002, 2001 and 2000, respectively. During fiscal 2002, 2001, and 2000, the Company reversed $12,419,000, $12,673,000 and $0, respectively, of unrecognized deferred compensation relating to employees that have terminated employment with the Company. The compensation expense is being recognized over the option vesting period of four years using the straight-line method. For the years ended December 31, 2002, 2001, and 2000, the Company recorded amortization of stock-based compensation of $16,539,000, $22,347,000 and $11,252,000, respectively, in connection with options granted to employees.

For options granted to consultants, the Company determines the fair value of the options using the Black-Scholes pricing model. The Company has recorded deferred stock-based compensation expense/(reversals of expense) of $(316,000), $(484,000) and $4,065,000 for the years ended December 31, 2002, 2001 and 2000, respectively, for options issued to non-employees in fiscal 2001 and 2000. The compensation expense is being recognized over the option vesting period of four years, using the method presented by FIN 28. For the years ended December 31, 2002, 2001 and 2000, the Company recorded amortization of stock-based compensation expense/(reversals of expense) of $45,000, $(138,000) and $2,120,000, respectively, in connection with options granted to consultants.

The Company recorded stock-based compensation expense of $2,010,000 related to stock options granted to non-employees in fiscal 2002.

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ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The Company accelerated the vesting of options to several employees in connection with related severance packages. The acceleration was accounted for in accordance with FIN 44 as a one-time charge to the statement of operations. The charges for December 31, 2002 and 2001 were $2,245,000 and $224,000, respectively. The charge was 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.

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

	Year Ended December 31,		
	2002	2001	2000
Cost of revenues	$ 3,399	$ 4,602	$ 2,939
Sales and marketing	3,002	3,920	2,357
General and administrative	10,663	9,763	5,774
Research and development	3,221	4,148	2,731
	$ 20,285	$ 22,433	$ 13,801

Note 10 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,	
	2002	2001
Deferred tax assets (liabilities):		
Start-up costs	$ (129)	$ (383)
Net operating loss carryforwards	74,290	59,220
Research and development credit	4,642	3,128
Deferred revenue	3,668	630
Other	2,511	545
Deferred tax assets	84,982	63,140

Less: Valuation allowance	(84,982)	(63,140)
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, 2002.

Reconciliation of the statutory federal income tax to the Company s effective tax:

	Year Ended December 31,	
	2002	**2001**
Tax at federal statutory rate	(34.00)%	(34.00)%
State, net of federal benefit	(6.00)	(3.00)
Deferred taxes not recognized	20.00	30.00
Amortization of stock-based compensation	11.15	6.00
Other	8.85	1.00
	0.00 %	0.00 %

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ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

As of December 31, 2002, the Company had a net operating loss carryforward of approximately $180.3 million for federal purposes and $87.8 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 $3.3 million and $1.9 million for federal and state income tax purposes, respectively. If not utilized, the federal carryforward will expire in various amounts beginning in 2017. The California 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 changes occur in the stock ownership of a company. In the event the Company has had a change in ownership, utilization of the carryforwards could be restricted.

Note 11 Supplemental Cash Flow Information

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

	Year Ended December 31,		
	2002	2001	2000
Taxes paid	$ 231	$ 100	$ 1
Interest paid	$ 143	$ 150	$ 382
Non-cash investing and financing activities:			
Note receivable for preferred stock	$	$	$ 75
(Repurchase) issuance of note receivable for common stock	$ (260)	$ (213)	$ 1,791
Fixed assets acquired under capital lease	$	$ 13	$ 2,209
Fixed assets acquired with accounts payable or accrued liabilities	$ 48	$ 640	$ 5,257
Accrual for IPO costs	$	$ 20	$ 557

(Conversion) issuance of warrants in conjunction with line of credit financings	$	$ (1,818)	$ 776
Deferred stock-based compensation	$ 13,289	$ 9,627	$ 91,752
Conversion of convertible subordinated notes into convertible preferred stock	$	$ 128,873	$ 14,000

Note 12 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.

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ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 13 Related Party Transactions

Loan to Officer

In April 2002, the Company issued a loan in the amount of $200,000 at a note of 9.5% per annum to a former officer of the Company, who at the time the loan was made was the Company s Chairman of the Board. The note is secured by common stock of the Company. Interest is payable annually, principal is due on June 3, 2004.

Employee Notes Receivable

In connection with the exercise of certain stock options granted under the Company s stock option plan, the Company has received promissory notes equal to the total exercise price of these stock options. These notes are full recourse promissory notes, which bear interest at 9.5% per annum, and accrued interest is payable annually on the anniversary of the issuance date of the note. During 2002, the original due date of the notes were extended by 18 months. The notes are collateralized by the shares of common stock held by employees. Promissory notes for the exercise of certain stock options totaling $892,000 and $1,484,000 were outstanding as of December 31, 2002 and 2001, respectively. These notes are classified as a reduction of stockholders equity (deficit).

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

Not applicable.

PART III

Certain information required by Part III is omitted from this Form 10-K because we intend to file a definitive Proxy Statement pursuant to Regulation 14A (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 4A Executive Officers of the Registrant 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.

ITEM 11. EXECUTIVE COMPENSATION.

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

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

The information required by this Item 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, 2002 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)) (c)
Equity compensation plans approved by security holders	7,670,000(1)(2)	$ 6.54	10,022,000(3)
Equity compensation plans not approved by security holders			
Total	7,670,000	$ 6.54	10,022,000

(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 each

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of 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 three million (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 one million five hundred thousand (1,500,000) shares.

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. CONTROLS AND PROCEDURES.

(a) *Evaluation of disclosure controls and procedures.*

Within the 90 days prior to the filing of this Annual Report on Form 10-K/A (the Evaluation Date), we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-14(c) and 15d-14(c) under the Exchange Act). Based upon that evaluation, our Chief Executive Officer and our Chief Financial Officer concluded that our disclosure controls and procedures are effective to ensure that material 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. It should be noted, however, that the design of any system of controls is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions, regardless of how remote.

(b) *Changes in internal controls.*

Subsequent to the Evaluation Date, there have been no significant changes in our internal controls or in other factors that could significantly affect these controls subsequent to the date of their last evaluation.

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PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES AND REPORTS ON FORM 8-K.

(a)

1. Consolidated Financial Statements

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

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

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.

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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, 2000	$ 33	$ 461	$	$	$ 494
Year ended December 31, 2001	494	1,399	(24)	13	1,882
Year ended December 31, 2002	1,882	1,068	(821)	(18)	2,111
Allowance for deferred taxes:					
Year ended December 31, 2000	7,269	25,254			32,523
Year ended December 31, 2001	32,523	30,617			63,140
Year ended December 31, 2002	63,140	21,842			84,982
Allowance for excess and obsolete inventory and abandoned product:					
Year ended December 31, 2000(1)					
Year ended December 31, 2001		555			555
Year ended December 31, 2002	555	51	(107)	(30)	469

(1) The Company did not have significant inventory during the year ended December 31, 2000 and accordingly, there is no related reserve.

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3. Exhibits

Exhibit Number	Description
3.1*	Amended and Restated Certificate of Incorporation of registrant.
3.2*	Amended and Restated Bylaws of registrant.
4.1*	Form of Specimen Common Stock Certificate.
4.2(1)	Stock Purchase Agreement, dated November 26, 2002, by and between certain investors and registrant.
10.1*	Amended and Restated Investors Rights Agreement, among registrant and certain of its stockholders, dated September 16, 2000.
10.2	Reserved.
10.3	Reserved.
10.4*	Lease Agreement by and between James Lindsey and registrant, dated June 20, 2000, for office space located at 881 Martin Avenue, Santa Clara, CA.
10.5	Reserved.
10.6	Reserved.
10.7*	Shelter Services Agreement between registrant and ELAMEX, S.A. de C.V. dated February 16, 2000.
10.7.1(7)	Amendment dated June 3, 2002 to Shelter Services Agreement by ELAMEX, S.A. DE C.V. and registrant.
10.8	Reserved.
10.9	Reserved.
10.10	Reserved.
10.11	Reserved.
10.12	Reserved.
10.13*	Registrant s 2001 Stock Incentive Plan.
10.14*	Registrant s Employee Stock Purchase Plan.
10.15*	Form of Indemnification Agreement by and between registrant and its Board of Directors.
10.16^(2)	Exclusive Marketing Agreement, dated October 18, 2001, by and between Discus Dental Impressions, Inc. and registrant.
10.17	Reserved.
10.18(3)	Agreement to confirm consulting and board duties, dated February 26, 2002, between Kelsey Wirth and registrant.
10.19(3)	Transition, Consulting and Separation Agreement, dated March 27, 2002, between Muhammad Ziaulluh Chishti and registrant.
10.20(3)	Employment Agreement dated March 27, 2002 between Thomas M. Prescott and registrant.
10.21(3)	Separation Agreement dated March 28, 2002 between Ike Udechuku and registrant.
10.22(4)	Employment Offer Letter dated July 10, 2002 for Roger E. George, Vice-President of Legal Affairs and General Counsel.
10.23(5)	Employment Offer Letter dated July 15, 2002 for David S. Thrower, Vice-President of Global Marketing.
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Exhibit Number	Description
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10.26(7)	Stock Option Agreement dated January 4, 2001 by and between Kelsey Wirth and registrant.
10.27(7)	Stock Option Agreement dated January 4, 2001 by and between Zia Chishti and registrant.
10.28(7)	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.
10.29(7)	Amendment to Master Professional Services Agreement dated May 20, 2002 by and between Invisible IT Inc. and registrant.
10.30(7)	Settlement Agreement and Mutual Release dated February 6, 2003 by and among GW Com, Inc., now known as Byair, Inc., Intelecady, Inc., James S. Lindsey and registrant.
10.31(7)	Consulting Agreement dated June 17, 2002 by and between Peter Riepenhausen and registrant.
10.32(7)	Settlement and General Release Agreement dated October 1, 2002 by and between Stephen Bonelli and registrant.
10.33(7)	Director Offer Letter dated March 6, 2003 for David E. Collins.
10.34(7)	Settlement Agreement dated November 27, 2002 by and between Phillippe Mollard and registrant.
10.35(7)	Loan and Security Agreement dated December 20, 2002 by and between Comerica Bank-California and registrant.
21.1*	Subsidiaries of the registrant.
23.1	Consent of PricewaterhouseCoopers LLP, Independent Accountants.
24.1	Power of Attorney.
99.1	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 2002.

* Incorporated herein by reference to the corresponding exhibit to Registrant s Form S-1, as amended, filed with the Securities and Exchange Commission on November 14, 2000 (File No. 333-49932).
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.

^ Portions of this exhibit have been omitted pursuant to a request for confidential treatment. Such omitted confidential information has been designated by asterisks (*****) and has been filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 under the Securities Exchange Act of 1934, as amended, pursuant to an application for confidential treatment.

(1) Incorporated by reference to Exhibit 4.1 filed with the registrant s Report on Form 8-K, filed with the Securities and Exchange Commission on November 21, 2002.

(2) Incorporated by reference to the exhibit bearing the same number filed with registrant s Annual Report on Form 10-K for the year ended December 31, 2002.

(3) Incorporated by reference to the exhibit bearing the same number filed with registrant s Quarterly Report on Form 10-Q for the quarter ended March 31, 2002.

(4) Incorporated by reference to Exhibit 10.18 filed with registrant s Quarterly Report on Form 10-Q for the quarter ended September 30, 2002.

(5) Incorporated by reference to Exhibit 10.19 filed with registrant s Quarterly Report on Form 10-Q for the quarter ended September 30, 2002.

(6) Incorporated by reference to Exhibit 10.20 filed with registrant s Quarterly Report on Form 10-Q for the quarter ended September 30, 2002.

(7) Previously filed.

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(b) Reports on Form 8-K

On November 21, 2002 Align filed a Report on Form 8-K with the Securities and Exchange Commission under Item 5 Other Events in connection with the private placement it completed in November 2002, and filed the related Stock Purchase Agreement as an exhibit to this Report on Form 8-K.

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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 August 13, 2003.

ALIGN TECHNOLOGY, INC.

By: /s/ THOMAS M. PRESCOTT

Thomas M. Prescott

President and Chief Executive Officer

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)	August 13, 2003
/s/ ELDON M. BULLINGTON **Eldon M. Bullington**	Chief Financial Officer and Vice President of Finance (Principal Financial Officer and Principal Accounting Officer)	August 13, 2003
*/s/ KELSEY WIRTH **Kelsey Wirth**	Director	August 13, 2003
*/s/ BRIAN DOVEY **Brian Dovey**	Director	August 13, 2003
*/s/ JOSEPH LACOB **Joseph Lacob**	Director	August 13, 2003
*/s/ H. KENT BOWEN **H. Kent Bowen**	Director	August 13, 2003
/s/ DAVID E. COLLINS **David E. Collins**	Director	August 13, 2003

/s/ GREGORY J. SANTORA	Director	August 13, 2003
Gregory J. Santora		
*By: /s/ THOMAS M. PRESCOTT	President, Chief Executive Officer and Director	August 13, 2003
Attorney-In-Fact		

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CERTIFICATIONS

I, Thomas M. Prescott, certify that:

1. I have reviewed this annual report on Form 10-K/A of Align Technology, Inc.;

2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;

3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;

4. The registrant s other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:

   a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;

   b) evaluated the effectiveness of the registrant s disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the Evaluation Date); and

   c) presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5. The registrant s other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant s auditors and the audit committee of registrant s board of directors (or persons performing the equivalent functions):

   a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant s ability to record, process, summarize and report financial data and have identified for the registrant s auditors any material weaknesses in internal controls; and

   b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant s internal controls; and

6. The registrant s other certifying officers and I have indicated in this annual report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: August 13, 2003

/s/ THOMAS M. PRESCOTT

Thomas M. Prescott

President and Chief Executive Officer

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I, Eldon M. Bullington, certify that:

1. I have reviewed this annual report on Form 10-K/A of Align Technology, Inc.;

2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;

3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;

4. The registrant s other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:

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   b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant s internal controls; and

6. The registrant s other certifying officers and I have indicated in this annual report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: August 13, 2003

/s/ ELDON M. BULLINGTON

Eldon M. Bullington

Chief Financial Officer and

Vice President of Finance

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