UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(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, 2001

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)

851 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 the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes [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 registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K, or any amendment to this Form 10-K. [ ]

The aggregate market value of voting stock held by non-affiliates of the registrant as of March 18, 2002 was $238,192,119. This calculation does not reflect a determination that persons are affiliates for any other purpose.

On March 18, 2002, 48,119,620 shares of the registrant's common stock were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement relating to its 2001 annual stockholders' meeting to be held on May 16, 2002 are incorporated by reference into Part III of this annual report on Form 10-K.

PART I

In addition to historical information, this report on Form 10-K contains forward-looking statements. 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 "Factors That May Affect Operating Results" and "Management's Discussion and Analysis of Financial Condition and Results of Operations." The Company undertakes 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.

ITEM 1. BUSINESS.

Overview

We design, manufacture and market Invisalign®, a proprietary new method for treating malocclusion, or the misalignment of teeth. Invisalign corrects malocclusion using a series of clear, removable appliances that gently move teeth to a desired final position. Because it does not rely on the use of metal or ceramic brackets and wires, Invisalign significantly reduces the aesthetic and other limitations associated with braces. Invisalign also offers dental professionals a new means of carrying out their diagnosis and treatment planning processes. We believe Invisalign has the potential to transform the traditional practice of orthodontics by appealing to people who would not otherwise seek treatment.

In the U.S. alone, over 200 million individuals have some form of malocclusion. Each year, less than one percent of these individuals, or approximately two million Americans, enter orthodontic treatment, spending approximately $7 billion in the aggregate. We believe Invisalign is a compelling treatment alternative for most of the patients who would seek traditional orthodontic treatment. In addition, given the significant benefits of Invisalign, we have the opportunity to expand the U.S. orthodontic market by addressing the needs of millions of individuals who would not otherwise seek treatment. Further, we believe the international opportunity is larger than the U.S. opportunity.

We received FDA clearance to market Invisalign in 1998 and started commercial sales in July 1999. Our 510(k) clearance from the FDA allows us to market the 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 130 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 unusually severe malocclusions.

Historically, we limited our training of dental professionals to orthodontists in the U.S and Canada. In October 2001, we expanded our training in the U.S. and Canada to include dentists. As of February 28, 2002, we had trained over 12,000 dental professionals worldwide to use Invisalign. Of those dental professionals trained, approximately 80% are dental professionals in the U.S. and Canada, which we consider our domestic market. Within our domestic market, we have trained over 7,300 orthodontists, representing approximately 80% of all practicing orthodontists in the U.S. and Canada, and over 2,300 dentists. As of February 28, 2002, over 4,300 of the worldwide dental professionals we have trained had submitted one or more cases to us, and over 44,000 patients have commenced treatment with Invisalign.

Our objective is to establish Invisalign as the standard method for treating orthodontic malocclusion. Our sales and marketing efforts focus on educating both consumers and dental professionals on the significant benefits of Invisalign. We continue to train dental professionals and work with them to increase the use of Invisalign within their practices. In September 2000, we initiated a national advertising campaign to create awareness of Invisalign as a treatment alternative and to stimulate demand for treatment with Invisalign. In 2001, we continued to advertise nationally using a broader marketing mix to drive consumer and dental professional demand and to reinforce the breadth of applicability of Invisalign.

Industry Background

Malocclusion

Malocclusion is one of the most prevalent clinical 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 treatment.

Traditional Orthodontic Treatment

Dental professionals today 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 two years 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 $3,000 to $5,000 and are generally not reimbursed by insurance. In addition, dental professionals commonly charge a premium for lingual or ceramic alternatives. Fees are based on the difficulty of the particular case and on the dental professional's estimate of chair time and are generally negotiated in advance. A treatment that exceeds the dental professional's estimate of chair time generally results in decreased fees per hour of chair time, or reduced profitability for the dental professional.

Limitations of Traditional Orthodontic Treatment

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

Unattractive appearance. Braces call attention to the patient's condition and treatment. In addition, braces trap food, which can further compromise appearance. Braces can also result in permanent discoloration of teeth. Many adults associate braces with adolescence. As a result of these and other limitations, less than one half of one percent of American adults with malocclusion elect 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 days after 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, 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 new system for treating malocclusion. Invisalign consists of two components: ClinCheck™ and Aligners.

ClinCheck. ClinCheck is an interactive Internet application that allows dental professional 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 our projected treatment, or may provide us with feedback for modification. We reflect any requested adjustments in a modified simulation. Upon the dental professional's approval of the ClinCheck simulation, we use the data underlying the simulation to manufacture the patient's Aligners.

Aligners. Aligners are custom-manufactured, clear, removable dental appliances that, when worn in 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, prescribe that the patient wear the final Aligner as a 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. 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.

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 significantly 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. We believe that ClinCheck is the only product that enables dental professionals to preview a course of treatment and the likely final outcome of treatment in an interactive three-dimensional computer model. ClinCheck allows dental professionals to analyze multiple treatment alternatives before selecting the alternative 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 a day.

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.

Significantly expanded patient base. We believe 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.

Higher fees. Dental professionals typically charge between $3,000 and $5,000 for a course of conventional treatment. Due to the substantial patient benefits of Invisalign, we believe dental professionals offering Invisalign have generally been able to command a significant premium. In our experience, the premiums charged by dental professionals for Invisalign have been comparable to other treatment alternatives that attempt to improve the aesthetics of conventional braces, such as ceramic and lingual braces.

Decreased dental professional and staff time. 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 significantly reduces dental professional and staff chair time and can increase practice throughput.

We believe the combination of increased patient volume, higher fees per case and reduced chair time has the potential to substantially 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 unusually 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 February 28, 2002, approximately 44,000 patients have entered treatment using Invisalign.

Our 510(k) clearance from the FDA 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 130 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 unusually severe malocclusions.

Approximately two million patients enter into traditional orthodontic treatment in the U.S. annually. These patients represent less than 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 natural 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 by addressing the primary limitations of braces, Invisalign will encourage this group to seek treatment. Adults, who are particularly sensitive to the aesthetic limitations of traditional treatment, represent our most significant market expansion opportunity.

We continue to focus on the domestic market opportunity and have expanded our focus on selected international markets, as we believe a large international market opportunity exists.

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 significantly increase the number of patients who seek orthodontic treatment annually. We successfully tested consumer advertising in two lead markets and in September 2000 initiated a national advertising campaign in order to create awareness of Invisalign as a treatment alternative and to

establish the Invisalign brand name. In 2001, we continued to advertise nationally using a broader 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 dentists. As of February 28, 2002, we had trained over 12,000 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 constrains 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 to broadly cover any algorithmic method of segmenting orthodontic treatment into a sequence of three or more steps, based on calculated initial and final 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 of unusually severe malocclusions. 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 even severe complexity. We are also undertaking post-marketing studies and making additional improvements to the product.

Build an international presence. Initially, we focused our sales and marketing efforts on the U.S. and Canadian market opportunities. While we continue to focus on this domestic market, we have begun to introduce Invisalign in selected international markets. We believe that potential international demand for Invisalign exceeds that of our domestic market.

Manufacturing

We produce highly customized, close tolerance, medical quality products in volume. To do so, we have developed a number of proprietary processes and technologies. These technologies include complex software solutions, destructive and white light scanning techniques, stereolithography and automated Aligner fabrication.

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

Manufacturing is coordinated in Santa Clara, California, where, as of December 31, 2001, we employed a manufacturing staff of approximately 135 people. In addition, we employed a software development team comprising approximately 30 software engineers with backgrounds in computational geometry, animation, computer-aided design and various manufacturing industries. We also employ approximately 500 software operators and other staff in our facilities in Lahore, Pakistan, who are responsible for the creation of treatment simulations. In late 2001, we began developing operations in the United Arab Emerites ("U.A.E.") and Costa Rica, which will also create treatment simulations. In addition, we outsource the fabrication and packaging of Aligners to a contract manufacturer based in Juarez, Mexico.

The Invisalign Treatment Process

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 treatment data which consists of an 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 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, 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 plaster models of the patient's dentition. We scan the plaster models 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 Lahore, Pakistan

*Preparation of computer-simulated treatment and viewing of treatment using ClinChe*ck. In Pakistan we transform this initial model into a customized, three-dimensional treatment plan that simulates appropriate tooth movement in a series of two-week increments. This simulation is then reviewed for adherence to prescribed clinical, treatment, and quality standards. Upon passing review, the simulation is then delivered to the prescribing dental professional via ClinCheck on our website at www.invisalign.com. The dental professional then reviews the ClinCheck simulation on a computer 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 facility using custom manufacturing techniques that we have adapted for use in orthodontic applications.

Manufacture of Aligners and shipment to the dental professional. We ship these molds to Juarez, Mexico, where our contract manufacturer fabricates Aligners by pressure forming polymeric sheets over each mold. The Aligners are then trimmed, polished, cleaned, packaged and, following final inspection, shipped directly to the prescribing dental professional. 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.

Historically, we have shipped Aligners in batches. The first batch, which typically represented the first several months of treatment, was produced once the prescribing dental professional approved ClinCheck. Thereafter, Aligners were sent at approximately six month intervals until completion of treatment. In mid-February 2001, for cases where ClinCheck was approved, we began shipping all the Aligners in a single batch. In addition, we began accelerating the shipments of Aligners for cases where ClinCheck was approved prior to mid-February 2001.

Throughput Management

Because we manufacture each case on a build-to-order basis, we cannot 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. In 2001 we upgraded our proprietary, three-dimensional treatment-planning software to enhance computer analysis of treatment data, which reduced time spent on manual and judgmental tasks for each case and thereby increased the efficiency of our technicians in Pakistan. 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 during 2001, we achieved certification to ISO 9001:1994, 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.

We custom manufacture Aligners on a build-to-order basis so 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 customer's expectations. However, Aligners are subject to the Invisalign product warranty, which covers defects in materials and workmanship. Defective or broken Aligners must be returned to us for credit evaluation. In the event that returned Aligners fall within the scope of the Invisalign product warranty, we will replace the Aligners at our expense. Our warranty is contingent upon proper use of the Aligners for the purposes for which they are intended. If a patient chooses not to wear the Aligners, and as a result, requests additional Invisalign treatment, the dental professional pays for the additional expense.

The Invisalign product warranty does not provide any assurances regarding the outcome of treatment using Invisalign. 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 molds of the patient's dentition to us. We use the molds 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. Under the Invisalign product warranty, we will provide patients with one mid-course correction at our expense to address significant deviations from the approved ClinCheck treatment plan.

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 mid-course correction or additional Aligners. However, in these cases, the mid-course correction and additional 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, event marketing, public relations and direct mail campaigns. We tested our consumer marketing strategy in two markets, Austin, Texas and San Diego, California. Based on the positive results of these initial marketing efforts, in September 2000, we launched a nationwide consumer marketing campaign to create awareness and stimulate demand for Invisalign. In 2001 we continued to advertise nationally using a broader marketing mix to drive consumer and dental professional demand and to reinforce the breadth of applicability of Invisalign.

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

- a general practice dentist;
- an orthodontist;
- our toll-free support line (1-800-INVISIBLE); and
- our website (www.invisalign.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 of our choice. Traditionally we have outsourced the telephone support function to a large national call center operator. During 2001, we transitioned this function in-house. We maintain the outsourced function for back-up and peak periods.

Professional Marketing

Professional marketing consists of training dental professionals and assisting them in building their practices. As of December 31, 2001, our sales team consisted of 32 salespeople experienced in orthodontic product sales. Approximately 31 technical support staff, together with the marketing department and our in-house orthodontic staff, support the sales team. Our sales and support staff has been engaged in marketing Invisalign to orthodontists since July 1999. In October 2001, through our partner Discus Dental, we began marketing Invisalign to general dentists in our domestic market. Under a five year marketing agreement, Discus Dental will act as our exclusive Invisalign marketing and sales representative providing training, certification, marketing and clinical support to general dentists in the U.S. and Canada.

As of February 28, 2002, we had trained over 12,000 dental professionals worldwide to use Invisalign. Of those dental professionals trained, approximately 80% are dental professionals in the U.S. and Canada, which we consider our domestic market. Within our domestic market, we have trained over 7,300 orthodontists, representing approximately 80% of all practicing orthodontists in the U.S. and Canada, and over 2,300 dentists. As of February 28, 2002, over 4,300 of the worldwide dental professionals we have trained had submitted one or more cases to us, and over 44,000 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, 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. As a result, we are able to complete these training workshops within one day. 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 market to local general practice dentists and to prospective patients through direct mail or other media. Indeed, many practices have commenced promotional activity in their local region with our assistance.

We have developed a system of tiering dental professionals that encourages our sales force to devote more time to those dental professionals most proficient in the use of Invisalign.

We use objective criteria, primarily the number of cases initiated with Invisalign, to tier dental professionals. Inquiries from prospective patients through our customer call center and our website are directed to higher tier dental professionals. We believe the tiering process will rapidly increase the penetration of our product within selected dental professionals' offices.

General 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. Through our agreement with Discus Dental, we educate these general dentists and staff to encourage them to recommend Invisalign to their patients.

Research and Development

As of December 31, 2001, our research and development team consisted of 21 individuals with medical device development, orthodontic and other relevant backgrounds. 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 line of products.

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 of even severe complexity. We are also undertaking post-marketing studies and making additional improvements to the product. In 2001, we upgraded our proprietary, three-dimensional treatment-planning software primarily to increase our manufacturing capacity and efficiency. Our product development team is testing enhanced materials and a number of complementary products that we expect will provide additional revenue opportunities.

Intellectual Property

We believe our intellectual property position represents a substantial business advantage. As of February 28, 2002, we have nine issued U.S. patents, 11 issued foreign patents, 52 pending U.S. patent applications, and 121 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 may issue in the future will be found to be valid and enforceable and sufficient to protect our technology or products.

Competition

We are not aware of any company that has developed or is marketing a system comparable to Invisalign. However, we compete for the attention of dental professionals with manufacturers of other orthodontic products. These suppliers include manufacturers of traditional orthodontic appliances such as 3M Company, Sybron Dental Specialities, Ormco 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;
- effectiveness of treatment;
- ease of use; and
- dental professionals' chair time.

We believe that Invisalign compares favorably 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 countries in which we sell our products.

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 device's and its 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 our Mexico-based contract manufacturer, Elamex. 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 personnel for our exclusive use. We have supplied Elamex with procedures for how to manufacture and ship our products and have trained Elamex's personnel, thus assuring 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, 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 will not be subject to regulations promulgated by the European Community, although we have the option to CE mark our product. We achieved certification to ISO 9001:1994 in fiscal 2001, which facilitates the commercialization of Invisalign outside the U.S.

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 operations 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, 2001, we had approximately 1,093 employees, of whom approximately 358 were employed in the U.S., with 637 employed in Pakistan, 42 in Europe and 56 in Latin America. Of our U.S. employees, approximately 135 are employed in manufacturing, 30 are software engineers, 32 are sales representatives, 31 are customer support staff, 21 are employed in research and development and 109 are employed in various management, administrative and support positions.

Risk Factors

The statements contained below and elsewhere in this report on Form 10-K 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 limitations, 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 report on Form 10-K 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.

Factors That May Affect Operating Results

Since we have a history of losses and negative operating cash flows, and we expect our operating expenses to continue to increase, we may not achieve or maintain profitability in the future.

We have incurred significant operating losses, negative operating cash flows and have not achieved profitability. From inception through July 2000, we spent significant funds in organizational and start-up activities, recruiting key managers and employees, developing Invisalign and developing our manufacturing and customer support resources. We also spent significant funds on clinical trials and training programs to train dental professionals in the use of Invisalign. We expect to have net losses and negative operating cash flows for at least the next 12 months.

We intend to increase our operating expenses as we continue to:

- scale our manufacturing operations;
- develop new software and increase the automation of our manufacturing processes;
- execute our national direct to consumer marketing campaign;
- increase the size of our sales force and dental professional training staff;
- expand our manufacturing operations from Pakistan to additional relatively lower wage countries, including the U.A.E. and Costa Rica;
- increase our international sales and marketing efforts;
- undertake quality assurance and improvement initiatives; and
- increase our general and administrative functions to support our growing operations.

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, 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 achieved profitability. As of December 31, 2001, we had an accumulated deficit of approximately $206.1 million.

We expect to expend significant capital to establish a national brand, build manufacturing infrastructure and develop both product and process technology. We believe that the existing cash balances, the proceeds from our initial public offering in January 2001 and other potential financing alternatives will be sufficient to meet our capital and operating requirements for at least the next 12 months.

We are currently working towards our objective of realizing profitability by achieving the key goal of successfully marketing our product throughout our domestic market and internationally, while controlling our expenses. The failure to win increased acceptance by orthodontists and dentists of Invisalign could have a material adverse effect on our business, results of operations and financial conditions.

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.

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 in the introduction of new production processes;
- inaccurate forecasting of revenue, production and other operating costs; and
- the development and marketing of directly 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.

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, 2001, approximately 3,700 orthodontists have submitted one or more cases to us. Our success depends upon increasing acceptance by orthodontists and dentists of Invisalign. Invisalign requires dental professionals and their staff to undergo special training and learn to interact with patients in new ways and to interact with us as a supplier. In addition, because Invisalign has only been in clinical testing since July 1997 and commercially available 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 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 in 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 which could compromise the effectiveness of their treatment. While 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, our success will depend upon the rapid acceptance of Invisalign by the substantially larger number of 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 dentists and orthodontists, 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 and levels of consumer confidence and consumer spending. If consumers prove unwilling to adopt Invisalign as rapidly or in the numbers that we anticipate, our operating results will be harmed.

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

Two of our key production steps are performed in manufacturing operations located outside the U.S. We currently rely on our facilities in Pakistan to create electronic treatment plans with the assistance of sophisticated software. In late 2001, we also began developing facilities in the U.A.E. and Costa Rica, which will perform these functions. We employ approximately 500 people in Lahore, Pakistan, most of who are Pakistani, in this effort. In addition, we rely on third party

manufacturers in Mexico to fabricate Aligners and to ship the completed product to customers. Our reliance on international operations exposes us to risks and uncertainties, including:

- political, social and economic instability;
- acts of war and acts of terrorism, particularly in light of the terrorist attacks of September 11, 2001;
- 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, our operating results may be harmed.

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

Our success will depend in part on our ability to maintain existing intellectual property and to obtain and maintain further intellectual property protection for our products, both in the U.S. and in other countries. Our inability to do so could harm our competitive position. As of February 28, 2002, we have nine issued U.S. patents and 52 pending U.S. patent applications. We have 11 foreign-issued patents and 121 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, 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 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, 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 2000, Ormco Corporation filed suit against us asserting an infringement of U.S. Patent Nos. 5,447,432 and 5,683,243. The complaint sought unspecified monetary damages and equitable relief. The complaint alleged that Invisalign infringed certain claims of the two patents relating to computer modeling of an ideal dentition and the production of orthodontic appliances based upon the ideal dentition. The suit has been dismissed but can be recommenced under certain circumstances. See "Item 3--Legal Proceedings." If the Ormco suit were recommenced and if Ormco were to prevail, we would have to seek a license from Ormco, which license might not be available on commercially reasonable terms or at all. In that event, we could be subject to damages or an injunction, which could materially adversely affect our business.

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 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. In addition, third party rapid prototyping bureaus fabricate some molds from which the Aligners are formed. As a result, if any of our third party manufacturers fail to deliver their components or if we lose their services, we may be unable to deliver our products in a timely manner and our business may be harmed. Finding substitute manufacturers may be expensive, time-consuming or impossible. Although we are in the process of developing the capability to fabricate all molds and Aligners internally, we may not be successful and may continue to rely on outsourcing in the future.

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 rapid growth may exceed the capacity 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 are growing rapidly, and our failure to manage this growth could harm our business. We have experienced significant growth in recent periods.

Our headcount increased from approximately 50 employees as of June 30, 1999 to approximately 1,100 employees as of December 31, 2001. We expect that our growth will 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, continued growth increases the challenges involved in a number of areas, including: recruiting and retaining sufficient skilled personnel, providing adequate training and supervision to maintain our high quality standards, and preserving our culture and values. Our inability to manage this growth effectively would 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. There is currently a shortage of skilled clinical, engineering and management personnel and intense competition for these personnel, especially in Silicon Valley where our headquarters is located. 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.

We experience competition from manufacturers of traditional braces and expect aggressive competition in the future.

We are not aware of any company that is marketing or developing a system directly comparable to Invisalign. However, 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 products 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 will be harmed.

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 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, which 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.

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 costs or reduce or eliminate certain of our activities or our revenues.

We face risks related to our international operations, 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 other countries. We may also incur significant costs in attempting to obtain and in maintaining 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 have recently launched sales of our product in Germany, France and the U.K. and intend to further expand our international operations. We do not know whether orthodontists, dentists and consumers will adopt Invisalign in sufficient numbers or as rapidly as we anticipate.

Our business exposes us to risks of product liability claims, and we may incur substantial expenses if we are sued for product liability.

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 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 could harm our business.

The market price for our common stock may be highly volatile.

The trading price of our common stock is likely to be highly volatile and could be subject to wide fluctuations in price in response to various factors, many of which are beyond our control, including:

- quarterly variations in our results of operations;
- changes in recommendations by the investment community or in their estimates of our revenues or operating results;

- speculation in the press or investment community;
- strategic actions by our competitors, such as product announcements or acquisitions; and
- general market conditions.

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

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

The interest of management could conflict with the interest of our other stockholders. As of December 31, 2001, our executive officers, directors and principal stockholders beneficially owned, in total, approximately 47.7% of our outstanding common stock. These stockholders, if acting together, would be able to influence significantly all matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. This could have the effect of delaying or preventing a change of control of the Company, which in turn could reduce the market price of our stock.

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. The leases for our facilities expire between 2002 and 2005. The combined monthly rent for the Santa Clara facilities is approximately $270,000.

We operate two facilities in Pakistan, both in the city of Lahore. The main facility comprises over 5,000 square feet of office space. The lease for this facility expires at the end of 2002. The second facility comprises over 10,000 square feet of office space. The lease for this facility expires in August 2010.

As of December 31, 2001 we have committed $1.2 million in funds to purchase approximately 215 acres of land in Pakistan.

ITEM 3. LEGAL PROCEEDINGS.

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. Pursuant to the settlement, Align will undertake to train and certify 5,000 general practice dentists each year over the next four years. In November 2001, the Court approved the Stipulation and Agreement of Settlement.

In January 2000, Ormco Corporation filed suit against us asserting infringement of U.S. Patent Nos. 5,447,432 and 5,683,243. The complaint sought unspecified and monetary damages and injunctive relief. In March 2000, we answered the complaint and asserted counterclaims seeking a declaration by the Court of invalidity and non-infringement of the asserted patents.

In June 2000, we 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 us 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 us of the issuance of U.S. Patent No. 6,244,861 and offered a license for this patent. No assurance can be given that Ormco will not bring another action against us or, that if brought, it will not be successful. Should the suit be recommenced and should our technology be found to infringe, we would have to seek a license from Ormco, which license might not be available on commercially reasonable terms or at all. In that event, we could be subject to damages or an injunction which could materially adversely affect our business. It is possible that, depending on the scope of any new patents that are issued to Ormco, Ormco will bring another patent action after a period of one year has passed.

The claims at issue in the Ormco suit relate to methods and systems for forming and manufacturing custom orthodontic appliances. The relevant claims are limited to the calculation of 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 our Pakistan facilities determines the final positioning of a patient's teeth but is not based on a derived or ideal dental archform of the patient.

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 which have been brought to our attention, there may be other more pertinent 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 securityholders during the fourth quarter of our 2001 fiscal year.

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:

Year Ended December 31, 2001	High	Low
Fourth Quarter	$ 5.59	$ 2.87
Third Quarter	$ 8.00	$ 2.18
Second Quarter	$ 12.07	$ 5.45

First Quarter (since January 30, 2001)	$ 16.88	$ 6.69

On March 18, 2002, the last reported sale price of our common stock on the Nasdaq National Market was $4.95 per share. As of March 18, 2002 there were approximately 549 holders of record of 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.

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

We did not issue any unregistered securities during the year ended December 31, 2001.

(c) Use of Proceeds from Sales of Registered Securities

On January 25, 2001 the Securities and Exchange Commission declared effective our Registration Statement on Form S-1 (File No. 333-49932) relating to our initial public offering of our common stock. The 10,000,000 shares offered by us under the Registration Statement were sold at a price of $13.00 per share on January 31, 2001. The managing underwriters for the offering were Deutsche Banc Alex. Brown, Bear, Stearns & Co. Inc., JP Morgan and Robertson Stephens. The underwriters also exercised an overallotment option on March 15, 2001 for 628,706 shares. The overallotment shares were sold at a price of $13.00 per share. The aggregate proceeds to the Company from the offering were $128.5 million after deducting the underwriting discounts and commissions of $9.7 million, and exclude expenses incurred in connection with the offering of approximately $2.3 million. Of the net proceeds, as of December 31, 2001, we have used net offering proceeds to purchase plant machinery and equipment, leasehold improvements and working capital in the amounts of approximately $17.0 million, $1.6 million and $53.2 million, respectively. No direct or indirect payments were made to directors, officers, general partners of the issuer or their associates, or to persons owning 10% or more of any class of equity securities of the issuer, or to any affiliates of the issuer in connection with the offering.

ITEM 6. SELECTED CONSOLIDATED FINANCIAL DATA.

The following selected consolidated financial data should be read in conjunction with the consolidated financial statements and notes thereto and "Management's Discussion and Analysis of Financial Condition and Results of Operations" appearing elsewhere in this Annual Report on Form 10-K.

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

	Year Ended December 31,				Period from Inception (April 3, 1997) to December 31, 1997
	2001	2000	1999	1998	
Consolidated Statement of Operations Data:					
Net Revenue	$ 46,384	$ 6,741	$ 411	$ --	$ --
Loss from operations	(98,845)	(81,115)	(14,705)	(3,951)	(688)
Other income (expense), net	1,381	(7,633)	(710)	176	24
Net loss before provision for income taxes	(97,464)	(88,748)	(15,415)	(3,775)	(664)
Provision for income taxes	10	--	--	--	--
Net loss	(97,474)	(88,748)	(15,415)	(3,775)	(664)
Dividend related to beneficial conversion feature of preferred stock.	(11,191)	(53,516)	--	--	--
Net loss available to common stockholders	$(108,665)	$(142,264)	$ (15,415)	$ (3,775)	$ (664)
Net loss per share available to common stockholders, basic and diluted	$ (2.57)	$ (25.64)	$ (3.65)	$ (1.33)	$ (0.43)
Shares used in computing net loss per share available to common stockholders, basic and diluted	42,247	5,548	4,218	2,842	1,542

	December 31,				
	2001	2000	1999	1998	1997
Consolidated Balance Sheet Data:					
Working capital	$ 63,747	$ 18,273	$ 10,027	$ 6,815	$ 1,370
Total assets	118,218	70,561	17,091	8,117	1,642
Total long-term liabilities	980	1,455	3	10	4
Convertible preferred stock and preferred stock warrants	--	130,691	32,755	12,147	2,164
Stockholders' equity (deficit)	99,402	(84,674)	(19,414)	(4,433)	(661)

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 report on Form 10-K. This discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. The actual results may differ materially from those anticipated in these forward-looking statements as a result of many factors, including but not limited to those set forth under "Factors That May Affect Operating Results" and elsewhere in this report on Form 10-K.

Overview

From our inception in April 1997 to July 2000, we were engaged in the design, manufacture and marketing of Invisalign, a proprietary new 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, clinical trials of Invisalign and to 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 correspond to each two-week stage of the ClinCheck simulation. Aligners are customized to perform the treatment prescribed for an individual patient by a dental professional using ClinCheck.

In the third quarter of 1999, we recognized revenue for the first time from the sale of Invisalign and related dental impression machines manufactured by ESPE America, Inc. We expect to sell dental impression machines to an orthodontist only once, if at all. Accordingly, sales of such machines are expected to represent a lower proportion of our revenue in the future. Substantially all our revenue is generated in the U.S. and Canada, which, taken together, we regard as our domestic market.

While our expansion outside of our domestic market is still in the initial stages, we do incur substantial operating costs outside of our domestic market. Two of our key production steps are performed in operations located outside of the U.S. In our facilities in Pakistan, technicians use a sophisticated, internally developed computer-modeling program to prepare electronic treatment plans, which are transmitted via the Internet back to the U.S. These files form the basis of our ClinCheck product and are used for the manufacture of Aligner molds. In addition, a third party manufacturer in Mexico fabricates and performs finishing work on completed Aligners and ships the completed products to our customers. Our costs associated with these operations are denominated in Pakistani rupees and Mexican pesos. Our reliance on international operations exposes us to risks and uncertainties that may affect our business or results of operations including, among others, political, social and economic instability, acts of war or terrorism, difficulties in staffing and managing international operations, controlling quality of manufacture, interruptions and limitations in telecommunication services, product or material transportation delays or disruption, and trade restrictions and changes in tariffs. However, we believe these risks are mitigated in Pakistan by the fact that our operations there do not involve the shipping or manufacturing of any physical products, and in late 2001, we began developing facilities in the U.A.E. and Costa Rica which will also perform this function. We believe the risks in Mexico are mitigated by the fact that our operations there are governed under the provisions of the North American Free Trade Agreement, or NAFTA.

In October 2001, we entered into an exclusive marketing agreement with Discus Dental Impressions, Inc. Under the terms of the agreement, Discus will act as our exclusive Invisalign marketing and sales representative providing training, certification, marketing and clinical support to general dentists in the U.S. and Canada. Discus is required to maintain minimum sales quotas and will earn a commission on all products shipped under the terms of the agreement. We are required, under the terms of the agreement, to provide minimum consumer advertising commensurate with Discus meeting minimum sales quotas. The initial term of the agreement expires December 31, 2006, but is renewable for five years if not terminated earlier. The agreement includes termination rights for convenience and for failure to meet agreed upon minimums.

We have not been profitable for any quarter since April 3, 1997 (inception). As of December 31, 2001, we had an accumulated deficit of $206.1 million. We expect to have net losses and negative operating cash flows for at least the next 12 months due, in part, to our national consumer advertising campaign, the expansion of manufacturing capacity, our launching of our international sales and marketing efforts and continued research and development efforts. We will need to generate significant revenue growth to achieve profitability and positive operating cash flow. Even if we do achieve profitability and positive cash flow, we may not be able to sustain or increase profitability or positive operating cash flow on a quarterly or annual basis.

We earn revenue primarily from the sale of Invisalign. Our revenue consists of the ClinCheck fee and the charge for each Aligner. We charge dental professionals a fixed fee for the treatment simulation viewed via ClinCheck on our website, www.Invisalign.com. This fee is invoiced when the dental professional orders ClinCheck prior to the production of Aligners. In addition, we charge dental professionals a fee for Aligners upon shipment.

Historically, we have shipped Aligners in batches. The first batch, which typically represented the first several months of treatment, was produced once the prescribing dental professional approved ClinCheck. Thereafter, Aligners were sent at approximately six month intervals until completion of treatment. In mid-February 2001, for cases where ClinCheck was approved, we began shipping all the Aligners in a single batch.

Fees from the sale of ClinCheck and Aligners, taken together, are treated as revenues from a single Invisalign case. For cases where ClinCheck was approved prior to mid-February 2001, revenues associated with a given case are recognized ratably as batches of Aligners are shipped to the dental professional. For orders placed subsequent to notification of our change to single batch shipments, all of the revenues associated with a given case, including ClinCheck fees, will be recognized at the time the Aligners are shipped. The costs of producing the ClinCheck treatment plan, which are incurred prior to the production of Aligners, are capitalized and recognized as related revenue is earned. In the cases where we expect a net loss, the entire loss is recognized immediately.

Results of Operations

Comparison of Years Ended December 31, 2001 and 2000:

Revenues. Revenues for the year ended December 31, 2001 increased to $46.4 million compared to $6.7 million for the year ended December 31, 2000. For the year ended December 31, 2001, revenues of $45.0 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. Cost of revenues for the year ended December 31, 2001 increased to $46.8 million compared to $20.3 million for the year ended December 31, 2000. Cost of revenues for the year 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 $50.6 million compared to $40.4 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 $32.7 million compared to $18.0 million for the year ended December 31, 2000, primarily due to increased headcount and related expenses. We expect administrative expenses to continue to increase in the future to support expanding business activities and the additional administrative costs related to being a public company.

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 $14.7 million compared to $9.2 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. 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. Pursuant to the settlement, Align will undertake to train and certify 5,000 general practice dentists each year over the next four years. In November 2001, the Court approved the Stipulation and Agreement of Settlement.

Other income (expense), net. Other income was $1.4 million for the year ended December 31, 2001 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 which we triggered 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, and we were therefore 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 at the commitment date of the Series D preferred stock offering of $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.

Deferred 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.

Comparison of Years Ended December 31, 2000 and 1999:

Revenues. Revenues for the year ended December 31, 2000 increased to $6.7 million compared to $411,000 for the year ended December 31, 1999. We recorded revenues for the first time in the third quarter of 1999. For the year ended December 31, 2000, revenues of $5.4 million were derived from the sale of Invisalign compared to revenues of $98,000 for the year ended December 31, 1999. The balance of our revenues for year ended December 31, 2000 and 1999 represented sales of dental impression machines. We expect to sell a dental impression machine to an orthodontist only once, if at all. Accordingly, sales of these machines are expected to represent a substantially lower proportion of our revenue in the future.

Cost of revenues. Cost of revenues includes the salaries 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. Cost of revenues for the year ended December 31, 2000 increased to $20.3 million compared to $1.8 million for the year ended December 31, 1999. Cost of revenues for the year ended December 31, 2000 includes $11.2 million of unabsorbed manufacturing costs due to a substantial increase in our manufacturing capacity in 2000.

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, 2000 increased to $40.4 million compared to $5.7 million for the year ended December 31, 1999. This increase resulted primarily from: increases in advertising expenses of $19.1 million; increases in headcount and related expenses of $6.2 million; expenses relating to participation in the annual convention of the American Association of Orthodontists of $1.9 million; expenses relating to orthodontist training of $1.3 million; and expenses related to the outsourced call center function to support our national advertising campaign of $1.0 million.

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, 2000 increased to $18.0 million compared to $3.5 million for the year ended December 31, 1999, primarily due to increased headcount and related expenses. We expect administrative expenses to continue to increase in the future to support expanding business activities and the additional administrative costs related to being a public company.

Research and development. Research and development expenses include 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, 2000 increased to $9.2 million compared to $4.2 million for the year ended December 31, 1999. Expenses through the third quarter of 1999, until we recognized revenue for the first time from the sale of Invisalign, include the costs of researching processes to manufacture our product.

Other income (expense), net. Other expense increased to $7.6 million for the year ended December 31, 2000 compared to other expense of $710,000 for the year ended December 31, 1999. This increase, partially offset by interest income on marketable securities, resulted primarily from non- cash interest expense 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. The difference between the conversion price and the fair value per share of the common stock on the commitment date for that offering resulted in a beneficial conversion feature of $53.5 million which has been reflected as a preferred stock dividend in the December 31, 2000 consolidated financial statements.

Deferred 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' 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 $13.4 million for the year ended December 31, 2000 and $394,000 for the year ended December 31, 1999.

Income Taxes

We have incurred immaterial amounts of income tax expense to date since we have not been profitable. As of December 31, 2001, we have aggregate federal and state net operating loss carryforwards of $312.5 million. As of December 31, 2001 we have recorded a full valuation allowance for our existing net deferred tax assets due to uncertainties regarding their realization. We also have aggregate federal and state research tax credit carryforwards of $3.1 million as of December 31, 2001. The federal and state net operating loss and research credit carryforwards expire beginning in the year 2017 for federal and 2005 for state purpose 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

Prior to our initial public offering, we financed our operations primarily through private sales of approximately $128.9 million of convertible preferred stock. We have also financed our operations through equipment leases and bank loans. In January 2001, we received proceeds, net of underwriting discounts and commissions and other expenses incurred, as a result of our initial public offering of approximately $126.0 million. As of December 31, 2001, we had $65.7 million in cash, cash equivalents and short-term and long-term marketable securities and an accumulated deficit of $206.1 million. Additionally, we have $723,000 of restricted cash as of December 31, 2001.

Net cash used in operating activities totaled $77.9 million in 2001, $58.8 million in 2000 and $11.6 million in 1999. The increase was primarily due to the increase in our net loss to $97.5 million in fiscal 2001, which is up from $88.7 million in fiscal 2000 and $15.4 million in fiscal 1999, and to a lesser extent, increases in accounts receivable. This was offset significantly by increased non-cash charges related to amortization of deferred stock compensation and depreciation and amortization.

Net cash used in investing activities totaled $2.0 million in 2001, $41.6 million in 2000 and $3.6 million in 1999. For fiscal 2001, cash used in investing activities was primarily the result of the investment of the initial public offering proceeds in marketable securities. Offsetting the cash used was cash provided by the maturities and sales of the marketable securities, as well as the decrease in our restricted cash balance. For fiscal 2000 cash used in investing activities was primarily used for the investment of the proceeds from the sale of preferred stock in marketable securities. Additionally, for the year ended December 31, 2000, there was a substantial increase in restricted cash of $15.6 million which primarily consisted of cash related to the transfer of funds to our media buying agent to fund our national advertising campaign. Offsetting the cash used was cash provided by the maturities and sales of the marketable securities. For fiscal 1999 cash used in investing activities was primarily the result of the investment of the proceeds from the sale of preferred stock in marketable securities. Additionally, in each of these years, there was a use of cash for the purchase of clinical and manufacturing equipment, computers and facilities to support the expansion of our operations.

Net cash from financing activities was $127.5 million in 2001, $96.4 million in 2000 and $19.6 million in 1999. For fiscal 2001, cash provided by financing activities was attributable primarily to net proceeds from the issuance of common stock principally through our initial public offering. For fiscal 2000 and 1999, cash provided by financing activities was attributable to the proceeds from the issuance of preferred stock and convertible promissory notes that were converted to preferred stock.

We finance capital purchases through cash and capital leases. We had capitalized lease obligations outstanding of $1.5 million at December 31, 2001 and $1.9 million at December 31, 2000.

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 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.

Quarterly Results of Operations

The following table sets forth certain quarterly financial information for the periods indicated. This information has been derived from unaudited financial statements that, in the opinion of management, have been prepared on the same basis as the audited information, and includes all normal recurring adjustments necessary for a fair presentation of such information. The results of operations for any quarter are not necessarily indicative of the results to be expected for any future periods.

	Three Months Ended							
	2001				2000			
	December 31	September 30	June 30	March 31	December 31	September 30	June 30	March 31
	(in thousands, except per share data)							
Revenues	$ 12,300	$ 12,912	$ 13,483	$ 7,689	$ 3,276	$ 1,439	$ 1,397	$ 629
Gross profit (loss)	2,118	1,647	(347)	(3,865)	(5,433)	(3,870)	(2,810)	(1,397)
Operating loss	(20,827)	(23,026)	(23,567)	(31,425)	(35,121)	(22,127)	(15,819)	(8,048)
Net loss	(20,719)	(22,503)	(22,294)	(31,958)	(35,437)	(21,839)	(23,392)	(8,080)
Net loss available to common stockholders	$ (20,719)	$ (22,503)	$ (22,294)	$ (43,149)	$ (44,803)	$ (21,839)	$ (67,542)	$ (8,080)
Net loss per share available to common stockholders, basic and diluted	$ (0.45)	$ (0.50)	$ (0.50)	$ (1.29)	$ (7.39)	$ (3.84)	$ (12.31)	$ (1.55)
Shares used in computing per share amounts, basic and diluted	45,660	45,035	44,518	33,574	6,066	5,682	5,489	5,225

Historical quarterly operating results do not necessarily reflect our expectations of future quarterly operating results. We believe that future operating results will fluctuate on a quarterly basis due to a variety of factors, including: the rate of adoption of Invisalign for the treatment of orthodontic malocclusion, the rate which manufacturing operations is scaled, the timing of automation of manufacturing processes and the extent of national direct to consumer marketing campaigns.

Critical Accounting Policies

Our discussion and analysis of our financial condition and results of operations are 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 management to make estimates and judgements that affect the reported amounts of assets and liabilities, revenue and expenses and disclosures at the date of the financial statements. On an on-going basis, we evaluate our estimates, including those related to accounts receivable, warranty accrual 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 judgements and estimates used in the preparation of our consolidated financial statements. We recognize revenues from product sales when there is pervasive evidence that an arrangement exits, delivery has occurred, the price is fixed and determinable, and collection is reasonably assured. Provisions for discounts and rebates to customers and other adjustments are provided for in the same period that the related product sales are recorded based upon analyses of historical discounts and rebates. We accrue for estimated warranty costs upon shipment of products. Our warranty policy is effective for shipped products which are considered defective or fail to meet the product specifications. We maintain an accounts receivable allowance for an estimated amount of losses that may result from customer's inability to pay for product purchased. If the financial condition of our customers were to deteriorate, resulting in an impairment of their ability to make payments, additional allowances may be required. We have established a valuation allowance to reduce our deferred tax assets to the amount that is more likely than not to be realized. We account for income taxes under the provisions of Statement of Financial Accounting Standards, or SFAS, No. 109, "*Accounting for Income Taxes*." Under this method, 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 thee 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 July 2001, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standards No. 141 ("SFAS 141"), *"Business Combinations,"* which establishes financial accounting and reporting for business combinations and supersedes APB Opinion No. 16, *Business Combinations*, and FASB Statement No. 38, *Accounting for Preacquisition Contingencies of Purchased Enterprises*. It requires that all business combinations in the scope of this Statement are to be accounted for using one method, the purchase method. The provisions of this Statement apply to all business combinations initiated after September 30, 2001, and also applies to all business combinations accounted for using the purchase method for which the date of acquisition is July 1, 2001, or later. To date, the Company has not engaged in a business combination.

In July 2001, the FASB issued Statement of Financial Accounting Standards No. 142 ("SFAS 142"), *"Goodwill and Other Intangible Assets,"* which establishes financial accounting and reporting for acquired goodwill and other intangible assets and supersedes APB Opinion No. 17, *Intangible Assets*. It addresses how intangible assets that are acquired individually or with a group of other assets (but not those acquired in a business combination) should be accounted for in financial statements upon their acquisition, and after they have been initially recognized in the financial statements. The provisions of this Statement are effective for fiscal years beginning after December 15, 2001. The Company will adopt SFAS 142 during fiscal year 2002. To date, the Company has not recorded goodwill or other intangible assets.

In October 2001, the FASB issued Statement of Financial Accounting Standards No. 144 ("SFAS 144"), "*Accounting for the Impairment or Disposal of Long- Lived Assets*," which is effective for fiscal years beginning after December 15, 2001 and interim periods within those fiscal periods. This Statement supersedes FASB Statement No. 121 and APB 30, however, this Statement retains the requirement of Opinion 30 to report discontinued operations separately from continuing operations and extends that reporting to a component of an entity that either has been disposed of (by sale, by abandonment, or in a distribution to owners) or is classified as held for sale. This Statement addresses financial accounting and reporting for the impairment of certain long-lived assets and for long-lived assets to be disposed of. Management does not expect the adoption of SFAS 144 to have a material impact on the Company's financial position and results of operations.

In May 2000, the Emerging Issues Task Force (EITF) issued EITF Issue No. 00- 14, "*Accounting for Certain Sales Incentives*." EITF Issue No. 00-14 addresses the recognition, measurement, and income statement classification for sales incentives that a vendor voluntarily offers to customers (without charge), which the customer can use in, or exercise as a result of, a single exchange transaction. Sales incentives that fall within the scope of EITF Issue No. 00-14 include offers that a customer can use to receive a reduction in the price of a product or service at the point of sale. The EITF agreed to change the transition date for Issue 00-14, dictating that a company should apply this consensus no later than the Company's annual or interim financial statements for the periods beginning after December 15, 2001. In June 2001, the EITF issued EITF Issue No. 00-25, *"Vendor Income Statement Characterization of Consideration Paid to a Reseller of the Vendor's Products*," effective for periods beginning after December 15, 2001. EITF Issue No. 00-25 addresses whether consideration from a vendor to a reseller is an adjustment of the selling prices of the vendor's products and, therefore, should be deducted from revenue when recognized in the vendor's statement of operations or a cost incurred by the vendor for assets or services received from the reseller and, therefore, should be included as a cost or expense when recognized in the vendor's statement of operations. Upon application of these EITFs, financial statements for prior periods presented for comparative purposes should be reclassified to comply with the income statement display requirements under these Issues. In September of 2001, the EITF issued EITF Issue No. 01- 09, *"Accounting for Consideration Given by Vendor to a Customer or a Reseller of the Vendor's Products*", which is a codification of EITF Issues No. 00-14, No. 00-25 and No. 00-22 "*Accounting for `Points' and Certain Other Time- or Volume-Based Sales Incentive Offers and Offers for Free Products or Services to be Delivered in the Future*." The Company is currently assessing the impact of the adoption of these issues on our financial statements.

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

Quantitative Disclosures

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

Interest Rate Risk. We are subject to interest rate risks on cash and cash equivalents, available-for-sale marketable securities, existing long-term debts and any future financing requirements. Interest rate risks related to marketable securities are managed by managing maturities in our marketable securities portfolio. The long-term debt at December 31, 2001 consists only of outstanding balances on lease obligations.

The fair value of our investment portfolio or related income would not be significantly impacted by changes in interest rates since the marketable securities maturities do not exceed fiscal year 2002 and the interest rates are primarily fixed. Our capital lease obligations of $1.5 million at December 31, 2001 carry a fixed interest rate of 6.53% and 11.15% per annum with principle payments due in 60 and 48 monthly installments, respectively, beginning in 2000.

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

	Expected Maturity date (as of December 31, 2001)						
	2002	2003	2004	2005	2006	Total	Fair value
	(in thousands)						
ASSETS:							
Cash, cash equivalents	$ 50,550	$ --	$ --	$ --	$ --	$ 50,550	$ 50,550
Short-term marketable securities	12,317	--	--	--	--	12,317	12,494
Weighted average interest rate	5.54%	--	--	--	--	--	--
Long-term marketable securities	$ --	$ 2,578	$ --	$ --	$ --	$ 2,578	$ 2,627
Weighted average interest rate	--	7.38%	--	--	--	--	--
LIABILITIES:							
Fixed rate debt lease obligation	$ 483	$ 512	$ 338	$ 130	$ --	$ 1,463	$ 1,463
Weighted average interest rate	8.30%	8.30%	6.53%	6.53%	--	--	--

Qualitative Disclosures

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

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

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

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

Currency Rate Risk. Our primary currency rate risk exposures relate to:

- Our decentralized or outsourced operations, whereby approximately $14.3 million of our expenses are related to operations outside the United States, denominated in currencies other than the U.S. dollar.

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

ITEM 8. CONSOLIDATED FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

REPORT OF INDEPENDENT ACCOUNTANTS

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

In our opinion, the accompanying consolidated balance sheets and the related consolidated statements of operations, of stockholders' equity (deficit) and of cash flows present fairly, in all material respects, the financial position of Align Technology, Inc. and subsidiaries at December 31, 2001 and 2000, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2001 in conformity with accounting principles generally accepted in the United States of America. These financial statements are the responsibility of the Company's management; our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits of these statements in accordance with auditing standards generally accepted in the United States of America, which require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers LLP

San Jose, California,
February 7, 2002

ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES

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

	December 31,	
	2001	2000
ASSETS		
Current assets:		
Cash and cash equivalents	$ 50,550	$ 2,828
Restricted cash	723	15,986
Marketable securities, short-term	12,494	9,633
Accounts receivable, net of allowance for doubtful accounts of $1,882 and $494 at December 31, 2001 and 2000, respectively	11,556	4,465
Inventories, net	1,549	2,024
Deferred costs	714	2,431
Other current assets	3,997	3,995
Total current assets	81,583	41,362
Property and equipment, net	32,021	21,100
Marketable securities, long-term	2,627	6,251
Other assets	1,987	1,848
Total assets	$ 118,218	$ 70,561
LIABILITIES, CONVERTIBLE PREFERRED STOCK, WARRANTS AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 4,376	$ 5,541
Accrued liabilities	11,426	14,753
Deferred revenue	1,551	2,350
Current portion of capital lease obligations	483	445
Total current liabilities	17,836	23,089
Capital lease obligations, net of current portion	980	1,455
Total liabilities	18,816	24,544
Commitments and contingencies (Note 5)		
Convertible preferred stock:		
$0.0001 par value; Authorized: none and 27,211 shares at December 31, 2001 and 2000, respectively. Issued and outstanding: none and 25,788 shares at December 31, 2001 and 2000, respectively, (aggregate liquidation preference: $0 and $134,306 at December 31, 2001 and 2000, respectively)	--	128,873
Preferred stock warrants	--	1,818

	--	130,691
Stockholders' equity (deficit):		
Preferred stock: $0.0001 par value; Authorized: 5,000 shares; no shares issued and outstanding at December 31, 2001 and 2000, respectively	--	--
Common stock: $0.0001 par value; Authorized: 200,000 and 120,000 shares at December 31, 2001 and 2000, respectively; Issued and outstanding: 47,771 and 9,622 shares at December 31, 2001 and 2000, respectively	5	1
Additional paid-in capital	355,055	105,828
Deferred stock-based compensation	(48,324)	(80,160)
Notes receivable from stockholders	(1,484)	(1,814)
Accumulated other comprehensive income	226	73
Accumulated deficit	(206,076)	(108,602)
Total stockholders' equity (deficit)	99,402	(84,674)
Total liabilities, convertible preferred stock, warrants, and stockholders' equity (deficit)	$ 118,218	$ 70,561

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

ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES

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

	Year Ended December 31,		
	2001	2000	1999
Revenues:			
Revenue--Invisalign	$ 44,955	$ 5,436	$ 98
Revenue--Ancillary products and other services	1,429	1,305	313
Total revenues	46,384	6,741	411
Cost of revenues:			
Cost of revenue and manufacturing costs--Invisalign	45,040	19,031	1,508
Cost of revenue--Ancillary products and other services	1,791	1,220	246
Total cost of revenues	46,831	20,251	1,754
Gross loss	(447)	(13,510)	(1,343)
Operating expenses:			
Sales and marketing	50,581	40,445	5,688
General and administrative	32,734	17,991	3,474
Research and development	14,683	9,169	4,200
Litigation settlement	400	--	--
Total operating expenses	98,398	67,605	13,362
Loss from operations	(98,845)	(81,115)	(14,705)
Interest income	4,261	2,306	362
Interest expense	(1,999)	(9,807)	(986)
Other expense	(881)	(132)	(86)
Net loss before provision for income taxes	(97,464)	(88,748)	(15,415)
Provision for income taxes	10	--	--
Net loss	(97,474)	(88,748)	(15,415)
Dividend related to beneficial conversion feature of preferred stock	(11,191)	(53,516)	--
Net loss available to common stockholders	$ (108,665)	$ (142,264)	$ (15,415)
Net loss per share available to common stockholders, basic and diluted	$ (2.57)	$ (25.64)	$ (3.65)
Shares used in computing net loss per share available to common stockholders, basic and diluted	42,247	5,548	4,218

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

ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)
For the years ended December 31, 2001, 2000 and 1999 (in thousands)

	Common Stock		Additional Paid-In Capital	Deferred Stock-based Compensation	Notes Receivable from Stockholders	Accumulated Other Comprehensive Income	Accumulated Deficit	Total
	Shares	Amount						
Balance at December 31, 1998	5,355	$ 1	$ 5	$ --	$ --	$ --	$ (4,439)	$ (4,433)
Net loss	--	--	--	--	--	--	(15,415)	(15,415)
Stock options exercised	331	--	42	--	--	--	--	42
Repurchase of common stock	(42)	--	(2)	--	--	--	--	(2)
Deferred stock compensation, net of cancellations	--	--	2,174	(2,174)	--	--	--	--
Amortization of deferred stock compensation	--	--	--	394	--	--	--	394
Balance at December 31, 1999	5,644	1	2,219	(1,780)	--	--	(19,854)	(19,414)
Net loss	--	--	--	--	--	--	(88,748)	(88,748)
Net change in unrealized gain from available-for-sale securities	--	--	--	--	--	73	--	73
Comprehensive loss								(88,675)
Stock options exercised	4,121	--	2,828	--	(1,814)	--	--	1,014
Repurchase of common stock	(143)	--	(48)	--	--	--	--	(48)
Deferred stock compensation, net of cancellations	--	--	91,752	(91,752)	--	--	--	--
Amortization of deferred stock compensation	--	--	--	13,372	--	--	--	13,372
Charge for accelerated vesting of employee stock options	--	--	429	--	--	--	--	429
Beneficial conversion feature embedded in convertible subordinated notes	--	--	8,648	--	--	--	--	8,648
Beneficial conversion feature embedded in preferred stock sold	--	--	53,516	--	--	--	--	53,516
Deemed dividend on preferred stock	--	--	(53,516)	--	--	--	--	(53,516)
Balance at December 31, 2000	9,622	1	105,828	(80,160)	(1,814)	73	(108,602)	(84,674)
Net loss	--	--	--	--	--	--	(97,474)	(97,474)
Net change in unrealized gain from available-for-sale securities	--	--	--	--	--	153	--	153
Comprehensive loss								(97,321)
Issuance of common stock to preferred stockholders upon conversion	26,998	3	128,870	--	--	--	--	128,873
Sale of common stock upon the completion of initial public offering, net of issuance costs of $12,200	10,629	1	125,976	--	--	--	--	125,977
Issuance of common stock upon exercise of stock options	260	--	184	--	--	--	--	184
Issuance of common stock relating to employee stock purchase plan	39	--	245	--	--	--	--	245
Issuance of common stock upon the conversion and the exercise of warrants	529	--	1,818	--	--	--	--	1,818
Repurchase of common stock	(306)	--	(266)	--	213	--	--	(53)
Deferred stock compensation, net of cancellations	--	--	(9,627)	9,627	--	--	--	--
Charge for accelerated vesting of employee stock options	--	--	224	--	--	--	--	224
Payments received on stockholders notes receivable	--	--	--	--	287	--	--	287
Interest accrued on stockholders notes receivable	--	--	--	--	(170)	--	--	(170)
Amortization of deferred stock compensation	--	--	--	22,209	--	--	--	22,209
Beneficial conversion feature embedded in convertible subordinated notes	--	--	1,803	--	--	--	--	1,803
Beneficial conversion feature embedded in preferred stock sold	--	--	11,191	--	--	--	--	11,191
Deemed dividend on preferred stock	--	--	(11,191)	--	--	--	--	(11,191)
Balance at December 31, 2001	47,771	$ 5	$ 355,055	$ (48,324)	$ (1,484)	$ 226	$ (206,076)	$ 99,402

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

ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Year Ended December 31,		
	2001	2000	1999
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net loss	$ (97,474)	$ (88,748)	$ (15,415)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	7,592	2,513	559
Amortization of deferred stock-based compensation	22,209	13,372	394
Amortization of accelerated vesting of stock options	224	429	--
Loss on retirement of fixed assets	35	98	--
Realized loss on marketable securities	--	10	--
Allowance for doubtful accounts	1,388	461	33
Amortization of capitalized financing costs and debt discount	--	834	984
Non-cash interest income on notes receivable from stockholders	(170)	(23)	--
Non-cash interest expense on convertible subordinated note	1,803	8,648	--
Non-cash accretion on marketable securities	(1,174)	--	--
Provision for excess and obsolete inventory	555	--	--
Changes in operating assets and liabilities:			
Accounts receivable	(8,479)	(4,612)	(347)
Deferred costs	1,717	(2,431)	--
Inventories	(80)	(1,658)	(366)
Other current assets	(1,886)	(1,425)	(187)
Accounts payable	(450)	4,401	672
Accrued liabilities	(2,866)	7,100	1,921
Deferred revenue	(799)	2,231	119
Net cash used in operating activities	(77,855)	(58,800)	(11,633)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchase of property and equipment	(19,175)	(13,571)	(2,463)
Decrease (increase) in restricted cash	15,263	(15,646)	(340)
Purchase of marketable securities	(72,219)	(19,645)	(5,906)
Maturities of marketable securities	54,412	1,250	3,365
Proceeds from sale of marketable securities	19,898	7,827	1,740
Change in other assets	(139)	(1,848)	--
Net cash used in investing activities	(1,960)	(41,633)	(3,604)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from issuance of common stock	138,606	1,037	42
Proceeds from issuance of convertible preferred stock, net of issuance costs	--	83,085	18,740
Proceeds from note receivable for preferred stock	--	--	76
Proceeds from payment on stockholders' notes receivable	287	--	--
Repurchase of common stock	(53)	(48)	(2)
Proceeds from convertible subordinated notes	--	14,000	750
Payments for incurred IPO costs	(10,853)	(1,327)	--
Proceeds from draw down of line of credit	--	5,000	--
Repayment of line of credit	--	(5,000)	--
Payments on capital lease obligations	(450)	(318)	(8)
Net cash provided by financing activities	127,537	96,429	19,598
Net increase (decrease) in cash and cash equivalents	47,722	(4,004)	4,361
Cash and cash equivalents, beginning of year	2,828	6,832	2,471
Cash and cash equivalents, end of year	$ 50,550	$ 2,828	$ 6,832

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

ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 1 Organization

Formation and business of the Company

Align Technology, Inc., (the "Company") was incorporated in April 1997 and is engaged in the development, manufacturing and marketing of Invisalign, used for treating malocclusion, or the misalignment of teeth. Invisalign uses a series of clear plastic "Aligners" to move the patients' teeth in small increments from their original state to a final treated state. The Company exited the development stage as of July 2000.

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

Note 2 Summary of Significant Accounting Policies

Basis of consolidation

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

Use of estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Fair value of financial instruments

The carrying amounts of certain of the Company's financial instruments including cash and cash equivalents and accounts payable approximate fair value due to their short maturities. Based on borrowing rates currently available to the Company for leases with similar terms, the carrying value of its lease obligations approximates fair value.

Cash and cash equivalents

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

Restricted cash

Restricted cash as of December 31, 2001 is primarily comprised of $723,000 for security on customer credit card transactions, on leases of administrative offices and others. Restricted cash as of December 31, 2000 is primarily comprised of $15,453,000 held in escrow for deposits on future advertising (Note 5) and $533,000 for security on customer credit card transactions, on lease of administrative offices and others.

Short- and long-term marketable securities

Marketable securities are classified as available- for-sale in accordance with Statement of Financial Accounting Standards ("SFAS") No. 115, "*Accounting for Certain Investments in Debt and Securities*" and are carried at fair value. Marketable securities classified as current assets have scheduled maturities of less than one year, while marketable securities classified as non-current assets have scheduled maturities of more than one year. Unrealized holding gains or losses on such securities are included in accumulated comprehensive income/(loss) in stockholders' equity (deficit). Realized gains and losses on sales of all such securities are reported in earnings and computed using the specific identification cost method.

There were $226,000 and $73,000 in unrealized gains as of December 31, 2001 and 2000, respectively, included in the comprehensive income in stockholders' equity (deficit).

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

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

The cost and fair value of available-for-sale securities at December 31, 2000 are as follows (in thousands):

	Cost	Unrealized Gain	Fair Value	Maturity date
Short-term marketable securities				
Commercial paper.....	$ 6,682	$ --	$ 6,682	January--March 2001
Corporate notes.....	2,937	14	2,951	September 2001
	$ 9,619	$ 14	$ 9,633	
Long-term marketable securities				
Corporate notes.....	$ 3,286	$ 30	$ 3,316	February--June 2002
Medium term notes.....	2,906	29	2,935	July 2002
	$ 6,192	$ 59	$ 6,251	

Certain risks and uncertainties

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

Financial instruments which potentially expose the Company to concentrations of credit risk consist primarily of cash equivalents and accounts receivable. The Company invests excess cash primarily in money market funds of major financial institutions, commercial paper and notes. The Company provides credit to customers in the normal course of business. Collateral is not required for accounts receivable, but ongoing credit evaluations of customers' financial condition are performed. The Company maintains reserves for potential credit losses and such losses have been within management's expectations.

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

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

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

Inventories

Inventories are stated at the lower of cost (determined on a first-in, first-out basis) or market.

Property and equipment

Property and equipment are stated at historical cost less accumulated depreciation and amortization. Depreciation and amortization are computed using the straight-line method over the estimated useful lives of the assets, which are: 3 years for computer software and hardware and 5 years for plant equipment, furniture, fixtures and equipment. Amortization of leasehold improvements is computed using the straight-line method over the estimated useful lives of the assets, or the remaining lease term, whichever is shorter. Upon sale or retirement, the asset's cost and related accumulated depreciation are removed from the accounts and any related gain or loss is reflected in operations.

Development costs for internal use software and web-site development

The Company accounts for development costs for internal used software in accordance with the AICPA Statement of Position 98- 1, *"Accounting for the Costs of Computer Software Developed or Obtained for Internal Use*" ("SOP 98-1"). The Company has also adopted Emerging Issues Task Force Issue No. 00-2 *"Accounting for the Costs of Developing a Web Site*".

Web site development and related costs consist of external and internal costs incurred to purchase and implement the web site software and significant enhancements used in the Company's business. Costs incurred in the development of application and infrastructure of the web site are capitalized and amortized over the useful life of the web site. Web site development costs of $495,000 and $397,000 had been capitalized as of December 31, 2001 and 2000, respectively. Amortization of web site development costs commenced in July 2000 upon launch of the web site. Accumulated amortization as of December 31, 2001 and 2000 amounted to $201,000 and $66,000, respectively.

Internal and external costs of designing, creating and maintaining web site content, graphics and user interface on the web site are expensed as incurred and included in the accompanying Consolidated Statement of Operations in accordance with SOP 98-1.

There was other software developed for internal use and capitalized as of December 31, 2001 and 2000 in the amount of $544,000 and $111,000, respectively. Amortization of the $111,000 began in January 2001 and amounted to $37,000 as of December 31, 2001. Amortization has not started on the additional $433,000 of capitalized costs as the software is not in use as of December 31, 2001.

Impairment of long-lived assets

The Company identifies and records impairment losses on long-lived assets used in operations when events and circumstances indicate that the assets are less than the carrying amounts of those assets. Recoverability is measured by comparison of the assets carrying amount to future net undiscounted cash flows the assets are expected to generate. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the projected discounted future net cash flows arising from the asset.

Revenue recognition

The Company has adopted the provisions of Staff Accounting Bulletin ("SAB") No. 101 *"Revenue Recognition in Financial Statements*" and believes that its current revenue recognition is in compliance with the SAB.

Revenue from the Invisalign product and Ancillary product sales are recognized upon receipt of a purchase order and product shipment provided no significant obligations remain and collection of the receivables is deemed probable. Up-front fees received in connection with the Invisalign product are deferred and recognized over the associated product shipments. The costs of producing the ClinCheck treatment plan, which are incurred prior to the production of Aligners, are capitalized and recognized as related revenues are earned. Ancillary product sales consist primarily of dental impression machines. The Company accrues for estimated warranty costs upon shipment of products in accordance with SFAS No. 5, "*Accounting for Contingencies*." Actual warranty costs incurred have not materially differed from those accrued. The Company's warranty policy is effective for shipped

products which are considered defective or fail to meet the product specifications. 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.

Service revenues which are earned under agreements with third parties for training of dental professionals and staff for Invisalign are recorded as the related expenses are incurred. Charges to third parties are based on negotiated rates which are intended to approximate the Company's anticipated costs.

The Company estimates its loss on the sale, and records a provision for the entire amount of estimated loss in the period such losses are determined. Accrued loss is set off against deferred costs in all those cases that are not in a net loss position. The sales recorded by the Company through September 30, 2000 had significant losses, the sales recorded by the Company between October 2000 and December 2001 have not had any significant losses.

Research and development

Research and development costs are expensed as incurred.

Advertising costs

The cost of advertising is expensed as incurred. For the years ended December 31, 2001, 2000 and 1999 advertising costs totaled $17,466,000, $20,804,000 and $1,722,000, respectively.

Foreign currency

The Company uses the U.S. dollar as its functional currency. Foreign currency assets and liabilities are re-measured into U.S. dollars at current exchange rates. Revenues and expenses are generally translated at average exchange rates in effect during each period. Gains or losses from foreign currency re-measurement are included in consolidated net earnings.

Income taxes

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

Accounting for stock-based compensation

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

Under APB 25, compensation expense for grants to employees is based on the difference, if any, on the date of the grant, between the fair value of the Company's stock and the option's exercise price. SFAS 123 defines a "fair value" based method of accounting for an employee stock option or similar equity investment. The pro forma disclosure of the difference between compensation expense included in net loss and the related cost measured by the fair value method is presented in Note 8.

The Company also adopted FASB issued Interpretation No. 44, ("FIN 44"), "*Accounting for Certain Transactions Involving Stock Compensation--an Interpretation of APB 25*."

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

Segments

The Company reports segment data based on the management approach which designates the internal reporting that is used by management for making operating decisions and assessing performance as the source of the Company's reportable operating segments. During all periods presented, the Company operated in a single business segment. No single foreign country accounted for 10% or more of assets or 10% or more of revenues in fiscal 2001, 2000 and 1999.

Net loss per share

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

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

	Year Ended December 31,		
	2001	2000	1999
Net loss available to common stockholders	$ (108,665)	$ (142,264)	$ (15,415)
Basic and diluted:			
Weighted-average common shares outstanding	45,189	6,861	5,334
Less: Weighted-average shares subject to repurchase	2,942	1,313	1,116
Weighted-average shares used in basic and diluted net loss per share	42,247	5,548	4,218
Net loss per share available to common stockholders	(2.57) $	(25.64) $	(3.65)

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

	Year Ended December 31,		
	2001	2000	1999
Preferred stock (as if converted)	--	26,209	16,253
Options to purchase common stock	5,489	2,862	1,285
Common stock subject to repurchase	1,969	3,608	654
Warrants	--	646	533
	7,458	33,325	18,725

Recent accounting pronouncements

In July 2001, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standards No. 141 ("SFAS 141"), *"Business Combinations,"* which establishes financial accounting and reporting for business combinations and supersedes APB Opinion No. 16, *Business Combinations*, and FASB Statement No. 38, *Accounting for Preacquisition Contingencies of Purchased Enterprises*. It requires that all business combinations in the scope of this Statement are to be accounted for using one method, the purchase method. The provisions of this Statement apply to all business combinations initiated after September 30, 2001, and also applies to all business combinations accounted for using the purchase method for which the date of acquisition is July 1, 2001, or later. To date, the Company has not engaged in a business combination.

In July 2001, the FASB issued Statement of Financial Accounting Standards No. 142 ("SFAS 142"), *"Goodwill and Other Intangible Assets,"* which establishes financial accounting and reporting for acquired goodwill and other intangible assets and supersedes APB Opinion No. 17, *Intangible Assets.* It addresses how intangible assets that are acquired individually or with a group of other assets (but not those acquired in a business combination) should be accounted for in financial statements upon their acquisition, and after they have been initially recognized in the financial statements. The provisions of this Statement are effective for fiscal years beginning after December 15, 2001. The Company will adopt SFAS 142 during fiscal year 2002. To date, the Company has not recorded goodwill or other intangible assets.

In October 2001, the FASB issued Statement of Financial Accounting Standards No. 144 ("SFAS 144"), "*Accounting for the Impairment or Disposal of Long- Lived Assets*," which is effective for fiscal years beginning after December 15, 2001 and interim periods within those fiscal periods. This Statement supersedes FASB Statement No. 121 and APB 30, however, this Statement retains the requirement of Opinion 30 to report discontinued operations separately from continuing operations and extends that reporting to a component of an entity that either has been disposed of (by sale, by abandonment, or in a distribution to owners) or is classified as held for sale. This Statement addresses financial accounting and reporting for the impairment of certain long-lived assets and for long-lived assets to be disposed of. Management does not expect the adoption of SFAS 144 to have a material impact on the Company's financial position and results of operations.

In May 2000, the Emerging Issues Task Force (EITF) issued EITF Issue No. 00- 14, *"Accounting for Certain Sales Incentives*." EITF Issue No. 00-14 addresses the recognition, measurement, and income statement classification for sales incentives that a vendor voluntarily offers to customers (without charge), which the customer can use in, or exercise as a result of, a single exchange transaction. Sales incentives that fall within the scope of EITF Issue No. 00-14 include offers that a customer can use to receive a reduction in the price of a product or service at the point of sale. The EITF agreed to change the transition date for Issue 00-14, dictating that a company should apply this consensus no later than the Company's annual or interim financial statements for the periods beginning after December 15, 2001. In June 2001, the EITF issued EITF Issue No. 00-25, *"Vendor Income Statement Characterization of Consideration Paid to a Reseller of the Vendor's Products*," effective for periods beginning after December 15, 2001. EITF Issue No. 00-25 addresses whether consideration from a vendor to a reseller is an adjustment of the selling prices of the vendor's products and, therefore, should be deducted from revenue when recognized in the vendor's statement of operations or a cost incurred by the vendor for assets or services received from the reseller and, therefore, should be included as a cost or expense when recognized in the vendor's statement of operations. Upon application of these EITFs, financial statements for prior periods presented for comparative purposes should be reclassified to comply with the income statement display requirements under these Issues. In September of 2001, the EITF issued EITF Issue No. 01-09, *"Accounting for Consideration Given by Vendor to a Customer or a Reseller of the Vendor's Products*", which is a codification of EITF Issues No. 00-14, No. 00-25 and No. 00-22 "*Accounting for `Points' and Certain Other Time- or Volume-Based Sales Incentive Offers and Offers for Free Products or Services to be Delivered in the Future*." The Company is currently assessing the impact of the adoption of these issues on our financial statements.

Note 3 Balance Sheet Components

Inventories consist of the following (in thousands):

	December 31,	
	2001	2000
Raw materials	$ 1,122	$ 1,183
Work in progress	182	294
Finished goods	245	547
	$ 1,549	$ 2,024

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

	December 31,	
	2001	2000

Clinical and manufacturing equipment	$ 20,277	$ 12,372
Computer hardware	7,267	4,809
Computer software	3,561	2,681
Furniture and fixtures	3,471	1,648
Land	458	--
Leasehold improvements	4,134	2,580
Construction in progress	3,470	--
	42,638	24,090
Less: Accumulated depreciation and amortization	(10,617)	(2,990)
	$ 32,021	$ 21,100

Property and equipment includes approximately $2,233,000 and $2,220,000 of assets under capital leases at December 31, 2001 and 2000, respectively. Accumulated amortization of assets under capital leases totaled approximately $749,000 and $334,000 at December 31, 2001 and 2000, respectively.

Depreciation expense and amortization was $7,592,000, $2,513,000 and $559,000 for the years ended December 31, 2001, 2000 and 1999, respectively.

Accrued liabilities consist of the following (in thousands):

	December 31,	
	2001	2000
Accrued marketing expenses	$ 1,830	$ 5,592
Accrued payroll and benefits	3,621	2,844
Accrued costs for property and equipment acquired	--	5,046
Other	5,975	1,271
	$ 11,426	$ 14,753

Note 4 Discus Dental Agreement

In October 2001, we entered into an exclusive marketing agreement with Discus Dental Impressions, Inc. Under the terms of the agreement, Discus will act as our exclusive Invisalign marketing and sales representative providing training, certification, marketing and clinical support to general dentists in the U.S. and Canada. Discus is required to maintain minimum sales quotas and will earn a commission on all products shipped under the terms of the agreement. We are required, under the terms of the agreement, to provide minimum consumer advertising commensurate with Discus meeting minimum sales quotas. The initial term of the agreement expires December 31, 2006, but is renewable for five years if not terminated earlier. The agreement includes termination rights for convenience and for failure to meet agreed upon minimums.

Note 5 Commitments and Contingencies

Operating leases

In October 1999, the Company entered into a non- cancelable operating lease agreement with GE Capital Fleet Services and offers vehicles to all salespeople. The lease term is for 3 years, commencing upon acceptance of delivery.

In June 2000, the Company entered into a non-cancelable operating lease to lease a manufacturing facility in Santa Clara, California. The lease term is for five years, commencing July 1, 2000. The Company paid $1,175,000 security deposit upon execution of the lease.

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

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

Total rent expense was $3,349,000, $2,146,000 and $295,000 for the years ended December 31, 2001, 2000 and 1999, respectively. The terms of the facility lease provide for rental payments on a graduated scale. The Company recognizes rent expense on a straight-line basis over the lease period, and has accrued for rent expense incurred but not paid.

The future minimum lease payments under operating leases as of December 31, 2001 are $3,103,000, $2,223,000, $2,185,000, $1,090,000, and $54,000 for the years ended December 31, 2002, 2003, 2004, 2005, and thereafter.

Advertising Commitments

In May 2000, the Company entered into an escrow agreement between TBWA Chiat/Day, Inc. ("TBWA") and Greater Bay Trust Company ("Escrow Agent"). TBWA has been engaged by the Company to procure non-cancelable television and radio media time on behalf of the Company. In consideration of the services provided by TBWA, the Company has agreed to deposit a certain amount with the Escrow Agent for purposes of repaying TBWA. The Company's total commitment will not at any time exceed the total amount held in escrow. At December 31, 2000, the Company had $15,453,000 held in money market funds with the Escrow Agent. This amount has been classified as restricted cash. The Company has subsequently used the funds and there are no advertising commitment escrow funds remaining in the escrow account as of December 31, 2001.

Contingencies

The Company was involved in a patent infringement proceeding with a plaintiff asserting infringement of two of its patents. On June 30, 2000, the Company entered into a stipulation of dismissal with the plaintiff whereby the plaintiff agreed not to recommence a suit against the Company for two years with respect to the disputed patents. Pursuant to the agreement, if a patent is subsequently issued to the plaintiff and the plaintiff believes the Company is infringing it, then the plaintiff may commence suit after one year from the effective date of the agreement and include in such action claims involving the two previously disputed patents. If any such action is successful, it could result in a significant monetary damages judgment against the Company.

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. Pursuant to the settlement, Align will undertake to train and certify 5,000 general practice dentists each year over the next four years. In November 2001, the Court approved the Stipulation and Agreement of Settlement.

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

Capitalized lease obligations

In February 2000, the Company leased a stereolithography apparatus from Leasing Technologies International, Inc. ("LTI") under a master lease agreement entered into between the Company and LTI in August 1999. Under the terms of the lease, the value of the leased equipment is $729,000 at a borrowing rate of 11.154% per annum. The term of the lease is for 48 months with a bargain purchase option at the end of the lease to purchase the equipment at 15% of the purchase price. Accordingly, the Company has capitalized the leased equipment in accordance with SFAS 13, "*Accounting for Leases.*"

In May and June 2000, the Company leased two stereolithography machines from 3D Capital Corporation ("3D") under a Master Lease Agreement entered into in March 2000 for a total value of $1,479,000 at a borrowing rate of 6.533% per annum for a period of 60 months. The Company has capitalized these machines in accordance with SFAS 13.

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

Year Ended December 31,	
2002	$ 578
2003	578
2004	367
2005	130
2006	--
Minimum lease payments	1,653
Less: Amount representing interest	(190)
Present value of minimum lease payments	1,463
Amount due within one year	(483)
Amount due after one year	$ 980

Land purchase commitment

As of December 31, 2001 the Company has committed $1.2 million in funds to purchase approximately 215 acres of land in Pakistan.

Note 6 Credit Facilities

The Company entered into a line of credit agreement (the "Line") with a financing institution (the "Lender") on April 12, 1999 to make available up to an aggregate principal amount of $5,000,000. The Line is available in minimum advances of $1,000,000 with each advance to be evidenced by a note bearing interest at 12% per annum. The agreement requires that each note shall be payable in 36 monthly installments of principal and interest. The assets of the Company are pledged as collateral for the loan agreement. Under the Line, the Company is required to maintain certain negative and financial covenants, which require, among other things, written consent from the Lender prior to the declaration and payment of dividends and sale of material assets of the Company. The Company did not draw money under this agreement in 1999. In connection with this Line the Company issued 533,334 warrants to purchase Series B convertible preferred stock at an exercise price of $1.50 per share.

In January 2000, the Company exercised its right to extend its draw period relating to the Line entered into with the Lender in April 1999 from an original draw expiration date of January 2000 to October 2000. In conjunction with the draw period extension, the Company issued the Lender a warrant to purchase 112,500 shares of the Company's Series C preferred stock at a price of $4.00 per share (Note 8). In April 2000, the Company drew down a total of $5,000,000 against the line. The note was subsequently repaid in full in July 2000.

Note 7 Convertible Preferred Stock

Convertible preferred stock at December 31, 2000 consisted of the following (in thousands):

	December 31, 2000
Series A: 4,350 shares authorized, issued and outstanding at December 31, 2000 (liquidation preference at December 31, 2000 $2,175)	$ 2,164
Series B: 7,650 shares authorized; 6,717 shares issued and outstanding at December 31, 2000 (liquidation preference at December 31, 2000 $10,076)	10,059
Series C: 5,313 shares authorized; 5,186 shares issued and outstanding at December 31, 2000 (liquidation preference at December 31, 2000 $20,745)	19,490
Series D: 9,898 shares authorized, 9,535 shares issued and outstanding at December 31, 2000 (liquidation preference at December 31, 2000 $101,310)	97,160
	$ 128,873

Sale of preferred securities

In May, June and October 2000, the Company sold 9,535,052 shares of Series D preferred shares for gross proceeds of $101,272,000. Included in the 9,535,052 total shares issued, the Company issued 1,321,202 Series D shares upon the conversion of the Convertible Subordinated Promissory Notes financing (the "Notes") and associated interest as discussed below. The issuance of Series D convertible preferred stock resulted in a beneficial conversion feature, calculated in accordance with Emerging Issues Task Force Issue No. 98-5, "*Accounting for Convertible Securities with Beneficial Conversion Features or Contingently Adjustable Conversion Ratios*" ("EITF 98-5"). Accordingly, the Company has recognized $47,564,000 as a charge to additional paid in capital to account for the deemed dividend on the preferred stock as of the issuance as of December 31, 2000. As noted, the Series D preferred shares have certain contingent rights and preferences that were perfected and caused the Company to record an incremental beneficial conversion feature charge.

The Company has accounted for a beneficial conversion feature embedded in convertible subordinated notes (the "Notes") entered into on May 15, 2000. The beneficial conversion feature, amounting to $7,689,000, represents an additional interest yield on the debt which may be converted at any time at the option of the holders into immediately convertible preferred stock. Accordingly, the beneficial conversion feature has been recorded as an immediate charge to interest expense in May 2000. Under the terms of the loan agreement, the Notes and associated accrued interest were converted into the Company's convertible Series D preferred stock in May 2000. The Company sold the Notes, in the aggregate face amount of $14,000,000, bearing a stated interest rate of 10% per annum and a maturity date one month from the date of issuance.

The 9,535,052 shares of Series D preferred stock that the Company issued in 2000 were subject to an antidilution conversion price adjustment feature which the Company triggered when it granted options to purchase its common stock beyond the number of options that were authorized under its 1997 Plan at the time the Company commenced its 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 the Company's Series D preferred stock offering) and the earlier of the closing of an initial public offering or January 31, 2001, the Company had granted more than an aggregate of 3,331,978 options to purchase its common stock, then the conversion price of the Company's Series D preferred stock would be adjusted downward from its original conversion price of $10.625 per share. As of December 31, 2000, the Company had granted 1,257,614 options to purchase shares of its common stock in excess of the 3,331,978 options permitted, and were therefore required to issue an additional 419,700 shares of common stock upon the conversion of the Series D preferred stock. The additional shares to be issued upon conversion of the Series D preferred stock resulted in a beneficial conversion feature, calculated in accordance with EITF 98-5. As of December 31, 2000, the Company recognized an incremental deemed dividend based on the fair value of the common stock at the commitment date of the Series D preferred stock offering of $5,952,000 related to the preferred stock sold and a charge to interest expense of $959,000 for the beneficial conversion feature embedded in the convertible subordinated notes that were previously converted.

As of the end of January 2001, the Company had granted an aggregate of 3,591,458 options to purchase shares of its common stock in excess of the 3,331,978 options permitted, and were therefore 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 the Company were required to issue upon conversion of the Series D preferred stock as of December 31, 2000. As a result, the Company recorded a deemed dividend for the year ended December 31, 2001 based on the fair value of the common stock at the commitment date of the Series D preferred stock offering of $11,191,000 related to the preferred stock sold and a charge to interest expense of $1,803,000 for the beneficial conversion feature embedded in convertible subordinated notes that were previously converted.

Convertible preferred stock

The rights, preferences and privileges of Series A, Series B, Series C and Series D preferred stock were as follows:

Voting rights

Holders of Series A, Series B, Series C and Series D preferred stock were entitled to one vote for each share of common stock into which such shares can be converted. Certain votes, as defined in the Company's Articles of Incorporation, require the approval of at least a majority of Series A, Series B, Series C and Series D preferred stock stockholders. The holders of Series A and Series B preferred stock, voting as separate classes, were each entitled to elect one member to the Company's Board of Directors. Beginning January 1, 2001, the holders of the Series D preferred stock were entitled to elect one member of the Company's Board of Directors in the event that the Company has not yet closed an initial public offering of its common stock at that time. The holders of common stock and Preferred Stock, voting together as a single class, were entitled to elect all remaining members of the Board of Directors.

Dividends

The holders of Series A, Series B, Series C and Series D preferred stock were entitled to noncumulative dividends, when and if declared by the Board of Directors, in the amount of $0.04, $0.12, $0.32 and $0.85, respectively, per share per annum, on each outstanding share of Series A, Series B, Series C and Series D preferred stock, subject to certain adjustments. No dividends have been declared or paid as of December 31, 2001.

Liquidation

In the event of liquidation or sale of the Company, each class of preferred stock was entitled to be paid out of the assets of the Company an amount of $0.50, $1.50, $4.00 and $10.625, respectively, for the Series A, Series B, Series C and Series D, plus all declared but unpaid dividends relating to preferred stock.

Conversion

Upon occurrence of the initial public offering (Note 1) all outstanding shares of convertible preferred stock were converted into shares of common stock. In accordance with the articles of incorporation the conversion price was $0.50 for Series A, $1.50 for Series B, $4.00 for Series C and $9.43 for Series D preferred stock. As a result of the revised conversion price for Series D preferred stock the Company issued 26,998,290 shares of common stock upon conversion of outstanding preferred stock. There was no convertible preferred stock authorized, issued or outstanding at December 31, 2001.

Note 8 Stockholders' Equity (Deficit)

Preferred stock

The Company has authorized 5,000,000 shares of $0.0001 par value preferred stock, none of which was issued or outstanding at December 31, 2001 and 2000.

Common stock

The holders of common stock are entitled to receive dividends whenever funds are legally available and when declared by the Board of Directors subject to the prior rights of holders of all classes of stock having priority rights as to dividends. No dividends have been declared or paid as of December 31, 2001.

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

Restricted stock purchase agreement

The Company has sold shares of its common stock to founders of the Company under agreements which provide for repurchase of the stock by the Company at the stock's original purchase price upon termination of employment. The Company's right to repurchase lapses at any time prior to the earlier of: (i) three years from date of agreement; (ii) the closing of an "Asset Transfer" or an "Acquisition"; or (iii) the voluntary liquidation, dissolution, or winding up of the Company. The Company has also sold shares of its common stock to employees, directors and consultants under the terms of the 1997 Equity Incentive Plan that includes an early exercise feature. The Company's right to repurchase under those terms lapses over the vesting period of the underlying option exercised. At December 31, 2001 and 2000, 1,969,488 and 3,608,442 shares of common stock, respectively, were subject to repurchase, including 104,516 shares of common stock which were subject to a right of repurchase at the Company's discretion until October 2002.

Warrants

In April 1999, in connection with a financing arrangement, the Company issued 533,334 warrants to purchase Series B convertible preferred stock at $1.50 per share. The warrants expire on January 26, 2006. The fair value of the warrants of $1,042,000 was calculated using the Black-Scholes pricing method and has been charged to preferred stock warrants. The related amount is being amortized as interest expense over the life of the notes. A total of $58,000 and $984,000 was amortized in 2000 and 1999, respectively.

In conjunction with the draw period extension, the Company issued the Lender a warrant to purchase 112,500 shares of the Company's Series C convertible preferred stock at a price of $4.00 per share. The warrants expire on January 26, 2006. The fair value of the warrants of $776,000 was calculated using the Black-Scholes pricing method and has been charged to preferred stock warrants and amortized as interest expense over the life of the note. A total of $776,000 was amortized as of December 31, 2000.

In April and June 2001, the Company issued a total of 528,615 shares of common stock upon net exercise of all of the warrants.

1997 Equity Incentive Plan

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

In January 2001 the Company granted options ("Executive Grant") to purchase 1,000,000 shares, at an exercise price of $15.00 per share, to each of the Company's Chief Executive Officer and President. The options were granted outside of the 1997 Plan and prior to the 2001 Stock Incentive Plan (the "2001 Plan") becoming effective and represent options for 2,000,000 shares of common stock in addition to the shares of common stock reserved for issuance under the 2001 Plan. The Executive Grant was approved by the stockholders in January 2001.

2001 Stock Incentive Plan

On January 4, 2001, the Board of Directors adopted the 2001 Plan, which will terminate no later than 2011, provides for the granting of incentive stock options, non statutory stock options and restricted stock purchase rights and stock bonuses to employees, and consultants. As of December 31, 2001, a total of 8,000,000 shares of common stock have been authorized for issuance under the 2001 Plan. The 2001 Plan was approved by the Stockholders prior to the initial public offering.

Activity under the 1997 Plan, the Executive Grant and the 2001 Plan are set forth below (in thousands, except per share data):

		Options Outstanding		
	Shares Available for Grant	Shares	Weighted Average Exercise Price	Aggregate Price
Balances at December 31, 1998.....	486	952	$ 0.11	$ 101
Increase in pool.....	1,600	--	--	--
Options granted.....	(737)	737	0.20	144
Options exercised.....	--	(331)	0.13	(42)
Options cancelled.....	73	(73)	0.14	(10)
Balances at December 31, 1999.....	1,422	1,285	0.15	193
Increase in pool.....	5,600	--	--	--
Options granted.....	(5,890)	5,890	0.86	5,044
Options exercised.....	--	(4,121)	0.69	(2,828)
Options cancelled.....	192	(192)	0.33	(64)
Balances at December 31, 2000.....	1,324	2,862	0.82	2,345
Increase in pool.....	10,000	--	--	--
Options granted.....	(3,423)	3,423	11.11	38,038
Options exercised.....	--	(260)	0.71	(184)
Stock repurchased.....	306		0.87	--
Options cancelled.....	536	(536)	1.88	(1,006)
Balances at December 31, 2001.....	8,743	5,489	$ 7.14	$ 39,193

The options outstanding and currently exercisable by exercise price at December 31, 2001 are as follows (in thousands, except per share data):

Options Outstanding				Exercisable	
Range of Exercise Prices	Number Outstanding and Exercisable	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Number of Shares as of December 31, 2001	Weighted Average Excercise Price
$ 0.05 - 0.40	683	7.85	$0.31	683	$0.31
1.07	1,686	8.85	1.07	1,686	1.07
2.13 - 6.60	552	9.21	4.29	113	2.23
7.46 - 7.84	270	9.51	7.76	1	7.80
8.60 - 9.80	235	9.34	8.82	1	8.75
10.00 - 13.06	63	9.39	10.24	--	--
15.00	2,000	9.01	15.00	--	--
$ 0.05 - 15.00	5,489	8.88	$7.14	2,484	$0.92

The Company has adopted the disclosure-only provisions of Statement of Financial Accounting Standards No. 123 ("SFAS No. 123"), "*Accounting for Stock-Based Compensation.*" Had compensation cost for the 2001 Plan, 1997 Plan and the Employee Stock Purchase Plan ("the Purchase Plan") been determined based on the fair value at the grant date for awards during 2001, consistent with the provisions of SFAS No. 123, the Company's pro forma net loss and pro forma net loss per share would have been as follows (in thousands, except per share amounts):

	Year Ended December 31,		
	2001	2000	1999
Net loss available to common stockholders, as reported	$(108,665)	$(142,264)	$ (15,415)
Net loss available to common stockholders, pro forma	$(114,365)	$(142,363)	$ (15,435)
Net loss per share available to common stockholders, as reported, basic and diluted	$ (2.57)	$ (25.64)	$ (3.65)
Net loss per share available to common stockholders, pro forma, basic and diluted	$ (2.71)	$ (25.66)	$ (3.66)

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

The value of each option grant is estimated on the date of grant using the minimum value method for 2000 and 1999 and using the Black- Scholes option valuation model for 2001 with the following weighted assumptions:

	Year Ended December 31,		
	2001	2000	1999
Risk-free interest rate	4.36%	5.17-6.71%	4.91-6.03%
Expected life	5 years	5 years	5 years
Expected dividends	--	--	--
Volitility	117%	N/A	N/A

The weighted average per share fair values of options granted during the year ended December 31, 2001, 2000 and 1999 were $9.25, $16.878 and $3.285, respectively.

Employee Stock Purchase Plan

On January 4, 2001, the Board of Directors adopted the Purchase Plan, authorizing the issuance of 1,500,000 shares of common stock pursuant to purchase rights granted to in the United States employees. The Purchase Plan is intended to qualify as an employee stock purchase plan within the meaning of Section 423 of the Internal Revenue Code of 1986, as amended. The Purchase Plan was approved by the Stockholders prior to the Initial Public Offering.

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

Under the Purchase Plan, the Company has sold approximately 39,000 shares to employees through December 31, 2001. The fair value of the employees' purchase rights was estimated using the Black-Scholes option pricing model with the following assumptions: risk-free interest rate of 3.47%; an expected life of 0.5 years; dividend yield of zero percent; and expected volatility of 117%. The fair value of those purchase rights granted in 2001 was $2.86 per share.

Stock-based compensation

During the year ended December 31, 1999, the Company recorded deferred stock-based compensation for the excess of the deemed fair market value over the exercise price at the date of grant of $1,772,000 related to options granted to employees. The Company has recorded additional deferred stock-based compensation of $3,530,000 and $87,687,000 related to options issued to employees to purchase common stock issued through December 31, 2001 and 2000, respectively. During fiscal 2001, 2000 and 1999, the Company reversed $12,673,000, none and none, respectively, of unrecognized deferred compensation relating to employees that have terminated employment with the Company. The compensation expense is being recognized over the option vesting period of four years using the straight-line method. For the years ended December 31, 2001, 2000 and 1999, the Company recorded amortization of stock-based compensation of $22,347,000, $11,252,000 and $267,000, respectively, in connection with options granted to employees.

During the year ended December 31, 1999, the Company recorded deferred stock-based compensation $402,000 related to options granted to consultants. For options granted to consultants, the Company determined the fair value of the options using the Black-Scholes pricing model. The Company has recorded additional deferred stock-based compensation of $(484,000) and $4,065,000 for options issued to consultants to purchase common stock issued in the year ended December 31, 2001 and 2000, respectively. The compensation expense is being recognized over the option vesting period of four years, using the method presented by FIN 28. For the years ended December 31, 2001, 2000 and 1999, the Company recorded amortization of stock-based compensation of $(138,000), $2,120,000 and $127,000, respectively, in connection with options granted to consultants.

Amortization of deferred stock compensation has been allocated to cost of revenues, sales and marketing, general and administrative and research and development expenses as follows (in thousands):

	Year Ended December 31,		
	2001	2000	1999
Cost of revenues	$ 4,579	$ 2,939	$ 80
Sales and marketing	3,726	2,357	111
General and administrative	9,760	5,345	106
Research and development	4,144	2,731	97
	$ 22,209	$ 13,372	$ 394

Accelerated Vesting

During fiscal 2001 and 2000, the Company accelerated the vesting of options to several employees in connection with a severance package. The acceleration was accounted for in accordance with FIN 44 as a one time charge of $224,000 and $429,000, respectively, to the statement of operations. The charge was equal to the intrinsic value difference between the exercise price of the accelerated options and the fair value of the common stock on the date of acceleration.

Note 9 Income Taxes

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

	Year Ended December 31,	
	2001	2000
Deferred tax assets (liabilities):		
Start-up costs	$ (383)	$ 1,920
Net operating loss carryforwards	59,220	28,830
Research and development credit	3,128	1,128
Other	545	645
Deferred tax assets	62,510	32,523
Less: Valuation allowance	(62,510)	(32,523)
Net deferred tax asset	$ --	$ --

Due to the uncertainty surrounding the realization of favorable tax attributes in future tax returns, the Company has placed a valuation allowance against all of its net deferred tax assets. At such time as it is determined that it is more likely than not that the deferred tax assets are realizable, the valuation allowance will be reduced. The valuation allowance increased $29,987,000, $25,254,000 and $5,345,000 during 2001, 2000 and 1999, respectively.

At December 31, 2001, the Company had federal and state net operating loss carryforwards of approximately $155,950,000 and $156,560,000, respectively, available to offset future regular and alternative minimum taxable income. The Company's federal and state net operating loss carry forwards will begin to expire in 2017 for federal purposes and 2005 for state purposes if not utilized.

At December 31, 2001, the Company had federal and state research and experimentation tax credit carry forwards of approximately $2,144,000 and $983,000, respectively, available to offset future income tax liabilities. The Company's federal research and experimentation credit will begin to expire in 2017.

The Tax Reform Act of 1986 limits the use of net operating loss and tax credit carry forwards in certain situations where changes occur in the stock ownership of a Company. If the Company should have an ownership change, as defined by the tax law, utilization of the carry forwards could be restricted.

Note 10 Supplemental Cash Flow Information

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

	Year Ended December 31,		
	2001	2000	1999
Taxes paid	$ 100	1	1
Interest paid	$ 150	382	614
Non-cash investing and financing activities:			
Note receivable for preferred stock	$ --	75	--
(Repurchase) issuance of note receivable for common stock	$ (213)	1,791	--
Fixed assets acquired under capital lease	$ 13	2,209	--
Fixed assets acquired with accounts payable or accrued liabilities	$ 640	5,257	643

Accrual for IPO costs	$ 20	557	--
(Conversion) issuance of warrants in conjunction with line of credit financing	$ (1,818)	776	1,042
Deferred stock-based compensation	$ 9,627	91,752	2,174
Conversion of convertible subordinated notes into convertible preferred stock	$ 128,873	14,000	750

Note 11 Employee Benefit Plan

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

Note 12 Related Party Transactions

Loan to Officer

In September 2000, the Company issued a loan in the amount of $95,000 at a rate of 6% per annum to the Company's Vice President of Corporate Strategy. The loan was due on demand, but in no event later than September 19, 2001. The Company forgave the loan in fiscal 2001.

Employee Notes Receivable

In connection with the exercise of certain stock options granted under the Company's stock option plan, the Company has received promissory notes equal to the total exercise price of these stock options. These notes are full recourse promissory notes, which bear interest at 9.5% per annum, and accrued interest is payable in full to the Company and are due on the second anniversary of the issuance date. The notes are collateralized by the shares of common stock held by employees. Promissory notes for the exercise of certain stock options totaling $1,484,000 and $1,814,000 were outstanding as of December 31, 2001 and 2000. These notes are classified as a reduction of stockholders' equity (deficit).

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

None.

PART III

Certain information required by Part III is omitted from this Form 10-K because the Company will file a definitive Proxy Statement pursuant to Regulation 14A (the "Proxy Statement") not later than 120 days after the end of the fiscal year covered by this Form 10-K, and certain information to be included therein is incorporated herein by reference.

ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT.

The information required by this Item is incorporated by reference to the Proxy Statement under the section captioned "Election of Directors."

ITEM 11. EXECUTIVE COMPENSATION.

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

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT.

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

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS.

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

PART IV

ITEM 14. EXHIBITS, FINANCIAL STATEMENT SCHEDULES, AND REPORTS ON FORM 8- K.

(a) Financial Statement Schedules and Exhibits

1. Financial Statement Schedules

None.

2. Exhibits

Exhibits submitted with the Annual Report on Form 10-K as filed with the Securities and Exchange Commission and those incorporated by reference to other filings are listed on the Exhibit Index.

EXHIBIT INDEX

Exhibit Number	Description of Document
3.1*	Amended and Restated Certificate of Incorporation of registrant.
3.2*	Amended and Restated Bylaws of registrant.
4.1*	Form of Specimen Common Stock Certificate.
10.1*	Amended and Restated Investors' Rights Agreement, among registrant and certain of its stockholders, dated September 16, 2000.
10.2*+	Employment Agreement between registrant and Stephen Bonelli, dated November 6, 2000.
10.3*	Lease and License Agreement by and between Pakistan Services Ltd. and registrant for its manufacturing space in Pakistan located at Pearl Continental, Pavilion 44, Lahore, Pakistan, dated March 4, 1999.
10.4*	Lease Agreement by and between James Lindsay and registrant, dated June 20, 2000, for office space located at 881 Martin Avenue, Santa Clara, CA.
10.5*	Sublease Agreement by and between GW Com, Inc. and registrant, dated July 2000, for office space located at 851 Martin Avenue, Santa Clara, CA.
10.6*	Lease Agreement by and between registrant and Saadia Kahwar Khan Chishti for manufacturing space in Pakistan located at the Bhallah House, Bhalla Stop, Multan Road, Lahore, Pakistan dated September 1, 2000.
10.7*	Shelter Services Agreement between registrant and Elamex, S.A. de C.V. dated February 16, 2000.
10.8*	Joint Development Agreement by and between registrant and 3D Systems dated September 9, 1999.
10.9*	Loan and Security Agreement by and between Comdisco Inc. and registrant, dated April 12, 1999.
10.10*	Secured Promissory Note Agreement by and between Comdisco Inc. and registrant, dated April 12, 2000.
10.11*	Warrant Agreement, dated April 12, 1999, by and between Comdisco and registrant.
10.12*	Warrant Agreement, dated January 7, 2000, by and between Comdisco and registrant.
10.13*+	Registrant's 2001 Stock Incentive Plan.
10.14*+	Registrant's Employee Stock Purchase Plan.
10.15*	Form of Indemnification Agreement by and between registrant and its Board of Directors.
10.16^	Exclusive Marketing Agreement, dated October 18, 2001, by and between Discus Dental Impressions, Inc. and registrant
10.17	Separation Agreement, dated August 16, 2001, between the registrant and Kenneth M. Vargha
21.1*	Subsidiaries of the registrant.
23.1	Consent of PricewaterhouseCoopers LLP, Independent Accountants.
24.1	Power of Attorney (see signature page)

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

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

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

(b) Reports on Form 8-K

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, on March 19, 2002.

ALIGN TECHNOLOGY, INC.
By: /s/ Zia Chishti
Zia Chishti
Chief Executive Officer and Chairman of the Board

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Zia Chishti and Stephen Bonelli, and each of them, as his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities, to sign any and all amendments (including post-effective amendments) to this Annual Report on Form 10-K, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or any of them, or their or his substitutes, may lawfully do or cause to be done by virtue thereof.

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

Name	Title	Date
/s/ Zia Chishti Zia Chishti	Chief Executive Officer and Chairman of the Board (Principal Executive Officer)	March 19, 2002
/s/ Stephen Bonelli Stephen Bonelli	Chief Financial Officer and Vice President, Finance (Principal Financial Officer and Principal Accounting Officer)	March 19, 2002
/s/ Kelsey Wirth Kelsey Wirth	Director	March 19, 2002
/s/ Brian Dovey Brian Dovey	Director	March 19, 2002
/s/ Joseph Lacob Joseph Lacob	Director	March 19, 2002
/s/ H. Kent Bowen H. Kent Bowen	Director	March 19, 2002

Note: Portions of this Exhibit are the subject of a Confidential Treatment Request by the registrant to the Securities and Exchange Commission. Such portions have been redacted and are marked with *** in place of the redacted language.**

EXCLUSIVE MARKETING AGREEMENT

THIS EXCLUSIVE MARKETING AGREEMENT ("Agreement") dated October 18, 2001 ("Effective Date"), is made and entered into by and between Align Technology, Inc., with principal offices at 851 Martin Ave., Santa Clara, California 95050 ("Align"), and Discus Dental Impressions, Inc., with principal offices at 8550 Higuera Street, Culver City, California 90232 ("Discus").

RECITALS

A. Align is a corporation having its principal office and place of business at 851 Martin Ave., Santa Clara, California 95050. Align is a corporation duly organized, validly existing and in good standing under the laws of the State of Delaware, with the corporate power to own property and carry on its business as contemplated by this Agreement.

B. Align is engaged in the manufacture, marketing and sale of clear orthodontic appliances to Orthodontic Dentists throughout the world. Each set of appliances, commonly referred to as an Invisalign® System, is custom manufactured by Align to fit an individual patient.

C. Discus is a corporation having its principal office and place of business at 8550 Higuera Street, Culver City, California 90232. Discus is a corporation duly organized, validly existing, and in good standing under the laws of the State of California, with the corporate power to own property and carry on its business as contemplated by this Agreement.

D. Discus is experienced in the direct marketing and distribution of professional dental products to dental professionals.

E. Align is desirous of having Discus become the exclusive, except as to Align and IASG (as defined below), marketing and sales representative for the Invisalign® System to Non-Orthodontic Dentists (as defined below) throughout the Territory (as defined below). As such representative Discus will solicit orders and provide Training and Sales Support (as such terms are defined below) for the Invisalign® System from Customers. The Invisalign® System will be shipped directly to the Non-Orthodontic Dentists by Align. Billing and collection will be performed by Align and Discus shall receive the Discus Commission (as defined below).

F. Align shall continue to market and sell the Invisalign® System to Orthodontic Dentists (as defined below) and, subject to the terms of Section II(D) hereof, IASG shall continue to market and sell the Invisalign® System to Non-Orthodontic Dentists within IASG's network.

G. The purpose of this Agreement is to set forth the respective rights, duties, obligations, and responsibilities of Align and Discus with respect to the marketing of the Invisalign® System and the provision of Training and Sales Support by Discus to Non-Orthodontic Dentists throughout the Territory.

NOW THEREFORE, in consideration of recitals and the covenants and conditions contained in this Agreement, the parties mutually agree as follows:

I. DEFINITIONS

Terms used herein shall have the meanings associated with common usage or general acceptance, whether industry specific or as used in general business transactions; except that as used in this Agreement the following terms shall have the meanings specified:

A. Affiliate - the term "Affiliate" as used in this Agreement shall mean, with respect to any specified Person, any other Person that directly, or indirectly through one or more intermediaries, controls, is controlled by, or is under common control with, such specified Person.

B. Align Product Trademark - the term "Align Product Trademark" as used in this Agreement shall mean a United States or Canadian Trademark that identifies a Product.

C. Align Site - the term "Align Site" as used in this Agreement shall mean Align's web site which is currently located at www.invisalign.com; or such successor web site(s) or URL as Align may designate.

D. Case Accepted - the term "Case Accepted" as used in this Agreement shall mean acceptance by Align, which acceptance shall not be unreasonably withheld or delayed, of a purchase order from a Non-Orthodontic dentist for an Invisalign® System from within the Territory, regardless of whether the Invisalign® System is for single arch or a dual arch.

E. Case Evaluation - the term "Case Evaluation" as used in this Agreement shall mean the review of the patient's initial tooth arrangement to determine whether the Invisalign® System is an appropriate treatment for the patient's malocclusion.

F. Change of Control of Discus - the term "Change of Control of Discus" as used in this Agreement shall mean the occurrence of any of the following with respect to Discus at any time after the date hereof: (1) the sale or transfer (in any one or more of a series of related transactions) of all or substantially all of the assets of Discus or of more than fifty percent (50%) of the outstanding voting stock of Discus, other than an offering of voting stock of Discus to the public pursuant to the rules of the Securities Act of 1933, as amended, to: (a) any Person who sells products that directly compete with clear polymeric shell appliance systems used to reposition teeth, (b) any Person who manufactures products that directly compete with clear polymeric shell appliance systems used to reposition teeth, or (c) any Person who has a financial interest material to such Person described in the foregoing clauses (a) or (b) (collectively, "Prohibited Persons"); or (2) the merger of Discus with or into any Prohibited Person.

G. Co-Branded Site - the term "Co-Branded Site" as used in this Agreement shall mean the portion of the Align Site which is established and co-branded by the parties in order to accept purchase orders for Products that are submitted by Customers.

H. Customer - the term "Customer" as used in this Agreement shall mean a Non-Orthodontic Dentist within the Territory.

I. Consumer Advertising - the term "Consumer Advertising" as used in this Agreement shall mean television, radio, print, outdoor, direct mail or other marketing or advertising used to create awareness in the general public of the availability of the Invisalign® System as a form of treatment for malocclusion.

J. Dentist - the term "Dentist" as used in this Agreement shall mean either a Non-Orthodontic Dentist or an Orthodontic Dentist.

K. Design Plan - the term "Design Plan" as used in this Agreement shall mean the set-up of a model of a patient's initial tooth arrangement in a three dimensional CAD program and the subsequent morphing (sometimes referred to as "staging") of the initial tooth arrangement by the CAD program to create each intermediate tooth arrangement for that patient.

L. Discus Commission - the term "Discus Commission" as used in this Agreement shall mean a commission equal to ***** of all payments received by Align in accordance with this Agreement for Product Sales to Customers.

M. Discus Products - the term "Discus Products" as used in this Agreement shall mean a product made or distributed by Discus, other than the Products, including, but not limited to, the Discus whitening gel and Splash Impression Material.

N. Fabrication - the term "Fabrication" as used in this Agreement shall mean the creation of an Invisalign® System including aligners for each anticipated intermediate tooth arrangement created pursuant to the patient's Design Plan.

O. Financing - the term "Financing" as used in this Agreement shall mean financing provided through a third party financial services company of the Non- Orthodontic Dentist's fee for the Invisalign® System.

P. IASG - the term "IASG" shall mean Invisalign Administrative Services Group, Incorporated, a wholly-owned subsidiary of Align.

Q. Intellectual Property Rights - the term "Intellectual Property Rights" as used in this Agreement means the Patents, the Trademarks, and all inventions, copyrights, know-how, trade secrets and all other proprietary rights that relate to the design, manufacture, operation or service of a parties' products or services or with respect to which a party has been granted rights by a third party.

R. Invisalign® System - the term "Invisalign® System" as used in this Agreement shall mean a system for repositioning teeth, comprising a plurality of individual appliances, and all improvements thereto as Align makes such improvements generally available to its customers. Each appliance is configured to be placed successively on the patient's teeth so as to reposition incrementally the teeth from an initial tooth arrangement, through a plurality of intermediate tooth arrangements, to a final tooth arrangement. The Invisalign® System is covered by

a series of Patents, properly assigned to Align in the United States Patent and Trademark Office, including but not limited to United States Patent Nos. 5,975,893, 6,183,248, 6,210,162, 6,217,325, 6,227,850 and 6,227,851.

S. Leads - the term "Leads" as used in this Agreement shall mean a telephone call made by any interested consumer to Align's call center to gather information about the Invisalign System and seek referral to a Dentist who is certified to use the Invisalign System.

T. Minimum Sales Quota - the term "Minimum Sales Quota" as used in this Agreement shall have the meaning set forth in Section VIII(D).

U. Non-Orthodontic Dentist - the term "Non-Orthodontic Dentist" as used in this Agreement shall mean a dentist, other than an Orthodontic Dentist, who is licensed in the Territory.

V. Non-Orthodontic Training Day - the term "Non-Orthodontic Training Day" shall mean a single full day of training provided by Discus to Customers in which all attending Customers become certified to use the Invisalign System.

W. On-Going Design Management - the term "On-Going Design Management" as used in this Agreement shall mean helping Non-Orthodontic Dentists work through problems that arise in the treatment of malocclusion that may or may not result during treatment with the Invisalign® System. Such On-Going Design Management may include a Design Plan and the Fabrication and delivery of a new Invisalign® System for a particular patient.

X. Orthodontic Dentist - the term "Orthodontic Dentist" as used in this Agreement shall mean a licensed practicing dentist, who has received a certificate in advanced graduate studies in orthodontics at an accredited dental institution.

Y. Patents - the term "Patents" as used in this Agreement shall mean any U.S. or foreign patents or any utility models that are in force and have not been declared wholly invalid by a court of competent jurisdiction.

Z. Patient Insurance Reimbursement - the term "Patient Insurance Reimbursement" as used in this Agreement shall mean the assignment of a procedure reimbursement code to allow patients to obtain reimbursement from dental insurance providers.

AA. Patient Prescription and Diagnosis Form- the term "Patient Prescription and Diagnosis Form" as used in this Agreement shall mean Align's standard form, or any modification thereof that Discus and Align may jointly agree upon, used to help qualify whether treatment of malocclusion with the Invisalign® System is appropriate for a particular patient.

AB. Person - the term "Person" as used in this Agreement shall mean an individual, corporation, partnership, limited partnership, limited liability company, syndicate, person (including, without limitation, a "person" as defined in Section 13(d)(3) of the Securities Exchange Act of 1934, as amended), trust, association, entity or government or political subdivision, agency or instrumentality of a government.

AC. Products - The term "Products" shall mean the products and services provided by Align to Dentists as listed on Exhibit A.

AD. Professional Liability Insurance Coverage - the term "Professional Liability Insurance Coverage" as used in this Agreement shall mean professional liability insurance which will cover incidents that may arise from treatment by a Non-Orthodontic Dentist through the use of the Invisalign® System, regardless of whether the particular Non-Orthodontic Dentist's primary professional liability policy excludes orthodontic treatment.

AE. Practice Based Marketing - the term "Practice Based Marketing" as used in this Agreement shall mean all marketing that may be used by Non-Orthodontic Dentists to create awareness among their existing patients, or in some cases potential patients, of the availability of the Invisalign® System as a form of treatment. Such Practice Based Marketing shall include but not be limited to counter cards, Invisalign® System product brochures, point of sale items within the dental office, direct mail, in-office Invisalign® System videos, and other advertising offered to Non-Orthodontic Dentists.

AF. Product Sales - the term "Product Sales" as used in this Agreement shall mean sales of Products to Customers.

AG. Sales Price - the term "Sales Price" as used in this Agreement shall mean the price for each Product set forth on Exhibit A.

AH. Sales Support - the term "Sales Support " as used in this Agreement shall include, without limitation, the following services: (1) training for Non-Orthodontic Dentists and their staffs on how to integrate the Invisalign System into their practice, (2) ongoing education regarding the ways in which Align processes cases and how Dentists can best and most effectively clinically treat a case, and (3) such other reasonable troubleshooting and sales support services as Align may reasonably request from time to time.

AI. Splash Impression Material - the term "Splash Impression Material" as used in this Agreement shall mean any hydrophilic vinyl polysiloxany impression material that Discus sells to Dentists under the Trademark "Splash" or any successor Trademark developed by Discus for the same products.

AJ. Territory - the term "Territory" as used in this Agreement shall mean the United States and Canada.

AK. Trade Advertising - the term "Trade Advertising" as used in this Agreement shall mean all marketing and advertising to Customers.

AL. Trademark - the term "Trademark" as used in this Agreement shall mean a trademark, service mark, logotype or symbol which has achieved common law trademark status in any jurisdiction and which identifies the products or services of a party or a third party, as the case may be.

AM. Training - the term "Training" as used in this Agreement shall mean teaching the Non-Orthodontic Dentists and their staffs: (1) the features and benefits of the Invisalign® System, (2) how to market the Invisalign® System using the Practice Based Marketing in order to generate cases, (3) how to evaluate a patient to determine whether the Invisalign® System may be an appropriate form of treatment, (4) how to gather, prepare and submit adequate information about the patient such that Align can properly prepare a Design Plan for that patient, including but not limited to the proper technique for taking an impression of sufficient quality as to permit Case Evaluation and a Design Plan, (5) how to teach patients the appropriate way to use the Invisalign® System, (6) how to use equipment and software that may be required to treat patients using the Invisalign® System, and (7) all aspects of prescribing, using, and promotion of Products in the Territory.

II. APPOINTMENT AND AUTHORITY

A. Appointment. Subject to the terms and conditions set forth herein, Align does hereby appoint Discus as the exclusive, except as to Align and IASG as provided herein, marketing and sales representative to solicit orders for Products from Customers and to perform the other obligations specified in this Agreement. Discus hereby accepts such appointment.

B. Restrictions. Discus shall not sell, offer to sell, or promote the Products outside the Territory, or to Orthodontic Dentists anywhere.

C. Referrals. Discus shall forward to Align all inquiries relating to the Products that Discus receives from Orthodontic Dentists within the Territory and from all customers or potential customers outside the Territory.

D. Exclusivity. In the event that Align receives requests for purchase of or information relating to the Products from Customers, Align shall forward such requests to Discus. Under no circumstances shall Align fabricate or accept orders for the Products (1) from Customers, (2) from IASG or a subagent of IASG for sales by IASG or any IASG subagent to Customers, or (3) from any Person, other than IASG, who Align knows intends to resell the Products to Customers, unless Align complies with Section III(F) below.

E. Subagents of Discus. Discus may appoint subagents with Align's prior written consent, which consent shall not be unreasonably withheld or delayed. Regardless of the appointment of subagents, Discus shall remain responsible for the performance of all its obligations hereunder. Discus shall notify Align in advance of all proposed agreements with subagents and shall submit to Align for its review any and all agreements and other documents between or involving Discus and any proposed subagent with respect to the sale of Products. All subagents must agree to be bound by the provisions of this Agreement, as well as any further reasonable terms and conditions which Align may at its sole discretion reasonably choose to impose.

F. Conflict of Interest. Discus warrants to Align that (1) neither Discus nor any Affiliate of Discus currently represents or promotes any lines or products that directly compete with clear polymeric shell appliance systems used to reposition teeth., and (2) during the term of this Agreement, neither Discus nor any Affiliate of Discus shall, without Align's prior written consent, distribute, sell, promote, or market within the Territory any lines or products that directly compete with clear polymeric shell appliance systems used to reposition teeth.

G. Independent Contractors. The relationship of Align and Discus established by this Agreement is that of independent contractors, and nothing contained in this Agreement shall be construed to give either party the power to direct and control the day-to-day activities of the other or allow one party to create or assume any obligation on behalf of the other for any purpose whatsoever, except for (1) the marketing of Products in accordance with the terms of this Agreement; (2) the solicitation and referral of orders from Non-Orthodontic Dentists to purchase Products from Align; and (3) the performance of other obligations specified in this Agreement. All financial obligations associated with Discus's business are the sole responsibility of Discus.

III. TERMS OF SALES OF PRODUCTS BY DISCUS

A. Purchase Orders. This Agreement contemplates that Customers shall submit purchase orders for Products (i) electronically using the Co-Branded Site, (ii) using written order forms, or (iii) otherwise. No Products shall be

furnished to a Customer by virtue of this Agreement alone, but shall require that a Customer submit a purchase order through one of the enumerated methods. All such purchase orders are subject to Align's acceptance, which acceptance shall not be unreasonably withheld or delayed.

B. Terms and Conditions. All purchase orders for Products submitted by Customers during the term of this Agreement shall be subject to the terms and conditions of this Agreement which shall supercede any terms or conditions contained in any communications between a Customer and Align or between Discus and Align, whether through the Co- Branded Site or otherwise.

C. Orders Submitted through Co-Branded Site. The parties will use reasonable efforts to create a mechanism within the Co-Branded Site, for example a unique identifier number, to enable the tracking of sales of Products to Customers who have completed the Training provided by Discus.

D. Sales Price Changes. The Sales Price for each Product may be changed by Align from time to time provided that (1) Align shall give Discus sixty (60) days prior notice before the change in Sales Prices becomes effective, and (2) the price of Invisalign Systems to Customers shall at all times be substantially the same as the prices charged by Align to Orthodontic Dentists.

E. Billing, Collection and Payments. Align shall be responsible for billing and collection of the Sales Price from the Customers for orders placed and fulfilled under this Agreement. Within fifteen (15) days of the end of each calendar month, Align shall pay Discus the Discus Commission for all Product Sales that are shipped by Align to Customers in such month. Align shall include with the monthly remittance the gross detail of invoices being remitted against such that Discus can verify the accuracy of the remittance. Any amounts owed to Discus by Align which have been received by Align and have not been remitted to Discus as required herein shall be subject to a service charge at the lower of the rate of one and one-half percent (1.5%) per month or the maximum rate permitted by law.

F. Orders Accepted by Align or IASG. In the event that Align fabricates or accepts orders for the Products (1) from Customers, (2) from IASG or a subagent of IASG for sales by IASG or any subagent of IASG to Customers, or (3) from any Person, other than IASG, who Align knows intends to resell the Products to Customers, Align agrees to do the following: (a) within ten (10) days of fabrication or receipt of the order, notify Discus of receipt of the order by providing to Discus a copy of the invoice for the order, (b) pay to Discus the Discus Commission for such Product sale in accordance with subsection (E) above, and (c) credit the Sales Price of the Product sale toward Discus' Minimum Sales Quota for the relevant sales period and the bonus calculations set forth in Section IV(G) below.

G. Bonus. If Discus exceeds the Minimum Sales Quota for a particular calendar year by an amount of Product Sales equal to ***** (a "Bonus Increment"), then Align shall pay to Discus, in addition to the normal Discus Commission the following bonus payments: ***** For example:

(a) If the Product Sales in any calendar year exceed the Discus Minimum Sales Quota for such calendar year by an amount equal to *****;

(b) If the Product Sales in any calendar year exceed the Minimum Sales Quota for such year by an amount equal to *****

(c) If the Product Sales in any calendar year exceed the Minimum Sales Quota for such year by an amount equal to *****

For the purpose of calculating these bonus payments in calendar year 2002, the three Minimum Sales Quotas that correspond with the three sales periods that fall within calendar year 2002 shall be added together and treated as a single Minimum Sales Quotas for calendar year 2002 and all sales attributable to meeting each of those Minimum Sales Quotas shall be added together to calculate whether Discus is entitled to a bonus under this Section III(G) for calendar year 2002.

For the purpose of calculating these bonus payments in calendar year 2003, the two Minimum Sales Quotas that correspond with the two sales periods that fall within calendar year 2003 shall be added together and treated as a single Minimum Sales Quotas for calendar year 2003 and all sales attributable to meeting each of those two Minimum Sales Quotas shall be added together to calculate whether Discus is entitled to a bonus under this Section III(G) for calendar year 2003. Any bonus amount payable under this Section III(G) shall be paid by Align within ninety (90) days of the end of the calendar year to which it applies.

IV. DISCUS RESPONSIBILITIES

A. Training and Sales Support by Discus. Discus shall, at its sole expense, provide initial and continuing Training of and Sales Support to Customers. The Training and Sales Support shall (1) be performed only by specially and properly trained personnel of Discus or agents of Discus, (2) be of the highest quality, and (3) be performed promptly. Discus shall at its sole expense develop and deliver to the Non-Orthodontic Dentists Practice Based Marketing materials and strategies. Align shall have the right to review and approve of all such materials, which

approval shall not be unreasonably withheld or delayed. Discus hereby agrees that (a) it shall use best efforts to provide Training to (i) at least 3000 Customers between the Effective Date and March 31, 2002 and (ii) at least 5000 Customers in each of the first four (4) years following the date of this Agreement, and (b) subject to Section IV(B)(2) below, it shall conduct eight (8) Non-Orthodontic Training Days by December 31, 2001, and an additional twenty-four (24) Non-Orthodontic Training Days by March 31, 2002

******* Confidential treatment requested for redacted portion.**

B. Support of Discus by Align. Align shall provide reasonable sales and technical training, and technical support to Discus's personnel, with the frequency and content of the training to be determined by agreement between Discus and Align. Align and Discus shall each pay its own costs for travel, food, and lodging during the training period. In addition to sales and technical training, Align shall cooperate with Discus in establishing efficient promotional procedures and policies, as set forth in Section VI(E) below. Align shall promptly respond to Discus's reasonable technical questions relating to the Products. Align agrees that (1) it shall provide any and all reasonable assistance requested by Discus (a) for the training of Discus' staff, (b) for the training of Discus' trainers, (c) for the training of Discus' sales force, and (d) with respect to the performance of Discus' obligations under this Agreement, and (2) in consideration of the Discus Non-Orthodontic Training Day commitments set forth in Section IV(A)(b) above, Align shall (a) provide two (2) full days of training to Discus' sales force by December 31, 2001, (b) it shall ensure that one (1) Align sales representative and one (1) Orthodontist certified to use the Invisalign System attend each of the Non-Orthodontic Training Days referenced in Section IV(A)(b) above.

C. Marketing and Promotion to Non-Orthodontic Dentists. Discus shall, at its sole expense, vigorously promote the sale of the Products to Customers, beginning as soon as feasible after the date of this Agreement, using generally the same channels and methods, exercising the same diligence, and adhering to the same standards that it employs with respect to other products sold by Discus. Discus shall advertise the Products in trade publications within the Territory, participate in appropriate trade shows, and directly solicit orders from Customers for the Products. Discus shall place twenty-four (24) or more national trade magazine advertisements per calendar year and exhibit Products at every non-orthodontic dental trade show in the Territory with two thousand (2000) or more Non-Orthodontic Dentists in attendance. Discus shall use reasonable efforts to keep Align apprised of Discus' plans and efforts with respect to such promotions, and Align may comment to Discus with respect to such promotions. Discus, however, shall have complete discretion with respect to all decisions.

D. Training Fees. For Training provided by Discus, Discus may charge each Customer a fee. Discus shall submit to Align for approval, which approval shall not be unreasonably withheld or delayed, the amount of the fee that each Customer shall be charged for the Training. The fee shall be no less than ***** per Non-Orthodontic Dentist. The fee for the Training shall be paid directly to Align by the Non-Orthodontic Dentist. Within ten (10) days of the end of any month in which Align receives fees from Non-Orthodontic Dentists to whom Discus provided Training, Align shall pay Discus a fee per Non-Orthodontic Dentist equal *****, plus *****.

E. Customer Service. Discus shall, at Discus's sole expense, provide any and all support for Customers and/or their staffs with regard to billing and payment collection.

F. Compliance with Laws and Good Commercial Practices. Discus shall use its best efforts to promote and sell the Products for use only by qualified Customers in compliance with local laws and regulations and good commercial practice and for uses and applications reasonably approved by Align for the Products. Discus and its employees and agents shall not promote the Products for any indications or applications, as the case may be, not approved for such Products by applicable regulatory authorities.

******* Confidential treatment requested for redacted portion.**

G. Customer Relationships and Reporting. Discus shall, at Discus's sole expense and consistent with the sales policies of Align and with good business practice: (1) place the Products in Discus's literature as soon as possible; (2) provide adequate contact with existing and potential customers within the Territory on a regular basis; and (3) assist Align in assessing customer requirements for the Products, including modifications and improvements thereto, in terms of quality, design, functional capability, and other features. Discus shall provide Align as reasonably requested by Align no more frequently than on a quarterly basis: market research information, as reasonably requested by Align for purposes of Align's market research, regarding competition and changes in the market within the Territory. In particular, market research information will include information on the practice types of the Non- Orthodontic Dentists who purchase Products, and Product adoption rates of Non-Orthodontic Dentists.

H. Patient Contact. Discus acknowledges and agrees that it shall not be permitted to contact or in any way communicate directly with patients in connection with its Training, Sales Support, marketing, promotion or customer support activities or for any other reason under this Agreement.

I. Recordkeeping. Align reserves the right to authorize a representative of Align, at Align's expense, to audit Discus's records relating to orders for and sales of the Products, the Training, the Sales Support, the Minimum Sales Quotas and any other matters necessary to confirm compliance with this Agreement in the Territory. Upon

prior written notice, Discus shall provide reasonable access to such records during normal business hours at Discus's business locations. Discus shall maintain all such records at Discus's location for the greater of two (2) years after termination of this Agreement or as long as required by regulatory requirements in the Territory. Discus shall promptly provide to Align all information and documents received or prepared by Discus relating to the Products. Discus reserves the right to authorize a representative of Discus, at Discus's expense, to audit Align's records relating to orders for and sales of the Products, the Training, the Minimum Sales Quotas case start kits and any other matters necessary to confirm compliance with this Agreement. Upon prior written notice, Align shall provide reasonable access to such records during normal business hours at Align's business locations. Align shall maintain all such records at Align's location for the greater of two (2) years after termination of this Agreement or as long as required by regulatory requirements in the Territory. Align shall promptly provide to Discus all information and documents received or prepared by Align relating to the sale of Products to Customers.

J. Limitation on Discus's Rights to the Products. Discus shall have no right to copy, modify, manufacture or remanufacture any Product or part thereof and no license under any of Align's Intellectual Property Rights is granted to Discus hereunder, except for the use of the Align Product Trademarks as expressly provided in Section X(F) below. Discus shall not make any changes, alterations, modifications or additions to the Products without prior written approval of Align.

V. ALIGN'S RESPONSIBILITIES

A. Supply of Information on Current and Future Distribution. In order to develop a coherent and strategic marketing and distribution plan for the Invisalign® System, Align shall provide to Discus a complete and detailed description of each and every current marketing, distribution and/or sales plan currently being implemented or planned for implementation with regard to the Invisalign® System, including but not limited to the creative project cooperatives and Align's distribution to Orthodontic Dentists, except that Align shall not be obligated to disclose any information which is subject to a confidentiality commitment of Align or which disclosure would violate privacy rights of individual patients.

B. Supply of Invisalign® System Training Information. To assist Discus in providing Training, Align shall provide to Discus, free of charge, any and all training materials that Align has developed or may develop in the future with regard to the Invisalign® System for use by Discus in its Training, which materials Discus may modify as it deems necessary. All modifications shall be submitted to Align for prior approval, which approval shall not be unreasonably withheld or delayed.

C. Supply of Invisalign® System Information. To assist Discus in the marketing of its Training to Customers and in the marketing of the Invisalign® System to Customers, patients and potential patients, Align shall provide to Discus, free of charge, any and all marketing materials that Align has developed or may develop in the future with regard to the Invisalign® System, which materials Discus may modify as it deems necessary. All modifications shall be submitted to Align for approval, which approval shall not be unreasonably withheld or delayed.

D. Case Evaluation. Align shall perform for the Customers, a Case Evaluation from a suitable impression (and, if available, periapical radiographs of the patient's teeth) to determine whether the Invisalign® System is an appropriate method for correcting malocclusion. Align shall use reasonable efforts to provide the conclusions of such evaluation to the originating Customer and Discus within two (2) business days of delivery of the impression to Align.

E. Discounts. Through the end of calendar year 2002, the parties agree that Discus shall have the right to offer first time users a Five Hundred Dollar ($500.00) discount off the Sales Price set forth on Exhibit A for that first time user's first Case Accepted. Discus agrees that the $500 first time user discount must be redeemed with respect to a Case Accepted within the thirty (30) days immediately following the training provided by Discus. Through the end of the first full calendar year of this Agreement, Align agrees that it shall credit any discounts or rebates, including but not limited to the $500 first time user discount, toward the Minimum Sales Quotas for sales periods during that calendar year.

F. Customer Service. Align shall provide technical support for the Customers and/or their staffs with regard to Case Evaluation and On-Going Design Management.

G. Clinical Evaluations for the Invisalign® System. Align shall provide to Discus as they become available clinical evaluation results for the Invisalign® System, which clinical evaluation results demonstrate its efficacy at treating Class I, Class II and Class III malocclusions (inclusive of subdivisions and extraction cases).

H. Fabrication of the Invisalign® System. Align shall use reasonable efforts to provide, in appropriate cases and for those Customers who request the service, ClinCheck for review by the Customer within seven (7) business days after acceptance. Align shall use reasonable efforts to provide any changes or modifications to the ClinCheck

treatment plan requested by the Customer within a reasonable amount of time. After ClinCheck has been approved by the Customer, Align shall use reasonable efforts to manufacture the Invisalign System and ship the Invisalign System to the Customer within seventeen (17) business days.

I. Case-Start Kits. Align shall provide to Discus as many case-start kits as Discus may need for the solicitation of purchase orders for Products from Customers which case-start kits Discus shall deliver to the Customers. Upon identification of an Invisalign® System candidate, the Customers and/or staffs shall complete the information in the case-start kit and return the information to Align for Case Evaluation. Align shall advise Discus of the arrival of a case-start kit as quickly as is reasonable under the circumstances.

J. Consumer Advertising. Each year Align and Discus shall jointly develop Consumer Advertising. Align, with the assistance of Discus, shall develop and draft a comprehensive Consumer Advertising plan not later than 60 days prior to the commencement of the calendar year. At its sole expense and consistent with the Consumer Advertising plan, Align shall itself or with the assistance of one or more third party(ies): (1) develop the Consumer Advertising pieces stated in the Consumer Advertising plan and (2) purchase the required media time and space for the Consumer Advertising stated in the Consumer Advertising plan. Each Consumer Advertising piece shall be shared with Discus and Discus shall provide comments to Align prior to use by Align. In support of Consumer Advertising, Align shall spend, at a minimum, the following amounts on Consumer Advertising provided that Discus has not given notice of termination of this Agreement:

a. From the Effective Date through the end of calendar year 2002*****.

b. For the calendar year 2003, *****.

c. For the calendar year 2004, *****.

d. For the calendar year 2005, *****.

e. For the calendar year 2006, *****.

Should this Agreement be renewed for the additional five-year period pursuant to Section VIII(B), the Consumer Advertising to Non-Orthodontic Dentists will be specified in the renewal agreement.

Without limiting the generality of the foregoing, Align specifically agrees that for no calendar year during the term of this Agreement or any renewal thereof, shall the Consumer Advertising spent by Align be less than ***** of the Minimum Sales Quota for such calendar year.

K. Allocation of Leads. Align shall allocate Leads generated by Consumer Advertising between Dentists who are certified to use the Invisalign System as follows:

(1) Dentists shall be assigned to one of three (3) tiers of preference for receiving Leads depending on factors ("Tiering Criteria") which include, without limitation: (a) the productivity of a Dentist (measured by the number of cases submitted on a monthly basis), and (b) a Dentist's proximity to a caller. Where possible, preference will be given by Align in assigning Leads to Dentists in higher tiers and no preference will be given to Orthodontic Dentists over Non-Orthodontic Dentists.

******* Confidential treatment requested for redacted portion.**

(2) Non-Orthodontic Dentists who have completed Training and been certified to use the Invisalign System but who have not yet submitted cases, will be placed in the top tier for a sixty (60) day trial period during which they will have the opportunity to demonstrate that they have the ability to perform in accordance with the then-applicable Tiering Criteria for the top tier. At the expiration of such sixty (60) day trial period one of the following things will happen: (a) if the Non-Orthodontic Dentist has performed in accordance with such Tiering Criteria, then he or she will remain in such tier, (b) if the Non-Orthodontic Dentist has failed to perform in accordance with such Tiering Criteria, then he or she will be re-assigned to the appropriate tier.

(3) The parties agree to review Tiering Criteria every six (6) months for modification, however Align shall have sole discretion over final decisions regarding Tiering Criteria and the assignments made pursuant thereto.

(4) The Tiering Criteria will be communicated to all Dentists who have been certified to use the Invisalign System.

L. Splashä Impression Material. Align shall use commercially reasonable efforts to promote the use of Discus' Splashä Impression Material with the Invisalign® System, provided such Splashä Impression Material remains safe and effective for its intended use.

M. *****

N. Aligner Design Services. Align agrees that (1) it shall use reasonable efforts to establish a separate legal entity that is wholly-owned by Align to provide aligner design services to Dentists, and (2) Discus shall receive a commission of ***** on sales of such aligner design services to Customers during the term of this Agreement.

VI. DISCUS AND ALIGN JOINT RESPONSIBILITIES

A. Financing Program. Align and Discus shall use reasonable efforts to develop sources of Financing for Customers for the Invisalign® Systems.

B. Professional Liability Insurance Coverage. Align and Discus shall use reasonable efforts to work with insurance providers to provide and develop a Professional Liability Insurance Coverage program for Customers for treatment using the Invisalign® System.

C. Patient Insurance Reimbursement. Align and Discus shall use reasonable efforts to work with dental insurance providers to allow for Patient Insurance Reimbursement.

D. Panoramic Radiographs and Cephalometric Radiographs. Align and Discus, in an effort to deliver a turn-key business model for the Customers, shall use reasonable efforts to develop and/or identify a network of radiology centers that are readily available to Customers throughout the Territory, such that Customers are able to refer patients to obtain, if necessary, panoramic radiographic and cephalometric radiographic images for transmission to Align for a Design Plan.

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E. Trade Advertising. Each year Align and Discus shall jointly develop Trade Advertising. Discus, with the assistance of Align, shall develop and draft a comprehensive Trade Advertising plan not later than 60 days prior to the commencement of the calendar year. At its sole expense and consistent with the Trade Advertising plan, Discus shall itself or with the assistance of one or more third party(ies): (1) develop the Trade Advertising pieces stated in the Trade Advertising plan and (2) purchase the required media time and space for the Trade Advertising stated in the Trade Advertising plan. Each Trade Advertising piece shall be shared with Align and Align shall provide comments to Discus prior to use by Discus.

F. Streamlining Case Evaluation. Both Discus and Align shall use reasonable efforts to simplify and streamline the Case Evaluation process to avoid false starts by the Customers (i.e. eliminate to the extent possible the sending of information on patients for whom the Invisalign® System is not an appropriate form of treatment).

VII. WARRANTIES AND LIMITATION OF LIABILITY

A. Align Warranty Disclaimer. EXCEPT (i) FOR THE WARRANTY MADE DIRECTLY TO CUSTOMERS OR END-USERS IN DOCUMENTATION INCLUDED WITH ALIGN'S PRODUCTS, OR (ii) AS EXPRESSLY PROVIDED OTHERWISE HEREIN, ALIGN MAKES NO WARRANTIES TO ANY PERSON OR ENTITY WITH RESPECT TO THE PRODUCTS OR ANY LICENSES OR SERVICES PROVIDED HEREUNDER AND DISCLAIMS ALL IMPLIED WARRANTIES, INCLUDING WITHOUT LIMITATION, WARRANTIES OF QUALITY, PERFORMANCE, NON-INFRINGEMENT, MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. NOR ARE THERE ANY WARRANTIES CREATED BY COURSE OF DEALING, COURSE OF PERFORMANCE OR TRADE USAGE. DISCUS' SOLE AND EXCLUSIVE REMEDY FOR INFRINGEMENT IS PROVIDED IN SECTION X(A) HEREOF. THE FOREGOING EXCLUSIONS ARE AN ESSENTIAL PART OF THIS AGREEMENT AND FORMED THE BASIS FOR DETERMINING THE DISCUS COMMISSION AND ANY OTHER FEES TO BE PAID TO DISCUS UNDER THIS AGREEMENT.

B. Discus Warranty Disclaimer. EXCEPT (i) FOR THE WARRANTY MADE DIRECTLY TO CUSTOMERS OR END-USERS IN DOCUMENTATION INCLUDED WITH DISCUS'S PRODUCTS, OR (ii) AS EXPRESSLY PROVIDED OTHERWISE HEREIN, DISCUS MAKES NO WARRANTIES TO ANY PERSON OR ENTITY WITH RESPECT TO THE DISCUS PRODUCTS OR ANY LICENSES OR SERVICES PROVIDED HEREUNDER AND DISCLAIMS ALL IMPLIED WARRANTIES, INCLUDING WITHOUT LIMITATION, WARRANTIES OF QUALITY, PERFORMANCE, NON-INFRINGEMENT, MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. NOR ARE THERE ANY WARRANTIES CREATED BY COURSE OF DEALING, COURSE OF PERFORMANCE OR TRADE USAGE. ALIGN'S SOLE AND EXCLUSIVE REMEDY FOR INFRINGEMENT IS PROVIDED IN SECTION X(A) HEREOF. THE FOREGOING EXCLUSIONS ARE AN ESSENTIAL PART OF THIS AGREEMENT.

C. LIMITATION OF LIABILITY. IN NO EVENT SHALL ALIGN BE LIABLE FOR COSTS OF PROCUREMENT OF SUBSTITUTE GOODS BY ANYONE. EXCEPT AS MAY BE SPECIFICALLY PROVIDED FOR IN SECTION X(A), ALIGN SHALL NOT BE LIABLE TO DISCUS OR ANY OTHER PERSON OR ENTITY UNDER ANY CONTRACT, STRICT LIABILITY, NEGLIGENCE OR OTHER LEGAL OR EQUITABLE THEORY, FOR ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL, PUNITIVE, EXEMPLARY OR INDIRECT DAMAGES OR LOST PROFITS, HOWEVER CAUSED, IN CONNECTION

WITH THE SUBJECT MATTER OF THIS AGREEMENT, WHETHER OR NOT ALIGN HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGE.

D. LIMITATION OF LIABILITY. IN NO EVENT SHALL DISCUS BE LIABLE FOR COSTS OF PROCUREMENT OF SUBSTITUTE GOODS BY ANYONE. EXCEPT AS MAY BE SPECIFICALLY PROVIDED FOR IN SECTION X(A), DISCUS SHALL NOT BE LIABLE TO ALIGN OR ANY OTHER PERSON OR ENTITY UNDER ANY CONTRACT, STRICT LIABILITY, NEGLIGENCE OR OTHER LEGAL OR EQUITABLE THEORY, FOR ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL, PUNITIVE, EXEMPLARY OR INDIRECT DAMAGES OR LOST PROFITS, HOWEVER CAUSED, IN CONNECTION WITH THE SUBJECT MATTER OF THIS AGREEMENT, WHETHER OR NOT DISCUS HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGE.

VIII. TERMINATION AND RENEWAL RIGHTS; CHANGE OF CONTROL OF DISCUS

A. Term. The term of the Agreement commences on the Effective Date and continues through December 31, 2006, unless terminated as set forth below.

B. Renewal Rights. Align shall have the right to extend the term of this Agreement for an additional five years through December 31, 2011 provided that it advises the Discus of its intent to renew in writing no later than February 28, 2006. Provided that Discus has met it Minimum Annual Sales Quotas for calendar years 2004 and 2005, Discus shall have the right to extend the term of this Agreement for an additional five years through December 31, 2011 provided that it advises Align of its intent to renew in writing no later than February 28, 2006. Both parties agree that they shall use best efforts to develop Minimum Sales Quotas for each of the five (5) years during the renewal term, each of which Minimum Sales Quotas the parties agree shall cover a calendar year. If by March 31, 2006, the parties are still unable to reach agreement on Minimum Sales Quotas for any of the five years of the renewal term, Discus and Align shall each appoint a non-employee director of its respective company to negotiate Minimum Sales Quotas for the renewal term. If the appointees are unable to reach an agreement by May 31, 2006, then the following terms shall apply:

(1) The Minimum Sales Quotas for each calendar year during the renewal period shall increase from the previous calendar year's Minimum Sales Quota by fifteen percent (15%); or

(2) Discus shall have an option, exercisable until June 30, 2006, to sell back all of its rights under this Agreement for a payment equal to three (3) multiplied by the total Discus Commissions earned by Discus during the twelve (12) month period beginning on July 1, 2005 and ending on June 30, 2006. Align shall make such payment in five equal installments of twenty percent (20%), each of which shall be paid no later than the following dates: September 30, 2006, October 31, 2006, November 30, 2006, December 31, 2006 and January 31, 2007.

C. Right of Discus to Terminate Agreement for Convenience. Discus shall have the right to terminate this Agreement at any time and for any reason upon one hundred eighty (180) days prior written notice to Align. Should another manufacturer, supplier, or provider of orthodontic appliances at anytime offer a product or system which includes multiple, pre-manufactured, removable orthodontic appliances and which represents a disruptive technology which significantly reduces present and/or anticipated future sales of Product, then Discus shall have the right to terminate this Agreement upon ninety (90) days written notice to Align.

D. Right of Align to Terminate Agreement for Discus Failure to Meet Minimum Sales Quota.

(1) Align's Termination Rights.

Except as expressly provided otherwise below, Align shall have the right to give written notice of termination of this Agreement to Discus within forty-five (45) days after the end of any sales period set forth below where Discus has failed to meet the following minimum sales quotas (each, a "Minimum Sales Quota"). In the event Align provides such termination notice, Align shall have the right to set the effective date of such termination to be any date within 180 days after the date of such termination notice. In the event that Align does not provide such notice or terminate this Agreement within the time periods provided, Align shall be deemed to have waived its termination rights with respect to that particular sales period although such waiver shall not affect Align's termination rights with respect to future sales periods.

a. The Minimum Sales Quota for the sales period extending from the execution of this Agreement through the end of March 2002 shall be *****

b. The Minimum Sales Quota for the sales period extending from April 1, 2002 through June 30, 2002 shall be *****.

c. The Minimum Sales Quota for the last six (6) months of calendar year 2002 shall be *****.

d. The Minimum Sales Quota for the first six (6) months of calendar year 2003 shall be *****.

e. The Minimum Sales Quotas for the last six (6) months of calendar year 2003 shall be *****.

f. The Minimum Sales Quota for the calendar year 2004 shall be *****.

g. The Minimum Sales Quota for the calendar year 2005 shall be *****.

h. The Minimum Sales Quota for the calendar year 2006, shall be *****

2. Exceptions to Align's Termination Rights.

Align's termination rights under this subsection (D) shall be subject to following:

******* Confidential treatment requested for redacted portion.**

(a) Align shall not have the right to terminate in any sales period if the cumulative sales for that sales period when combined with the sales during the immediately preceding two (2) sales periods meet or exceed the combined Minimum Sales Quotas for the three (3) sales periods.

(b) In addition, in the event that Discus meets eighty percent (80%) of any particular Minimum Sales Quota, Discus shall have one-half (1/2) of the following sales period (the "Cure Period") to achieve thirty-five percent (35%) of the Minimum Sales Quota for the Cure Period, in which case Align shall not have the right to terminate this Agreement for Discus' failure to meet the Minimum Sales Quota for the sales period immediately preceding the Cure Period. However, if Discus fails to achieve thirty-five percent (35%) of the Minimum Sales Quota during the Cure Period, Align shall have the right to (a) give written notice of termination of this Agreement to Discus within forty-five (45) days after the end of such Cure Period, and (b) set the effective date of such termination to be any date within 180 days after the date of such termination notice. In the event that Align does not provide such notice or terminate this Agreement within the time periods provided, Align shall be deemed to have waived its rights with respect to that particular sales period and Cure Period although such waiver shall not affect Align's rights with respect to future sales periods or Cure Periods.

(c) In the event Discus achieves at least sixty percent (60%) of the Minimum Sales Quota for such sales period and Align then elects to terminate this Agreement at the end of such sales period (the "Final Sales Period") or following the failure to cure as provided for in the preceding section, then Align will pay Discus the following amounts for all orders received from Non-Orthodontic Dentists who (i) have submitted an order for at least one case prior to the effective date of any termination of this Agreement under this Section (D), and (ii) either paid for such order prior to or within ninety (90) days of the effective date of any termination of this Agreement under this Section (D)(X) fifty percent (50%) of the Discus Commission for all orders received from such Non-Orthodontic Dentists in the next twelve (12) month period immediately following the Final Sales Period; (Y) thirty-three percent (33%) of the Discus Commission for all orders received from such Non-Orthodontic Dentists in the second twelve (12) month period following the Final Sales Period; and (Z) twenty percent (20%) of the Discus Commission for all orders received from such Non-Orthodontic Dentists in the third twelve (12) month period following the Final Sales Period.

E. Align's Right to Terminate Agreement for Convenience. At any time after December 31, 2003, Align has the right, upon sixty (60) days' notice to Discus, to terminate this Agreement by paying to Discus an amount equal to five times Discus's past twelve month's revenue calculated based on the "Discus Commission" that Discus received in the twelve (12) months ending at the end of the month immediately prior to such termination.

F. Mutual Right to Terminate for Cause. If either party is in default in the performance of any material provision of this Agreement, then the non-defaulting party shall have the right to terminate this Agreement by giving written notice to the defaulting party which termination shall become effective thirty (30) days after receipt by the defaulting party unless the defaulting party cures the breach within such thirty (30) day period.

G. Mutual Right to Terminate for Insolvency. At the discretion of the non-insolvent party, this Agreement shall terminate immediately upon notice to the other party (1) upon the institution by or against such other party of insolvency, receivership or bankruptcy proceedings or any other proceedings for the settlement of such party's debts, (2) upon such party making an assignment for the benefit of its creditors, or (3) upon such party's dissolution or ceasing to do business.

(H) Effect of a Change of Control of Discus.

1. Definitions. For purposes of this Section VIII(H), the following terms shall have the meanings specified:

(a) The term "Excess Sales Quota Percentage" for any period of time shall mean the percentage derived from the following calculation: (i) the Product Sales for such period of time calculated on an annualized basis (e.g., multiplied by the number two (2) if the period of time is six (6) months or two calendar quarters, and multiplied by four (4) if the period of time is three (3) months or one (1) calendar quarter); minus (ii) the applicable Original Annual Minimum Sales Quota; divided by (iii) the applicable Original Annual Minimum Sales Quota.

(b) The term "Original Minimum Annual Sales Quota" shall mean: (i) ***** in the case of calendar year 2002; (ii) ***** in the case of calendar year 2003; (iii) ***** in the case of calendar year 2004; (iv) ***** in the case of calendar year 2005; and (v) *****.

2. (H) Effect of a Change of Control of Discus.

1. Definitions. For purposes of this Section VIII(H), the following terms shall have the meanings specified:

(a) The term "Excess Sales Quota Percentage" for any period of time shall mean the percentage derived from the following calculation: (i) the Product Sales for such period of time calculated on an annualized basis (e.g., multiplied by the number two (2) if the period of time is six (6) months or two calendar quarters, and multiplied by four (4) if the period of time is three (3) months or one (1) calendar quarter); minus (ii) the applicable Original Annual Minimum Sales Quota; divided by (iii) the applicable Original Annual Minimum Sales Quota.

(b) The term "Original Minimum Annual Sales Quota" shall mean: (i) ***** in the case of calendar year 2002; (ii) *****in the case of calendar year 2003; (iii) ***** in the case of calendar year 2004; (iv) ***** in the case of calendar year 2005; and (v) ***** in the case of calendar year 2006.

2. Effect of a Change of Control of Discus. A Change of Control of Discus (as defined in Section I(F) above) shall have the following effects:

(a) Effective the first day of the first full calendar quarter following the effective date of the Change of Control of Discus, the Minimum Sales Quotas set forth in Section (VIII)(D)(1) above shall become quarterly Minimum Sales Quotas which shall be calculated as follows.

(i) The Minimum Sales Quota for the first quarter of any calendar year during the remaining term of this Agreement shall be equal to the applicable Original Annual Minimum Sales Quota multiplied by the higher of (X) 18%, or (Y) the Excess Sales Quota Percentage for the prior six (6) months.

******* Confidential treatment requested for redacted portion.**

(ii) The Minimum Sales Quota for the second quarter of any calendar year during the remaining term of this Agreement shall be equal to the applicable Original Minimum Annual Sales Quota, multiplied by the higher of (X) 22%, or (Y) the average of (I) the Excess Sales Quota Percentage the prior three (3) months (i.e., the just-ended first quarter in such calendar year), and (II) the Excess Sales Quota Percentage for the prior fourth, fifth and six months (i.e., the fourth quarter from the immediately preceding calendar year).

(iii) The Minimum Sales Quota for the third quarter of any calendar year during the remaining term of this Agreement shall be equal to the applicable Original Minimum Annual Sales Quota, multiplied by the higher of (X) 28%, or (Y) the Excess Sales Quota Percentage for the prior six (6) months.

i. The Minimum Sales Quota for the forth quarter of any calendar year during the remaining term of this Agreement shall be equal to the applicable Original Minimum Annual Sales Quota, multiplied by the higher of (X) 32%, and (Y) the Excess Sales Quota Percentage for the prior six (6) months.
ii. EXAMPLES:

a. *****

(b) Section VIII(D)(2)(c) shall terminate in its entirety.

A. Return of Materials. All instructional, promotional, advertising, and similar materials, as well as all customer database(s) developed jointly or solely by either party for performance hereunder, as well as Intellectual Property Rights or other data (including customer databases), photographs, samples, literature, and sales aids of every kind developed hereunder shall, to the extent that they are Align's property, remain the property of Align. Additionally, upon termination, any and all copyrights which may have been obtained by Discus on Invisalign® promotional materials shall be assigned to Align. Within thirty (30) days after the termination of this Agreement, Discus shall ship all such items in Discus's possession or under Discus's control, as well as any records, files or other information related to patients of Customers, to Align, as Align may direct, at Align's expense. Discus shall not make, use, dispose of or retain any copies of any confidential items or information which may have been entrusted by Align to Discus or any records, files or other information related to patients of Customers. Effective upon the termination of this Agreement, Discus shall cease to use all of Align's Intellectual Property Rights.

B. Limitation on Liability. In the event of termination by either party in accordance with any of the provisions of this Agreement, neither party shall be liable to the other due to such termination, for compensation, reimbursement or damages on account of the loss of prospective profits or anticipated sales or on account of expenditures, inventory, investments, leases or commitments in connection with the business or goodwill of

Align or Discus. Termination shall not, however, relieve either party of obligations incurred prior to the termination.

******* Confidential treatment requested for redacted portion.**

C. Post-Termination Use of Materials. After termination of this Agreement, Discus shall not use any signs, equipment, advertising matter or material that refer to or are related to Align and shall not act or omit to act in any way that may indicate or suggest a relationship with Align and shall immediately return to Align all Align's property, promotional material, and proprietary information.

D. Non-Competition. Should this Agreement be terminated by either party for any reason, Discus agrees that for a period of eighteen (18) months following such termination, neither Discus nor any Affiliate of Discus, shall, without Align's prior written consent, distribute, sell, promote or market in the Territory any lines or products that directly compete with clear polymeric shell appliance systems used to reposition teeth. NOTWITHSTANDING ANY CONTRARY PROVISION CONTAINED HEREIN, IN THE EVENT OF A BREACH OF THE FOREGOING COVENANT BY DISCUS, AN AMOUNT EQUAL TO THE DISCUS COMMISSIONS EARNED BY DISCUS IN THE LAST TWELVE MONTHS OF THE TERM OF THE AGREEMENT SHALL BE PAID BY DISCUS TO ALIGN AS LIQUIDATED DAMAGES. BECAUSE ALIGN'S UP-FRONT AND ONGOING COSTS RELATED TO THIS AGREEMENT TO INTRODUCE A NEW AND UNIQUE PRODUCT TO NON-ORTHODONTIC DENTISTS IN THE TERRITORY AND TO THE MARKETING RIGHTS GRANTED TO DISCUS IN CONNECTION THEREWITH ARE SUBSTANTIAL, INCLUDING WITHOUT LIMITATION, COSTS RELATED TO THE FOLLOWING: (i) ALIGN'S SALES, MARKETING AND DISTRIBUTION SUPPORT AND TECHNICAL TRAINING FOR DISCUS, (ii) ALIGN'S CONSUMER ADVERTISING DEVELOPMENT OBLIGATIONS, (iii) ALIGN'S CONSUMER ADVERTISING SPENDING COMMITMENTS SET FORTH IN SECTION V(J), AND (iv) ALIGN'S VARIOUS OTHER OBLIGATIONS SET FORTH HEREIN, THE PARTIES ACKNOWLEDGE THAT ALIGN'S ACTUAL DAMAGES IN THE EVENT OF SUCH A BREACH BY DISCUS WOULD BE EXTREMELY DIFFICULT OR IMPRACTICABLE TO DETERMINE. THEREFORE, BY PLACING THEIR SIGNATURES BELOW, THE PARTIES ACKNOWLEDGE THAT THE LIQUIDATED DAMAGES AMOUNT HAS BEEN AGREED ON, AFTER NEGOTIATION AS THE PARTIES' REASONABLE ESTIMATE OF ALIGN'S DAMAGES AND AS ALIGN'S EXCLUSIVE REMEDY AGAINST DISCUS IN THE EVENT OF A BREACH OF THIS SECTION VIII(K) BY DISCUS. IN THE EVENT DISCUS SHOULD CHALLENGE THE APPLICABILITY OR EFFICACY OF THIS PROVISION OR IF THIS PROVISION SHOULD BE HELD TO BE VOID OR UNENFORCEABLE FOR ANY REASON, ALIGN SHALL BE ENTITLED TO ANY AND ALL OTHER DAMAGES AND REMEDIES OTHERWISE PROVIDED AT LAW.

ALIGN'S INITIALS _____ DISCUS' INITIALS _____

I. WARRANTIES AND REPRESENTATIONS

A. Align Representations. Align warrants and represents that it has the authority and right to execute, enter into, and perform this Agreement and that it has no conflicting agreements which prevent it from fulfilling its responsibilities enumerated herein, provided that Discus hereby acknowledges and agrees that any resale, marketing, distribution or like agreement between Align and IASG shall not be deemed a conflicting agreement for purposes of this Section IX(A).

B. Discus Representations. Discus warrants and represents that it has the authority and right to execute, enter into, and perform this Agreement and that it has no conflicting agreements which prevent it from fulfilling its responsibilities enumerated herein.

II. INTERPRETATION AND ENFORCEMENT

A. Indemnification. THIS INDEMINFICATION PROVISION STATES THE PARTY'S ENTIRE LIABILITY FOR INFRINGEMENT CLAIMS.

(1) Align Indemnification for Infringement Actions. Align has the obligation to defend Discus, its officer, directors, and/or shareholders, or at Align's option to settle, and Align agrees, at Align's own expense, to defend Discus, its officer, directors, and/or shareholders, or at Align's option to settle, any third party claim, suit or proceeding brought against Discus, its officer, directors, and/or shareholders to the extent such claim, suit or proceeding alleges that use of a Product infringes on such third party's United States or Canadian Patent or United States or Canadian Trademark and Align agrees to indemnify Discus, its officer, directors, and/or shareholders against any and all damages, costs and expenses (including legal fees) that a court awards in a final judgment against Discus under any such claim or action. The foregoing obligation of Align does not apply with respect to Product or portions or components thereof (a) that are not supplied by Align, (b) that are used in violation of this Agreement or in a manner not provided for or described in documentation accompanying the Products, (c) that are modified after shipment by Align, if the alleged infringement relates to such modification, (d) that are combined with other products, processes or materials where the alleged infringement relates to such combination, (e) with respect to which the Customer or patient continues allegedly infringing activity after being notified thereof or after being informed of modifications that would have avoided the alleged infringement, or (f)

where use of the Product is incident to an infringement not resulting primarily from the Products. Align's obligation also shall not apply to trademark infringements involving any marking or branding not applied by Align or involving any marking or branding applied at the request of Discus. If any Product or any portion of a Product becomes, or in Align's opinion is likely to become, the subject of a claim of infringement, then Align may, at its option and expense, (i) procure for the Customer(s) the right to continue using the Product or portion of a Product, as the case may be, or (ii) replace or modify the affected Product or portion of a Product, as the case may be, so that it becomes non-infringing. If neither alternative is reasonably available, Align may terminate this Agreement.

(2) Align Indemnification for Product Liability Actions. Align has the obligation to defend Discus, its officer, directors, and/or shareholders, or at Align's option to settle, and Align agrees, at Align's own expense, to defend Discus, its officer, directors, and/or shareholders, or at Align's option to settle, any third party claim, suit or proceeding brought against Discus, its officer, directors, and/or shareholders to the extent such claim, suit or proceeding alleges that use of any of the Products cause injury to anyone, except to the extent that the injury was caused by negligence or intentional acts of Discus. Align further agrees to indemnify Discus, its officer, directors, and shareholders against any and all damages, costs and expenses (including legal fees) that a court awards in a final judgment against Discus, its officer, directors, and/or shareholders under any such claim or action.

(3) Discus Indemnification for Infringement Actions. Discus has the obligation to defend Align, its officer, directors, and/or shareholders, or at Discus's option to settle, and Discus agrees, at Discus's own expense, to defend Align, its officer, directors, and/or shareholders, or at Discus's option to settle, any third party claim, suit or proceeding brought against Align, its officer, directors, and/or shareholders to the extent such claim, suit or proceeding alleges that use of a Discus Product infringes on such third party's United States or Canadian Patent or United States or Canadian Trademark and Discus agrees to indemnify Align, its officer, directors, and/or shareholders against any and all damages, costs and expenses (including legal fees) that a court awards in a final judgment against Align under any such claim or action. The foregoing obligation of Discus does not apply with respect to Discus Product or portions or components thereof (a) that are not supplied by Discus, (b) that are used in violation of this Agreement or in a manner not provided for or described in documentation accompanying the Discus Products, (c) that are modified after shipment by Discus, if the alleged infringement relates to such modification, (d) that are combined with other products, processes or materials where the alleged infringement relates to such combination, (e) with respect to which the Customer or patient continues allegedly infringing activity after being notified thereof or after being informed of modifications that would have avoided the alleged infringement, or (f) where use of the Product is incident to an infringement not resulting primarily from the Discus Products. Discus's obligation also shall not apply to trademark infringements involving any marking or branding not applied by Discus or involving any marking or branding applied at the request of Align. If any Discus Product or any portion of a Discus Product becomes, or in Discus's opinion is likely to become, the subject of a claim of infringement, then Discus may, at its option and expense, (i) procure for the Customer(s) the right to continue using the Discus Product or portion of a Discus Product, as the case may be, or (ii) replace or modify the affected Discus Product or portion of a Discus Product, as the case may be, so that it becomes non-infringing. If neither alternative is reasonably available, Discus may terminate this Agreement.

(4) Discus Indemnification for Product Liability Actions. Discus has the obligation to defend Align, its officer, directors, and/or shareholders, or at Discus's option to settle, and Discus agrees, at Discus's own expense, to defend Align, its officer, directors, and/or shareholders, or at Discus's option to settle, any third party claim, suit or proceeding brought against Align, its officer, directors, and/or shareholders to the extent such claim, suit or proceeding alleges that use of a Discus Product causes injury to anyone, except to the extent that the injury was caused by negligence or intentional acts of Align. Discus further agrees to indemnify Align, its officer, directors, and/or shareholders against any and all damages, costs and expenses (including legal fees) that a court awards in a final judgment against Align under any such claim or action.

B. Indemnification Procedures. A party's obligations to indemnify the other party with respect to any third party claim, action or proceeding shall be conditioned upon the indemnified party: (1) providing the indemnifying party with prompt written notice of such claim, action or proceeding, (2) permitting the indemnifying party to assume and solely control the defense of such claim, action or proceeding and all related settlement negotiations, with counsel chosen by the indemnifying party, and (3) cooperating at the indemnifying party's request and expense with the defense or settlement of such claim, action or proceeding which cooperation shall include providing reasonable assistance and information. No indemnified party shall enter into any settlement agreement for which it will seek indemnification under this Agreement from the indemnifying party without the prior written consent of the indemnifying party. Nothing herein shall restrict the right of a party to participate in a claim, action or proceeding through its own counsel and at its own expense.

C. Intellectual Property Rights.

(1) Discus agrees that (a) Align owns all right, title, and interest in the product lines that include the Products and in and to all Align's Intellectual Property Rights, and (b) except as expressly provided otherwise herein, Discus shall not, by virtue of this Agreement, acquire any right, title or interest in or to any Align's Intellectual

Property Right. The use by Discus of any Align's Intellectual Property Rights is authorized only for the purposes herein set forth, and upon termination of this Agreement for any reason such authorization shall cease.

(2) Except as expressly provided otherwise herein, Align agrees that shall not by virtue of this Agreement, acquire any right, title or interest in or to any of Discus' Intellectual Property Rights.

D. Sale Conveys no Right to Manufacture or Copy. The Products are offered for sale and are sold by Align subject in every case to the condition that such sale does not convey any license, expressly or by implication, to manufacture, duplicate or otherwise copy or reproduce any of the Products. Discus shall take appropriate steps with the Customers, as Align may request, to inform them of and assure compliance with the restrictions contained in this Section X(D).

E. Confidentiality.

(1) Each party acknowledges that by reason of its relationship to the other hereunder, it will have access to certain proprietary information and materials designated "proprietary" concerning the other party's business, plans, customers, technology, and products (the "Confidential Information"). Without limiting the generality of the foregoing, Align's Intellectual Property Rights shall be considered Confidential Information of Align and Discus' Intellectual Property Rights shall be considered Confidential Information of Discus. Each party agrees that it will not use in any way for its own account or the account of any third party (except for the purpose of performing its obligations under this Agreement), nor disclose to any third party, any such Confidential Information revealed to it by the other party without the express written consent of the disclosing party. Each of the parties further agrees to use the same degree of care concerning Confidential Information as it uses to protect its own confidential and proprietary technical information to prevent the unauthorized disclosure to any third party of the Confidential Information received from the disclosing party hereunder. The parties agree that they shall acquire no rights with respect to Confidential Information of the other party received hereunder. The parties agree that the Confidential Information received by a disclosing party hereunder shall not be disclosed to any third party or to any employee, officer or director of the receiving party, except to those employees, officers and directors whose responsibilities require such disclosure for purposes of performing the parties' obligations under this Agreement; provided that such employees, officers and directors have entered into confidentiality agreements with provisions substantially similar to those set forth in this Section X(E).

(2) The obligations hereunder shall not apply to Confidential Information:

i. which the receiving party can demonstrate by written records was known to the receiving party prior to the date of disclosure by the disclosing party; provided that such information was not obtained by the receiving party through disclosure by a third party receiving such information in confidence from the disclosing party;

ii. which is now in the public knowledge, or becomes public knowledge in the future other than by breach of this Agreement by the receiving party;

iii. which, as can be established by written records, is independently developed by the receiving party without benefit of Confidential Information received from the disclosing party;

iv. which is disclosed to the receiving party, after the date of disclosure by the disclosing party, by a third party having a right to make such disclosure;

v. which is required to be disclosed by applicable law or proper legal, governmental or other competent authority or included in any filing or action taken by the receiving party to obtain government approval to market the Products; provided, however, that when permitted by the provisions of local laws, the receiving party shall use its reasonable best efforts to protect the confidentiality of such Confidential Information submitted to governmental agencies or authorities pursuant to this Agreement and provided further that, with regard to a court order or similar process, the party whose information is to be disclosed shall be notified sufficiently in advance of such requirement so that it may seek a protective order (or equivalent) with respect to such disclosure, which the other party shall fully comply with; or

vi. which is required to be provided to Align to support sales of Products to Customers.

(3) Upon termination of this Agreement, the receiving party shall return to the disclosing party any tangible copies of any Confidential Information provided to it by the disclosing party hereunder, and any notes taken by employees, officers and directors of the receiving party regarding the Confidential Information disclosed to it.

(4) The obligations of this Section X(E) shall (a) apply to Confidential Information relating to the subject matter of this Agreement disclosed during or prior to the execution hereof and (b) survive termination of this Agreement for any reason.

(5) Neither party shall issue a press release which discusses this Agreement or the other party without text approval from the other party, which approval shall not be unreasonably withheld or delayed, except that either party may issue a press release which that party in good faith deems necessary to comply with securities or other governmental rules or requirements.

F. Align Product Trademarks.

(1) Use. Subject to subsection (F)(2) below, during the term of this Agreement, Discus shall have the right to indicate to the public that Discus is an authorized representative of the Align Product Trademarks and to advertise within the Territory such Products under the Align Product Trademarks. Discus shall not alter or remove any Align Product Trademark applied to the Products at the factory. Except as set forth in this Section X(F), nothing contained in this Agreement shall grant to Discus any right, title or interest in the Align Product Trademarks and Discus is prohibited from seeking or assisting in the registration of Align Product Trademarks on behalf of Discus or anyone other than Align.

(2) Approval of Representations. All representations of the Align Product Trademarks that Discus intends to use shall first be submitted to Align for approval, which shall not be unreasonably withheld or delayed, of design, color, and other details or shall be exact copies of those used by Align. If any Align Product Trademarks are to be used in conjunction with another trademark on or in relation to the Products, then the Align Product Trademark shall be presented equally legibly, equally prominently, and of equal or greater size than the other but nevertheless separated from the other so that each appears to be a mark in its own right, distinct from the other mark.

(3) Further Assurances Regarding Align Product Trademarks. At no time during or after the term of this Agreement shall Discus challenge or assist others to challenge any Align Product Trademarks or the registration thereof, or use or register, or attempt to use or register, any Trademarks, marks or trade names confusingly similar to any Align Product Trademarks.

(4) Further Assurance Regarding General Trademarks. Without in any way limiting subsection (F)(3) above, the parties hereby agree that at no time during or for a period of eighteen (18) months after the term of this Agreement shall either party challenge or assist others to challenge any Trademark of the other party or the registration thereof, or use or register, or attempt to use or register, any Trademarks, marks or trade names confusingly similar to those of the other party.

G. Notices. Any notice, request, demand or other communication required or permitted to be given under this Agreement may be given by personal delivery in writing, by registered or certified mail, postage prepaid, return receipt requested, or by facsimile transfer (telefax). Notice shall be deemed complete on the date of actual receipt, or five (5) business days after mailing in the case of mailed notice. Said notices shall be mailed or delivered as follows:

(1) In the case of Discus, to Mr. Robert Hayman, President, Discus Dental Impressions, Inc., at the address set forth in Recital I(C) hereof, or by Facsimile at (310) 845- 1513, or to such other person or address as Discus may from time to time furnish to Align.

(2) In the case of Align to, Mr. Zia Chishti, Chief Executive Officer, Align Technology, Inc., at the address set forth in Recital I(A) hereof, or by Facsimile at (408) 727- 1393, or to such other person or address as Align may from time to time furnish to Discus.

H. Entire Agreement. This Agreement sets forth the entire agreement and understanding of the parties relating to the subject matter herein and merges all prior discussions between them. No modification of or amendment to this Agreement, nor any waiver of any rights under this Agreement, shall be effective unless in writing signed by the party to be charged.

I. Assignment. This Agreement constitutes a personal contract and neither Align nor Discus shall be permitted to transfer or assign any rights or duties under this Agreement, or any part thereof, without the prior written consent of the other party, except that (1) Align may assign its right and duties in whole to an acquirer of all or substantially all of its equity securities, assets or product lines that are the subject of this Agreement; and (2) Discus shall have the right to assign any of its rights or duties under this Agreement to (a) either Discus Dental, Inc. or Westside Packaging, Inc., which companies the parties recognize are affiliates of Discus with one-hundred percent (100%) common ownership, or (b) subject to the provisions of Section VIII(H), an acquirer of all or substantially all of its equity securities, assets or product lines that are the subject of this Agreement.

J. Force Majeure. Nonperformance of either party shall be excused to the extent that performance is rendered impossible by strike, fire, flood, governmental acts or orders or restrictions, failure of suppliers, war, terrorism or any other reason where failure to perform is beyond the reasonable control of and is not caused by the negligence of the non-performing party.

K. No Implied Waivers. The failure of either party at any time to require the performance by the other party of any provision hereof shall not affect in any way the full right to require such performance at any time thereafter, and

the waiver by either party of a breach of any provision hereof shall not be taken or held to be a waiver of the provision itself.

L. Controlling Law. This Agreement shall be governed by, and construed and interpreted in accordance with, the laws of the State of California, United States of America, without reference to conflict of laws principles or statutory rules of arbitration. Subject to Section X(M) below, the federal and state courts within the State of California, United States of America shall have exclusive jurisdiction to adjudicate any dispute arising out of this Agreement. Discus and Align hereby expressly consents to (1) the personal jurisdiction of the federal and state courts within California, (2) service of process being effected upon either party by registered mail sent to the address set forth at the beginning of this Agreement, and (3) the uncontested enforcement of a final judgment from such court in any other jurisdiction wherein either party or any assets of either party are present.

M. Arbitration and Attorneys' Fees. Any dispute, controversy or claim arising out of or relating to this Agreement, or breach thereof, shall be submitted to and finally resolved by arbitration under and in accordance with the commercial rules of the American Arbitration Association, which shall administer the arbitration and act as appointing authority. The arbitration shall take place in San Jose, California, and shall be the exclusive forum for resolving such dispute, controversy or claim. The decision of the arbitrators shall be executory, final and binding upon the parties hereto and judgment upon the award in the arbitration may be entered in any court having jurisdiction thereof. The expense of the arbitration (including, without limitation, the awarding of attorneys' fees to the prevailing party) shall be paid as the arbitrator determines.

N. Severability. If any provision of this Agreement is or becomes or is held to be invalid or unenforceable, such provision shall be deemed amended to the narrowest extent necessary to conform to applicable laws so as to remain valid and enforceable or, if it cannot be so amended without materially altering the intentions of the parties hereto, it shall be stricken and the remainder of this Agreement shall remain in full force and effect.

O. No Third Party Rights. Except the right to indemnify the officers, directors, and shareholders of each company as provided for in Sections X(A)(1) and X(A)(2), nothing in this Agreement, whether express or implied, is intended to confer any rights or remedies under or by reason of this Agreement on any persons other than the parties hereto.

P. Counterparts. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original and all of which together shall constitute one instrument.

Q. Binding Effect. A mutually agreed consideration for Align's entering into this Agreement is the reputation, business standing, and goodwill already honored and enjoyed by Discus under Discus's present ownership, and, accordingly, subject to Section X(I) Discus agrees that Discus's rights and obligations under this Agreement may not be transferred or assigned directly or indirectly without the prior written consent of Align. Subject to the foregoing sentence, this Agreement shall be binding upon and inure to the benefit of the parties hereto and their successors and assigns.

R. Headings. The section headings of this Agreement are for convenience of reference only and shall not be deemed to alter or affect any provision hereof.

S. Construction. Where the context or construction requires, all words applied in the plural shall be deemed to have been used in the singular, and vice versa; the masculine shall include the feminine and neuter, and vice versa; and the present tense shall include the past and future tense, and vice versa

T. Survival. Except to the extent expressly provided to the contrary in this Agreement, any rights to accrued payments, any right of action for breach of the Agreement prior to termination, and the following provisions shall survive the termination of this Agreement: Sections I (as applicable), II(F), II(G), III(B), IV(I), IV(J), VII in its entirety, VIII(B)(2) (in accordance with its terms), VIII(D)(c), VIII(E), VIII(I), VIII(J), VIII(K), VIII(L), IX in its entirety, X(A)-(E), X(F)(3) and X(G)-(T).

EXECUTED on the date first above written.

/S/ Robert Hayman

Robert Hayman

President & Chief Executive Officer

Discus Dental Impressions, Inc.

/S/ Zia Chishti

Zia Chishti

Chief Executive Officer

Align Technology, Inc.

EXHIBIT A

LIST OF PRODUCTS, SERVICES AND PRICES

EXHIBIT A

LIST OF PRODUCTS, SERVICES AND PRICES

*****

Notes:

******* Confidential treatment requested for redacted portion.**

a. Case Set-up includes all processing through ClinCheck®.

b. 3:3 submission option must be indicated on the Design Plan form.

c. Covers the costs associated with one (1) case refinement, if necessary.

d. Not available with 3:3 submission option.

e. Required if patient undergoes significant dental work or trauma during the course of treatment, or if the patient does not comply with device instructions.

f. Includes up to 5 sets of additional aligners after the final stage. If case is not completed within 5 stages of the final aligner stage, additional aligners will be billed as a Mid-Course Correction.

g. Add shipping charge. For U.S. domestic shipping, add $15.00 for each shipment. For international shipping, including Canada and Mexico, add $25.00 for each shipment. Any duties and taxes will be paid by the consignee or an agent appointed by the consignee.

August 16, 2001

Kenneth M. Vargha
3938 Woodcreek Lane
San Jose, CA 95117

Dear Ken:

This letter (the "Agreement") is to confirm the agreement between you and Align Technology, Inc. (the "Company") regarding your separation from employment with the Company.

1. Your employment with the Company terminated on August 15, 2001 (the "Separation Date"). You have no right to employment with the Company after the Separation Date, and the Company has no obligation to employ you after that date. You acknowledge that you have been paid all salary, accrued but unused vacation, and all wages of every kind earned by you through the Separation Date.
2. You agree that prior to the execution of this Agreement you were not entitled to receive any monetary payments or benefits from the Company, and that the only payments and benefits that you are entitled to receive from the Company in the future are those specified in this Agreement.
3. Although you are not otherwise entitled to receive any further payments from the Company, following the Effective Date of this Agreement, the Company will continue your current base pay at the rate of Five Thousand Eight Hundred Thirty Eight Dollars and 46/00 ($5,838.46) biweekly, less applicable deductions and withholdings, for a period of four (4) months following the Separation Date, payable on the Company's normal payday (the "Severance Payments"). In addition, the Company will continue your health benefits coverage under COBRA for a period of four (4) months, through December 31, 2001. The Company will also give you four (4) months of service credit after your Separation Date for the purpose of option vesting (the "Acceleration"). All such accelerated option shares shall be vested and exercisable as of the Separation Date.
4. You acknowledge and agree that you have been granted the following four (4) options to purchase shares of Company Common Stock pursuant to the Align Technology Inc. 1997 Equity Incentive Plan (the "Plan"), and that each of those option grants was accompanied by a Stock Option Agreement: (i) an incentive stock option ("ISO") granted on October 28, 1998 for 100,000 shares at a price of $0.15 per share (the "1998 Option"); (ii) an ISO granted on May 18, 2000 for 50,000 shares at a price of $0.40 per share (the "May 2000 Option"); (iii) an ISO granted on September 29, 2000 for 75,116 shares at a price of $1.065 per share (the "September 2000 ISO"); and (iv) a non-statutory option (NSO) granted on September 29, 2000 for 48,384 shares at a price of $1.065 per share (the "September 2000 NSO"). The Plan and your Stock Option Agreement documents are incorporated into this Agreement by reference. You agree that as of the Separation Date, including the Acceleration, your 1998 Option was vested as to 81,250 shares, your May 2000 Option was vested as to 23,958 shares, your September 2000 ISO was vested as to 21,908 shares, and your September 2000 NSO was vested as to 14,112 shares.
    a. You acknowledge that on December 15, 1999 and May 24, 2000, by paying an aggregate of $14,062.50 in the form of cash and delivering executed Early Exercise Stock Purchase Agreements and their attached Assignments Separate from Certificate and joint Escrow Instructions, you early exercised an aggregate of 93,750 shares under the 1998 Option, 12,500 of which are subject to the Company's right of repurchase under the Stock Purchase Agreements that you executed as part of your early exercise. Accordingly, the Company hereby repurchases, and you hereby sell to the Company, 12,500 of the shares that you early exercised under the 1998 Option. As part of this repurchase, the Company will deliver payment in the amount of One Thousand Eight Hundred Seventy Five Dollars and 00/00 ($1,875.00) (12,500 shares x $0.15 per share).
    b. You acknowledge that on May 24, 2000, by paying $12,083.20 in cash and delivering an executed Early Exercise Stock Purchase Agreement and the attached Assignment Separate from Certificate and Joint Escrow Instructions you early exercised 30,208 shares under the May 2000 Option, 6,250 of which are subject to the Company's right of repurchase under the Stock Purchase Agreement that you executed as part of your early exercise. Accordingly, the Company hereby repurchases, and you hereby sell to the Company 6,250 of the shares you early exercised under the May 2000 Option. As part of this repurchase, the Company will deliver payment in the amount of Two Thousand Five Hundred Dollars and 00/00 ($2,500.00) (6,250 shares x $0.40 per share).
    c. You acknowledge that on November 13, 2000, by paying $34,540.08 in the form of a promissory note executed by you and delivering the executed Early Exercise Stock Purchase Agreement and its attached Assignment Separate from Certificate and Joint Escrow Instructions to the Company, you early exercised 32,432 shares under the September 2000 ISO, 10,524 of which are subject to the Company's right of repurchase under the Early Exercise Stock Purchase Agreement that you executed as part of the early exercise. Accordingly, the Company hereby repurchases, and you hereby sell to the Company 10,524 of the shares that you early exercised under the September 2000 ISO. You acknowledge and agree that, under the terms of your promissory note, you are responsible for payment of accrued interest on all the exercised shares under the September 2000 ISO through December

11, 2001, your last day to provide payment per the terms of your Promissory Note. You acknowledge and agree that, as a result, the sum of Twenty Three Thousand Three Hundred Thirty Two Dollars and Two Cents ($23,332.02) (21,908 x $1.065 per share) in principal, together with Three Thousand Four Hundred Fifty Eight Dollars and Fifty Five Cents ($3,458.55) in interest, for a total of Twenty Six Thousand Seven Hundred Ninety Dollars and Fifty Seven Cents ($26,790.57) is due to the Company under the terms of your promissory note.

d. You acknowledge that on November 13, 2000, by paying $22,543.92 in the form of a promissory note executed by you and delivering the executed Early Exercise Stock Purchase Agreement and its attached Assignment Separate from Certificate and Joint Escrow Instructions to the Company, you early exercised 21,168 shares under the September 2000 NSO, 7,056 of which are subject to the Company's right of repurchase under the Early Exercise Stock Purchase Agreement that you executed as part of the early exercise. Accordingly, the Company hereby repurchases, and you hereby sell to the Company 7,056 of the shares that you early exercised under the September 2000 NSO. You acknowledge and agree that, under the terms of your promissory note, you are responsible for payment of accrued interest on all the exercised shares under the September 2000 NSO through December 11, 2001, your last day to provide payment per the terms of your Promissory Note. You acknowledge and agree that, as a result, the sum of Fifteen Thousand Twenty Nine Dollars and Twenty Eight Cents ($15,029.28) (14,112 x $1.065) in principal, together with Two Thousand Two Hundred Fifty Seven Dollars and Thirty Seven Cents ($2,257.37) in interest, for a total of Seventeen Thousand Two Hundred Eighty Six Dollars and Sixty Five Cents ($17,286.65), is due to the Company under the terms of your promissory note.

You will be provided with a stock certificate for the 54,770 shares (12,500 not yet in certificate under the 1998 Option + 6,250 not yet in certificate under the May 2000 Option + 21,908 under the September 2000 ISO +14,112 under the September 2000 NSO). Except as otherwise provided herein, each of these 54,770 shares and the 86,458 shares previously released in certificate will remain subject to all terms and conditions of the Stock Purchase Agreements and Stock Option Agreements that you executed, as well as the terms of the Plan, the Early Exercise Stock Purchase Agreements and their attachments. You agree that you will have no right to exercise the 1998 Option, the May 2000 Option, the September 2000 ISO Option or the September 2000 NSO Option as to any additional shares. In consideration for receiving the Severance Payments, health benefits coverage, the Acceleration and other good and sufficient consideration as described in paragraph 3 of this Agreement, you waive and release and promise never to assert any claims or causes of action, whether or not now known, against the Company or its predecessors, successors, subsidiaries, officers, directors, agents, employees and assigns, with respect to any matter, including but not limited to, any matter arising out of or connected with your employment with the Company or the termination of that employment, including without limitation, claims of wrongful discharge, emotional distress, defamation, fraud, breach of contract, breach of the covenant of good faith and fair dealing, any claims of discrimination or harassment based on sex, age, race, national origin, disability or on any other basis, under Title VII of the Civil Rights Act of 1964, as amended, the California Fair Employment and Housing Act, and all other federal and state laws and regulations relating to employment.

5. In consideration for receiving the Severance Payments, health benefits coverage, the Acceleration and other good and sufficient consideration as described in paragraph 3 of this Agreement, you agree to remain available to answer questions and assist in the transition of your job duties through December 31, 2001.
6. You expressly waive and release any and all rights and benefits under Section 1542 of the *Civil Code of the State of California* (or any analogous law of any other state), which reads as follows: "A general release does not extend to claims which the creditor does not know or suspect to exist in his favor at the time of executing the release, which, if known by him, must have materially affected his settlement with the debtor."
7. Nothing contained in this Agreement shall constitute or be treated as an admission by you or the Company of liability, of any wrongdoing, or of any violation of law.
8. At all times in the future, you will remain bound by the Company's Employee Proprietary Information and Inventions Agreement signed by you on, September 11, 1998, a copy of which is attached.
9. You promise that you have returned to the Company all Company documents and materials, all Company equipment, and all other physical and intellectual property of the Company, including any and all copies or other reproductions of such property.
10. You agree that for a period of one (1) year following the Separation Date, you will not encourage, solicit or recruit any employee of the Company to leave the Company for any reason, including for the purpose of accepting employment with another company. As part of this non-solicitation promise, you agree not to interview any employee of the Company, or provide any input to any third party interested in hiring a Company employee during the one (1) year period following the Separation Date.
11. You agree that you will not disclose to others the fact or terms of this Agreement, except that you may disclose such information to members of your immediate family, attorney or accountant in order for such individuals to render services to you, so long as such individual agrees to keep such information confidential. You may respond to any inquiry that is subject to this nondisclosure agreement by stating that you cannot answer that question due to the terms of this nondisclosure agreement.

12. You agree that you have not and will not make any derogatory, disparaging or negative statements about the Company, its products, officers, directors or employees. The Company agrees it has not and will not to make any derogatory, disparaging or negative statements about you. Upon inquiry by prospective employers or other third parties, the Company will limit its statements regarding your employment to verification of the dates of your employment, your salary, and your position held.
13. Notwithstanding paragraphs 12 and 13, you may respond truthfully and accurately to any questions put to you in a legal proceeding to which you have been subpoenaed to testify. However, if you are so subpoenaed, you will promptly notify the Company in writing of such action and give the Company a reasonable opportunity to quash the subpoena or otherwise apply for a court order limiting the scope of your testimony.
14. You understand and agree that all of the covenants made by you and contained in this Agreement, including and without limitation those covenants contained in paragraphs 5, 6, 7, 9, 10, 11, 12 and 13 of this Agreement, are material inducements for the making of this Agreement and that, for the breach thereof, the Company will be released from each and every of its obligations under this Agreement and entitled to pursue its legal and equitable remedies, including, without limitation, the right to recover all Severance Payments, stock and the value of health care benefits, as well as to seek injunctive relief; provided, however, that any and all such remedies shall be pursued pursuant to paragraph 15 of this Agreement.
15. You agree that any controversy involving the construction or application of any terms, covenants or conditions of this Agreement, or any claims arising out of any alleged breach of this Agreement will be governed by the Federal Arbitration Act and will be submitted to and settled by final and binding arbitration in Santa Clara County, California in accordance with the Commercial Rules of the American Arbitration Association. The parties further understand and agree that the arbitration shall be instead of any civil litigation and that the arbitrator's decision shall be final and binding to the fullest extent permitted by law and enforceable by any court having jurisdiction thereof.
16. You agree that except for documents incorporated into this Agreement by reference, this Agreement renders null and void any and all prior agreements between you and the Company.
17. This Agreement shall be construed and interpreted in accordance with the laws of the State of California.

Please indicate your agreement with the above terms by signing below.

Sincerely,

/s/ Jo-Ann Byrne

Jo-Ann Byrne
Director of Human Resources

My agreement with the above terms is signified by my signature below. Furthermore, I acknowledge that I have read and understand this Agreement and that I sign this release of all claims voluntarily, with full appreciation that at no time in the future may I pursue any of the rights I have waived in this release.

Dated: August 28, 2001

"Effective Date

/s/ Kenneth M. Vargha

Kenneth M. Vargha

EXHIBIT 23.1

CONSENT OF INDEPENDENT ACCOUNTANTS

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (File No. 333-55020 and No. 333-82874) of Align Technology, Inc. of our report dated February 7, 2002 relating to the consolidated financial statements, which appears in this Form 10-K.

PricewaterhouseCoopers LLP
San Jose, California
March 27, 2002