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;