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 wil