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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, 2000

OR

[_]TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

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 No.)

851 Martin Avenue
Santa Clara, California 95050
(408) 470-1000
(Address, including zip code, of principal executive offices and 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 [_] No [X]

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K ((S)229.405 of this chapter) 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. [X]

The aggregate market value of voting stock held by non-affiliates of the registrant as of March 19, 2001 was $193,188,843. This calculation does not reflect a determination that persons are affiliates for any other purpose.

On March 19, 2001, 47,335,050 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 15, 2001 are incorporated by reference into Part III of this annual report on Form 10-K.

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ALIGN TECHNOLOGY, INC.

FORM 10-K

For The Year Ended December 31, 2000

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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 the Invisalign(R) System, a proprietary new method for treating malocclusion, or the misalignment of teeth. The System 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, the System significantly reduces the aesthetic and other limitations associated with braces. The Invisalign System also offers orthodontists a new means of carrying out their diagnosis and treatment planning processes. We believe the Invisalign System 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 the Invisalign System is a compelling treatment alternative for most of the patients who would seek traditional orthodontic treatment. In addition, given the significant benefits of our System, 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 the Invisalign System in 1998 and started commercial sales of the System in July 1999. Our 510(k) clearance from the FDA allows us to market the Invisalign System to treat patients with any type of malocclusion. We voluntarily restrict the use of the Invisalign System 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 the Invisalign System 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 orthodontists use the Invisalign System as a complete treatment for mild and moderate malocclusions and as a component of treatment for unusually severe malocclusions.

As of February 2001, we had trained approximately 6,400 orthodontists to use the Invisalign System, representing over 70% of all practicing U.S. and Canadian orthodontists. As of February 28, 2001, nearly 2,600 of the orthodontists we have trained had submitted one or more cases to us, and approximately 14,800 patients have commenced treatment with the Invisalign System.

Our objective is to establish the Invisalign System as the standard method for treating orthodontic malocclusion. Our sales and marketing efforts focus on educating both consumers and orthodontists on the significant benefits of the System. We continue to train orthodontists and work with them to increase the use of the Invisalign System within their practices. In September 2000, we initiated a national advertising campaign to create awareness of the Invisalign System as a treatment alternative and to stimulate demand for treatment with the System.

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. Only a relatively small proportion of people with malocclusion seek treatment because of the compromised aesthetics, discomfort and other drawbacks associated with conventional orthodontic treatments.

Traditional Orthodontic Treatment

Orthodontists apply traditional techniques and principles of treatment developed in the early 20th century. In the U.S., orthodontists treat malocclusion primarily with metal archwires and brackets, commonly referred to as braces. Occasionally, in an attempt to improve treatment aesthetics, orthodontists use ceramic, tooth-colored brackets or bond brackets on the inside, or lingual surfaces, of the patient's teeth. Orthodontists 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 orthodontist involvement, or chair time. To initiate treatment, an orthodontist will diagnose a patient's condition and create an appropriate treatment plan. In a subsequent visit, the orthodontist 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 orthodontist 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 orthodontist must tighten the braces to a degree sufficient to achieve sustained tooth movement during the interval. In a final visit, the orthodontist removes each bracket and residual cement from the patient's teeth.

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

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, orthodontists have not had a means to model the movement of teeth over a course of treatment. Accordingly, orthodontists 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 orthodontist'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 orthodontist.

- Physical demands on orthodontists. The manipulation of wires and brackets requires sustained manual dexterity and visual acuity, and may place other physical burdens on the orthodontist.

- 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 orthodontist.

Due to the poor aesthetics, discomfort and other limitations of braces, relatively few people with malocclusion elect 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 orthodontists for a treatment system that increases the predictability and efficiency of treatment and enhances practice profitability.

The Align Solution

Our Invisalign System is a proprietary new system for treating malocclusion. The Invisalign System consists of two components: ClinCheck(TM) and Aligners.

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

Upon review of the ClinCheck simulation, the orthodontist 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 orthodontist'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 orthodontist may, in his or her discretion, prescribe that the patient wear the final Aligner as a retainer.

Benefits of the Invisalign System

We believe that the Invisalign System provides benefits to patients and orthodontists that have the potential to establish the System 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 orthodontist.

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 Orthodontist

- Ability to visualize treatment and likely outcomes. We believe that ClinCheck is the only product that enables orthodontists to preview a course of treatment and the likely final outcome of treatment in an interactive three-dimensional computer model. ClinCheck allows orthodontists 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 the Invisalign System are consistent with those of traditional orthodontics. Orthodontists can complete our initial training and certification program within a day.

- Ease of use. When treating patients with the Invisalign System, orthodontists 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 the Invisalign System 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 our System will allow orthodontists to attract patients who would not otherwise seek orthodontic treatment.

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

- Decreased orthodontist and staff time. The Invisalign System reduces both the frequency and length of patient visits. The Invisalign System 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 the Invisalign System significantly reduces orthodontist 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 the Invisalign System

In some instances, the Invisalign System may have certain limitations relative to conventional treatment. Aligners cost more to produce than conventional braces, and we charge orthodontists more than they generally pay for the supplies used in conventional treatment. Depending on the individual pricing policies of each orthodontist, the cost of the Invisalign System to the patient may be greater than for conventional braces. Orthodontists must also incorporate our manufacturing cycle times into their overall treatment plan. Once an orthodontist 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 the Invisalign System 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 the Invisalign System to both patients and orthodontists.

Our Target Market

Commercial sales of our Invisalign System commenced in the U.S. in July 1999. As of February 28, 2001, approximately 14,800 patients have entered treatment using the Invisalign System.

Our 510(k) clearance from the FDA allows us to market the Invisalign System to treat patients with any type of malocclusion. We voluntarily restrict the use of the Invisalign System 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 the Invisalign System 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 orthodontists use the Invisalign System as a complete treatment for mild and moderate 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 the Invisalign System.

In addition, we believe that we have an immediate and substantial market expansion opportunity. Our market research indicates that the great 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, our Invisalign System 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 are currently focused on the domestic market opportunity but we also believe that a large international market opportunity exists.

Business Strategy

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

Educate orthodontists and stimulate demand for Invisalign System treatment. Our market research indicates that the great majority of people with malocclusion who desire treatment do not elect traditional treatment because of its many limitations. By communicating the benefits of the Invisalign System to both orthodontists and consumers, we intend to significantly increase the number of patients who seek orthodontic treatment annually. As of February 2001, we had trained approximately 6,400 orthodontists in the U.S. and Canada on the use and benefits of the Invisalign System. We have successfully tested consumer advertising in two lead markets and in September 2000 initiated a national advertising campaign in order to create awareness of the Invisalign System as a treatment alternative and to establish the Invisalign brand name.

Communicate practice benefits of the Invisalign System to orthodontists. The Invisalign System provides substantial financial incentives to orthodontists 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 orthodontists 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, including Pakistan and Mexico. 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. The Invisalign System represents a significant technological advancement in orthodontics. We believe that our issued patents, multiple pending patents and other intellectual property provide 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. The Invisalign System can provide complete treatment for those patients with mature dentition and mild or moderate malocclusion. In addition, we believe that the System can provide partial treatment of unusually severe malocclusions. In an effort to demonstrate the System's ability to comprehensively treat such cases, we are undertaking post-marketing studies and making additional improvements to the product.

Build an international presence. In the near term, we intend to focus our sales and marketing efforts on the U.S. and Canadian market opportunities. However, we are developing our strategy for introducing the Invisalign System in selected international markets. We believe that potential international demand for the Invisalign System exceeds that of our domestic markets.

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, laser, destructive and white light scanning techniques and stereolithography, wax modeling and other rapid prototyping methods.

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 2000, we employed a manufacturing staff of approximately 250 people. In addition, we employed a software development team comprising approximately 30 software engineers with backgrounds in computational geometry, animation, computer-aided design and manufacturing industries. We also employ approximately 610 software operators and other staff in our facilities in Lahore, Pakistan, who are responsible for the creation of treatment simulations. In addition, we outsource the fabrication and packaging of Aligners to a contract manufacturer based in Juarez, Mexico.

The Invisalign Treatment Process

The Invisalign System treatment process comprises the following five stages:

Orthodontic diagnosis and transmission of treatment data to us. In an initial patient visit, the orthodontist determines whether the Invisalign System is an appropriate treatment. The orthodontist 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 System 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 orthodontist 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 orthodontist's prescription electronically to our facilities in Lahore, Pakistan.

Preparation of computer-simulated treatment and viewing of treatment using ClinCheck. 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 transmitted back to our Santa Clara facility for review. Upon passing review, the simulation is then delivered to the prescribing orthodontist via ClinCheck on our website at www.invisalign.com. The orthodontist then reviews the ClinCheck simulation on a computer and, on occasion, asks us to make adjustments. By reviewing and amending the treatment simulation, the orthodontist retains control over the treatment plan and, thus, participates in the customized design of the Aligners. At this point, the orthodontist may also invite the patient to review ClinCheck, allowing the patient to see the projected course of treatment. The orthodontist 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 orthodontist. 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 orthodontist. In certain cases, orthodontists may use the Invisalign System 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.

To date, we have shipped Aligners in batches. The first batch, which typically represents the first several months of treatment, is produced once the prescribing orthodontist approves ClinCheck. Thereafter, Aligners are sent at approximately six month intervals until treatment is complete. We are in the process of changing the pattern of Aligner shipments. 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. Our next generation of software is being developed to enhance computer analysis of treatment data, reducing time spent for each case on manual and judgmental tasks, thereby increasing the efficiency of our technicians in Pakistan. We are also developing an automated system for the fabrication of Aligners currently conducted in Mexico.

In order to scale our manufacturing capacity, we continue to add labor and invest in facilities and capital equipment. In particular, we recently expanded our operations to two facilities in Santa Clara, California, together totaling approximately 70,000 square feet, which serve as our manufacturing headquarters. We are also expanding our technician base in Pakistan and continue to hire in Santa Clara.

Quality Assurance

Our quality assurance team maintains compliance with FDA regulations, monitors customer satisfaction with our products and services, and helps ensure a high level of quality of final product. The prescribing orthodontist's review of the ClinCheck treatment simulation represents an important step in our overall quality control procedures.

Because we custom manufacture Aligners on a build-to-order basis, we do not offer refunds on our products. 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, any additional Invisalign treatment requested as a result is provided at the orthodontist's expense.

The Invisalign product warranty does not provide any assurances regarding the outcome of treatment using the Invisalign System. However, if actual treatment results deviate significantly from the approved ClinCheck treatment plan, the orthodontist 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 orthodontist submit new molds of the patient's dentition to us. We use the molds to create a new ClinCheck treatment plan for the orthodontist 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. Mid-course corrections have only been requested in a limited number of cases.

In the event that an orthodontist 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 orthodontist may

request a mid-course correction or additional Aligners. However, in these cases, the mid-course correction and additional Aligners are provided at the orthodontist's expense. In addition, should an orthodontist request a replacement for a lost Aligner, we charge the orthodontist for the cost of the replacement Aligner.

Sales and Marketing

We market the Invisalign System by communicating the System's benefits directly to consumers with a nationwide advertising campaign. Based on our experience with advertising and commercial sales in our test markets, we believe that making consumers aware of the Invisalign System as a new treatment alternative generates significant demand for the System. In order to serve anticipated demand in North America, we are training a broad base of orthodontists.

Consumer Marketing

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 the Invisalign System. Our national consumer marketing efforts primarily focused on television advertising and will be supported by print, public relations and direct mail campaigns.

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. From the inception of our national advertising campaign in September 2000 through December 31, 2000, our support line received approximately 300,000 calls and we received a comparable number of visitors to our website. Our telephone support line and our website not only provide consumers with information on the Invisalign System, but, importantly, also allow us to channel consumer interest to orthodontists of our choice. Traditionally we have outsourced the telephone support function to a large national call center operator. Currently, we are transitioning this function in-house. We will maintain the outsourced function for back-up and peak periods.

Professional Marketing

As of December 31, 2000, our sales team consisted of 30 salespeople experienced in orthodontic product sales. Approximately 40 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 the Invisalign System to orthodontists since July 1999. Professional marketing consists of training orthodontists and assisting them in building their practices. In addition, we are creating awareness of the Invisalign System among general practice dentists to help them refer patients to orthodontists.

As of February 2001, we had trained approximately 6,400 orthodontists, representing over 70% of the practicing orthodontists in the U.S. and Canada. As of February 28, 2001, nearly 2,600 orthodontists had submitted one or more cases to us. Our sales and orthodontic teams conduct training primarily in a workshop format. The key topics covered in training include case selection criteria, 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.

The Invisalign System relies on the same orthodontic principles that apply to traditional treatment, and we present our training material in a manner consistent with orthodontists' 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 orthodontists confirms our belief that training represents a minimal barrier to adoption for most orthodontists.

After training, sales representatives follow up with orthodontists to ensure that their staff is prepared to handle Invisalign System cases. Such follow up may include assisting orthodontists in taking dental impressions, establishing an Internet connection and familiarizing them with our website. Sales representatives may also provide practice-building assistance, including helping orthodontists 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.

To facilitate adoption of the Invisalign System, we sell machines to some of our customers to assist them in preparing the impressions required for submission of Invisalign cases. These machines are manufactured by ESPE America, Inc.

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

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

General dentists play an important role in informing their patients about orthodontics and are a key source of referrals to orthodontists. There are over 120,000 active general practice dentists in the U.S. and Canada. We have commenced educating these general dentists and staff to encourage them to recommend the Invisalign System to their patients. We communicate with the dental community using a combination of direct mail, telemarketing, journal advertising and trade shows.

Research and Development

As of December 31, 2000, our research and development team consisted of 17 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 the Invisalign System, establishing the ability of the System 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 clinical applicability of the Invisalign System, enhancing the software used in the manufacturing process and enhancing our line of products.

We are conducting a number of post-marketing studies to establish the effectiveness of the System in comprehensively treating unusually severe cases of malocclusion. We are developing a next-generation of 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, 2001, we have two issued U.S. patents and 46 pending U.S. patent applications. We have two foreign-issued patents and 111 pending foreign patent applications. One of our issued U.S. patents is written to 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. 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 our Invisalign System. However, we compete for the attention of orthodontists with manufacturers of other orthodontic products. These suppliers include manufacturers of traditional orthodontic appliances such as 3M Company, Sybron Dental Specialities 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
- .orthodontist chair time.

We believe that the Invisalign System compares favorably with respect to each of these factors.

Government Regulation

FDA Regulation of Medical Devices. The Invisalign System 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.

The Invisalign System 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 the Invisalign System 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, our Invisalign System received 510(k) Pre-Market Notification by the FDA, allowing us to market the Invisalign System in the U.S. In addition, we have recently applied for FDA registration for our Santa Clara facility. The manufacture and distribution of the Invisalign System 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.

When introduced in Europe, the Invisalign System will be 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 are working toward the certification of our manufacturing process under ISO 9001, which will facilitate the commercialization of the Invisalign System 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 orthodontist 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, 2000, we had approximately 1,065 employees, of whom approximately 455 were employed in the U.S., with the balance employed in Pakistan. Of our U.S. employees, approximately 250 are employed in manufacturing, 30 are software engineers, 30 are sales representatives, 40 are customer support staff, 17 are employed in research and development and 88 are employed in various management, administrative and support positions.

We employ a staff of approximately 610 employees in our two facilities in Pakistan, most of whom are computer operators and approximately 50 of whom are dental and orthodontic supervisors. We believe that our relations with our employees are good.

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 the Invisalign System and developing our manufacturing and customer support resources. We also spent significant funds on clinical trials and training programs to train orthodontists in the use of the Invisalign System. We expect to have net losses and negative operating cash flows for at least the next 18 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 orthodontist training staff;
- 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 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 have only recently begun selling our Invisalign System in commercial quantities. 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 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 fall 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 our Invisalign System declines or fails to develop as we expect, our revenue will decline.

We expect that revenue from the sale of our Invisalign System will continue to account for a substantial portion of our total revenue. Continued and widespread market acceptance of our System is critical to our future success. The Invisalign System may not achieve market acceptance at the rate at which we expect, or at all, which could reduce our revenue.

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

As of February 28, 2001, nearly 2,600 orthodontists have submitted one or more cases to us. Our success depends upon increasing acceptance by orthodontists and dentists of the Invisalign System. The Invisalign System requires orthodontists 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 our Invisalign System has only been in clinical testing since July 1997 and commercially available since July 1999, orthodontists may be reluctant to adopt it until more historical clinical results are available. Also, increasing adoption by orthodontists 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 the Invisalign System could result in significant adverse publicity and consequently in reduced acceptance by orthodontists. If our Invisalign System does not achieve growing acceptance in the orthodontic and dental communities, our operating results will be harmed.

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

Our Invisalign System 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 orthodontists and patients regarding our Invisalign System as both an alternative to braces and as a clinical method for treatment of malocclusion, our success will depend upon the rapid acceptance of our System 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. If consumers prove unwilling to adopt our Invisalign System as rapidly or in the numbers that we anticipate, our operating results will 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, 2001, we have two issued U.S. patents and 46 pending U.S. patent applications. We have two foreign-issued patents and 111 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 the Invisalign System 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 have limited experience in manufacturing our products and if we encounter manufacturing problems or delays, our ability to generate revenue will be limited.

We have manufactured a limited number of our products to date. Our manufacturing processes rely on complex three-dimensional scanning, geometrical manipulation and modeling technologies that have historically not been used on the scale we require. Each item that we manufacture is geometrically unique and we have not manufactured our products in the commercial volumes which will be required to make us profitable. Accordingly, we may be unable to establish or maintain reliable, high-volume manufacturing capacity. Even if this capacity can be established and maintained, the cost of doing so may increase the cost of our products. We may encounter difficulties in scaling up production to meet demand, including:

- problems involving production yields;
- shortages of key manufacturing equipment;
- shortages of qualified personnel, in particular dental and orthodontic personnel;

. failure to develop new software processes; and

. compliance with applicable Quality System regulations enforced by the FDA.

Our manufacturing process is complex. Since all our products are designed for individual patients, we manufacture our products to fill purchase orders rather than maintaining inventories of assembled products. If demand for our products exceeds our manufacturing capacity, we could develop a substantial backlog of customer orders. If we are unable to establish and maintain larger-scale manufacturing capabilities, our ability to generate revenue will be limited and our reputation in the marketplace would be damaged.

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 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. We employ approximately 610 people in Lahore, Pakistan, in this effort. We anticipate that we will need to expand our personnel and facilities in Pakistan in order to scale our manufacturing operations. 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:

. difficulties in staffing and managing international operations;

. controlling quality of manufacture;

. political, social and economic instability;

. interruptions and limitations in telecommunication services;

. product 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, our operating results 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 50 employees as of June 30, 1999 to approximately 1,065 employees as of December 31, 2000. In mid-2000, we approved major renovations and expansions to our existing facilities. 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 our Invisalign System. 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 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. Please see "Business--Government Regulation" for a more detailed discussion of the regulations that govern our industry.

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. See "Business--Government Regulation."

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.

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.

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, negative operating cash flows since inception and have not achieved profitability. As of December 31, 2000, we had an accumulated deficit of approximately $108.6 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 the U.S. and internationally, while controlling our expenses. The failure to win increased acceptance by orthodontists and dentists of the Invisalign System 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. According, 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.

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 March 19, 2001, our executive officers, directors and principal stockholders beneficially owned, in total, approximately 54% of our outstanding common stock. As a result, these stockholders are able to exercise control over 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 70,000 square feet of space where we house our manufacturing, customer support, software engineering and administrative personnel. The lease for the larger of the two Santa Clara facilities will expire in August 2005, while the lease for the smaller facility, roughly 15,000 square feet, will expire in August 2002. The combined monthly rent for the Santa Clara facilities is approximately $240,000.

We operate two facilities in Pakistan, both in the city of Lahore. Each facility accommodates approximately 325 employees. 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.

ITEM 3. LEGAL PROCEEDINGS

On February 22, 2001 a complaint was filed against us by Jon L. Richter in the United States District Court for the Eastern District of Pennsylvania. Mr. Richter, a general practice dentist, purports to sue on behalf of himself and all licensed dentists in the U.S., excluding orthodontists. Mr. Richter alleges that we reached an agreement with unspecified orthodontists to restrict the sales of the Invisalign System only to orthodontists, and thereby violated U.S. antitrust laws. The complaint seeks injunctive relief and damages. While the Invisalign System is not available to dentists, we have not entered into any agreements with orthodontists restricting the distribution of the Invisalign System. For this reason, among others, we believe the lawsuit is without merit.

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. 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 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.

On December 12, 2000 an Action by Written Consent of the Stockholders of Align Technology, Inc. was circulated to the Company's stockholders. The matter which was voted on was an amendment of the Company's 1997 Equity Incentive Plan to increase the number of shares authorized under the Plan by 1,300,000 shares. The amendment to the 1997 Equity Incentive Plan was approved by a majority of the holders of the Company's common stock as well as each series of the Company's preferred stock, with the holders of Series C preferred stock approving the amendment with greater than 67% of the shares voted.

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.

As of March 19, 2001 there were 540 holders of record of our common stock.

We have never paid or declared any cash dividends on our common stock or other securities and do not anticipate paying cash dividends in the foreseeable future. We currently intend to retain all future earnings, if any, for use in the operations of our business.

(b) Sales of Unregistered Securities

During the year ended December 31, 2000, we granted options to purchase 5,890,000 shares of common stock to existing and new employees and consultants at a weighted average exercise price of $0.86 per share. The options were granted pursuant to our 1997 Stock Incentive Plan.

In May, June and October 2000, we sold 9,535,052 shares of Series D preferred stock to a group of investors for a total cash consideration of $101,272,000.

The foregoing transactions did not involve any underwriters, underwriting discounts or commissions, or any public offering, and we believe that each transaction was exempt from the registration requirements of the Securities Act by virtue of Section 4(2) and Regulation D promulgated thereunder or Rule 701 pursuant to compensatory benefit plans and contracts relating to compensation as provided under Rule 701. The recipients in each transaction represented their intention to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof, and appropriate legends were affixed to the share certificates and instruments issued in these transactions. All recipients had adequate access, through their relationships with us, to information about us.

(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 $128,501,055 after deducting the underwriting discounts and commissions of $9,672,123, and exclude expenses incurred in connection with the offering of approximately $2,300,000. 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. No proceeds from the sale of registered securities were received in the year ended December 31, 2000.

ITEM 6. SELECTED CONSOLIDATED FINANCIAL DATA.

The selected consolidated statement of operations data for 2000, 1999 and 1998 and consolidated balance sheet data as of December 31, 2000 and 1999 set forth below have been derived from our consolidated financial statements, and are qualified by reference to our consolidated financial statements audited by PricewaterhouseCoopers LLP, independent accountant included herein. The selected consolidated statement of operations data for the period from inception (April 3, 1997) to December 31, 1997 and the consolidated balance sheet data as of December 31, 1997 and 1998 have been derived from our audited financial statements not included herein. These historical results are not necessarily indicative of the results of operations to be expected for any future period.

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

	Year Ended December 31,			Period from Inception (April 3, 1997) to December 31,
	2000	1999	1998	1997
Consolidated Statement of Operations Data:				
Net Revenue	$ 6,741	$ 411	$ --	$ --
Loss from operations	(81,115)	(14,705)	(3,951)	(688)
Net loss	(88,748)	(15,415)	(3,775)	(664)
Dividend related to beneficial conversion feature of preferred stock	(53,516)	--	--	--
Net loss available to common stockholders	(142,264)	(15,415)	(3,775)	(664)
Net loss per share available to common stockholders, basic and diluted	$ (25.64)	$ (3.65)	$ (1.33)	$(0.43)
Shares used in computing net loss per share available to common stockholders, basic and diluted	5,548	4,218	2,842	1,542

	December 31,			
	2000	1999	1998	1997
Consolidated Balance Sheet Data:				
Working capital	$ 18,273	$ 10,027	$ 6,815	$1,370
Total assets	70,561	17,091	8,117	1,642
Total long term liabilities	1,455	3	10	4
Convertible preferred stock and preferred stock warrants	130,691	32,755	12,147	2,164
Stockholders' deficit	(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 the Invisalign System, a proprietary new system for treating malocclusion, or the misalignment of

teeth. In July 1999, we commenced commercial sales of our Invisalign System. Prior to July 1999, we devoted nearly all our resources to developing our software and manufacturing processes, clinical trials of the Invisalign System and to building our sales force, customer support and management teams. We exited the development stage in July 2000.

The Invisalign System has two components: ClinCheck and Aligners. ClinCheck is an Internet-based application that allows orthodontists 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 an orthodontist using ClinCheck.

In the third quarter of 1999, we recognized revenue for the first time from the sale of the Invisalign System 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 an exploratory stage, 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, difficulties in staffing and managing international operations, controlling quality of manufacture, political, social and economic instability, 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 Mexico by the fact that our operations there are governed under the provisions of the North American Free Trade Agreement, or NAFTA.

We incurred net losses of $88.7 million in 2000, $15.4 million in 1999 and $3.8 million in 1998. As of December 31, 2000, we had an accumulated deficit of $108.6 million. We expect to have net losses and negative operating cash flows for at least the next 18 months due, in part, to our national consumer advertising campaign, the expansion of manufacturing capacity and continued research and development efforts.

We earn revenue primarily from the sale of our Invisalign System. Our revenue consists of the ClinCheck fee and the charge for each Aligner. We charge orthodontists a fixed fee for the treatment simulation viewed via ClinCheck on our website, Invisalign.com. This fee is invoiced when the orthodontist orders ClinCheck prior to the production of Aligners. In addition, we charge orthodontists a fee for Aligners as we ship them. Fees from the sale of ClinCheck and Aligners, taken together, are treated as revenue from a single System and are recognized ratably as batches of Aligners are shipped to the orthodontist.

We also earn ancillary revenue from the sale to orthodontists of dental impression machines. To facilitate adoption of the Invisalign System, we sell machines to some of our customers to assist them in preparing the impressions required for submission of Invisalign cases. These machines, which cost approximately $600 each, are manufactured by ESPE America, Inc. Many of our customers have adequate dental impression making equipment or pay general dentists to take impressions on their behalf and, as such, do not purchase an impression machine from us.

To date, we have shipped Aligners in batches. The first batch, which typically represents the first several months of treatment, is produced once the prescribing orthodontist approves ClinCheck. Thereafter, Aligners are sent at approximately six month intervals until treatment is complete.

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. For orders placed subsequent to notification of our change to single batch shipments, all of the revenue associated with a given case, including ClinCheck fees, will be recognized at the time the Aligners are shipped. Payment terms will range from 30 days from case acceptance to net 90 days from Aligner shipment.

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.

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.

Results of Operations

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 revenue for the first time in the third quarter of 1999. For the year ended December 31, 2000, revenue of $5.4 million was derived from the sale of our Invisalign System compared to revenue of $98,000 for the year ended December 31, 1999. The balance of our revenue 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. As we employ this manufacturing capacity to produce higher volumes of the Invisalign System, combined with the resultant manufacturing efficiencies and our recent price increase, we expect to record positive gross margins. We currently believe it will be at least 12 months before we are able to achieve positive gross margins.

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 expense 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 the Invisalign System, include the costs of researching processes to manufacture our product.

Interest and other income (expense), net. Net interest and other expense increased to $7.6 million for the year ended December 31, 2000 compared to $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. In January 2001, we recorded non-cash interest expense of $1.8 million related to the beneficial conversion feature embedded in convertible subordinated notes.

Dividend related to beneficial conversion feature of preferred stock. In 2000 we issued 9,535,052 shares of Series D preferred stock. The difference between the conversion price and the fair value per share of the common stock on the commitment date 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. In January 2001, we recorded the final dividend related to the beneficial conversion feature of preferred stock of $11.2 million.

Comparison of Years Ended December 31, 1999 and 1998:

Revenues. Revenues were recorded for the first time in 1999. For the year ended December 31, 1999, we recorded $411,000 in revenues from sales of the Invisalign System and related ancillary products. Approximately $98,000 was derived from the sale of the Invisalign System products. The balance of our revenue, or $313,000, represented sales to orthodontists of dental impression machines.

Cost of revenues. We incurred cost of revenues of $1.8 million relating to the manufacture of products sold for the year ended December 31, 1999. No cost of revenues was incurred in 1998.

Sales and marketing. Sales and marketing expense increased to $5.7 million in 1999 compared to $133,000 in 1998, primarily due to the hiring of our sales force, the training of doctors to support our commercial launch and the testing of direct advertising in two markets. Sales and marketing expenses in 1998 were insignificant because we had not commercially launched our product.

General and administrative. General and administrative expenses for the year ended December 31, 1999 increased to $3.5 million compared to $2.3 million for the year ended December 31, 1998, primarily due to growth in our administrative staff, rent on our facilities and other general expenses as we prepared for commercial launch of the Invisalign System.

Research and development. Research and development expenses for the year ended December 31, 1999 increased to $4.2 million compared to $1.5 million for the year ended December 31, 1998, primarily due to the development of manufacturing processes and continuation of our clinical trials.

Interest and other income (expense), net. Net interest and other expense for the year ended December 31, 1999 increased to $710,000 compared to net interest and other income of $176,000 in 1998 primarily due to non-cash interest expense created by the amortization of warrants issued in connection with a line of credit.

Income Taxes

We have not incurred any income tax expense to date since we have not been profitable. As of December 31, 2000, we had federal and state net operating loss carryforwards of $75.9 million. As of December 31, 2000 we had recorded a full valuation allowance for our existing net deferred tax assets due to uncertainties regarding their realization. We also have federal and state research tax credit carryforwards of $1.1 million as of December 31, 2000. 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

Historically, we have funded our operations with the proceeds from the sale of our common and preferred stock, equipment leases and bridge loans. As of December 31, 2000, we had $12.5 million in cash, cash equivalents and short-term marketable securities and an accumulated deficit of $108.6 million. Additionally, we have $16.0 million of restricted cash of which $15.5 million is held in an escrow account to fund our national advertising campaign.

Net cash used in operating activities totaled $58.8 million in 2000, $11.6 million in 1999 and $3.8 million in 1998. In each of these years net cash used by operating activities consisted primarily of net operating losses, partially offset by increases in accounts payable and accrued liabilities, depreciation and amortization, and amortization of deferred stock-based compensation. Additionally, in 2000 operating losses were partially offset by non-cash interest expense derived from a beneficial conversion feature on a convertible subordinated note, subsequently converted to Series D preferred stock.

Net cash used in investing activities totaled $41.6 million in 2000, $3.6 million in 1999 and $3.8 million in 1998. In each of these years, net cash used in investing activities consisted primarily of purchases of property and equipment and marketable securities offset by sales and maturities of 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. These funds are due to be released to cover expenses related to our national advertising campaign over the next three quarters.

Net cash from financing activities was $96.4 million in 2000, $19.6 million in 1999 and $10.0 million in 1998. In May 2000, we sold $14.0 million of convertible promissory notes to preferred stockholders. Also in May 2000, the convertible promissory notes were converted to preferred stock. In May, June and October 2000, we sold $83.1 million of preferred stock to investors, net.

We expect that our operating expenses will increase with an overall increase in the level of our business activity, including increased sales and the related costs of products sold, the launch of our national consumer advertising campaign, continuing efforts to expand our manufacturing capacity, research and development and other costs. We expect the change of pattern of Aligner shipments in February 2001 will have a negligible effect on our cash flows. In addition, we may use cash to fund acquisitions of complementary businesses or technologies.

In January 2001, we completed our initial public offering of 10 million shares of common stock. In March 2001, the underwriters exercised an overallotment option for 628,706 shares. Net proceeds to us were approximately $126.2 million. We believe the net proceeds from the offering will be sufficient to meet our operating, working capital and capital expenditure requirements for at least the next 12 months. Thereafter, we may find it necessary to obtain additional equity or debt financing. In the event additional financing is required, we may not be able to raise it on acceptable terms or at all.

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							
	2000				1999			
	March 31	June 30	September 30	December 31	March 31	June 30	September 30	December 31
	(in thousands, except per share data)							
Revenues	$ 629	$ 1,397	$ 1,439	$ 3,276	$ --	$ --	$ 77	$ 334
Gross loss	(1,397)	(2,810)	(3,870)	(5,433)	--	--	(280)	(1,063)
Operating loss	(8,048)	(15,819)	(22,127)	(35,121)	(1,650)	(2,541)	(3,883)	(6,631)
Net loss	(8,080)	(23,392)	(21,839)	(35,437)	(1,582)	(2,781)	(4,210)	(6,842)
Net loss available to common stockholders	(8,080)	(67,542)	(21,839)	(44,803)	(1,582)	(2,781)	(4,210)	(6,842)
Net loss per share available to common stockholders, basic and diluted	(1.55)	(12.31)	(3.84)	(7.39)	(0.42)	(0.69)	(0.96)	(1.45)
Shares used in computing per share amounts, basic and diluted	5,225	5,489	5,682	6,066	3,743	4,061	4,379	4,710

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 the Invisalign system 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.

Recent Accounting Pronouncements

In June 1998, the Financial Accounting Standards Board, or FASB, issued Statement of Financial Accounting Standards No. 133, "Accounting for Derivative Instruments and Hedging Activities," or SFAS No. 133. SFAS No. 133 establishes accounting and reporting standards for derivative investments, including certain derivative instruments embedded in other contracts, and for hedging activities. In July 1999, the FASB issued Statement of Financial Accounting Standards No. 137, "Accounting for Derivative and Hedging Activities--Deferral of the Effective Date of FASB Statement No. 133," or SFAS No. 137. SFAS No. 137 deferred the effective date of SFAS No. 133 until fiscal years beginning after June 15, 2000. We will adopt SFAS No. 133 during fiscal 2001. To date, we have not engaged in derivative or hedging activities and do not expect SFAS No. 133 to have a material impact upon our financial results.

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, 2000 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, 2000 carry a fixed interest rate of 6.53% and 11.15% per annum with principle payments due in 48, respectively 60 equal annual installments 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, 2000)						
	2001	2002	2003	2004	2005	Total	Fair value
	(in thousands)						
ASSETS:							
Cash, cash equivalents..	$2,828	$ --	$ --	$ --	$ --	$2,828	$2,828
Short-term marketable securities.....	9,633	--	--	--	--	9,633	9,633
Weighted average interest rate.....	1.94%	--	--	--	--		
Long-term marketable securities.....	$ --	$6,251	$ --	$ --	$ --	$6,251	$6,251
Weighted average interest rate.....	--	6.84%	--	--	--		
LIABILITIES:							
Fixed rate debt lease obligation.....	$ 579	$ 574	$ 574	$ 348	$ 130	$2,205	$1,900
Weighted average interest rate.....	8.30%	8.30%	6.53%	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 $3.6 million of our expenses are related to operations outside the United States, denominated in currencies other than the U.S. dollar.

- Our investments in a foreign subsidiary being directly from the U.S. parent, resulting in U.S. dollar investments in foreign currency functional companies.

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.

ALIGN TECHNOLOGY, INC. AND SUBSIDIARY

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REPORT OF INDEPENDENT ACCOUNTANTS

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

In our opinion, the accompanying consolidated balance sheets and the related consolidated statements of operations, of stockholders' deficit and of cash flows present fairly, in all material respects, the financial position of Align Technology, Inc. and subsidiary at December 31, 2000 and 1999, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2000, 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 9, 2001, except for Note 13
which is as of March 15, 2001

ALIGN TECHNOLOGY, INC. AND SUBSIDIARY

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

	December 31, 2000	December 31, 1999
ASSETS		
Current assets:		
Cash and cash equivalents	$ 2,828	$ 6,832
Restricted cash	15,986	340
Marketable securities, short-term	9,633	5,253
Accounts receivable, net of allowance for doubtful accounts of $ 494 and $33 at December 31, 2000 and 1999, respectively	4,465	314
Inventories	2,024	366
Deferred costs	2,431	--
Other current assets	3,995	669
Total current assets	41,362	13,774
Property and equipment, net	21,100	3,317
Marketable securities, long-term	6,251	--
Other assets	1,848	--
Total assets	$ 70,561	$ 17,091
LIABILITIES, CONVERTIBLE PREFERRED STOCK, WARRANTS AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$ 5,541	$ 1,572
Accrued liabilities	14,753	2,050
Deferred revenue	2,350	119
Current portion of capital lease obligations	445	6
Total current liabilities	23,089	3,747
Capital lease obligations, net of current portion	1,455	3
Total liabilities	24,544	3,750
Commitments and contingencies (Note 4)		
Convertible preferred stock:		
$0.0001 par value; Authorized: 27,211 shares; Issued and outstanding: 25,788 and 16,253 shares at December 31, 2000 and 1999, respectively, (aggregate liquidation preference: $134,306 and $32,996 at December 31, 2000 and 1999, respectively)	128,873	31,713
Preferred stock warrants	1,818	1,042
	130,691	32,755
Stockholders' deficit:		
Common stock: $0.0001 par value; Authorized: 120,000 shares; Issued and outstanding: 9,622 and 5,644 shares at December 31, 2000 and 1999, respectively	1	1
Additional paid-in capital	105,828	2,219
Deferred stock-based compensation	(80,160)	(1,780)
Notes receivable from stockholders	(1,814)	--
Accumulated other comprehensive income	73	--
Accumulated deficit	(108,602)	(19,854)
Total stockholders' deficit	(84,674)	(19,414)
Total liabilities, convertible preferred stock, warrants, and stockholders' deficit	$ 70,561	$ 17,091

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

ALIGN TECHNOLOGY, INC. AND SUBSIDIARY

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

	Year Ended December 31,		
	2000	1999	1998
Revenues:			
Revenue--Invisalign	$ 5,436	$ 98	$ --
Revenue--Ancillary products	1,305	313	--
Total revenues	6,741	411	--
Cost of revenues:			
Cost of revenue and manufacturing costs--Invisalign	19,031	1,508	--
Cost of revenue--Ancillary products	1,220	246	--
Total cost of revenues	20,251	1,754	--
Gross loss	(13,510)	(1,343)	--
Operating expenses:			
Sales and marketing	40,445	5,688	133
General and administrative	17,991	3,474	2,344
Research and development	9,169	4,200	1,474
Total operating expenses	67,605	13,362	3,951
Loss from operations	(81,115)	(14,705)	(3,951)
Interest income	2,306	362	185
Interest expense	(9,807)	(986)	--
Other expense	(132)	(86)	(9)
Net loss	(88,748)	(15,415)	(3,775)
Dividend related to beneficial conversion feature of preferred stock	(53,516)	--	--
Net loss available to common stockholders	$(142,264)	$(15,415)	$(3,775)
Net loss per share available to common stockholders, basic and diluted	$ (25.64)	$ (3.65)	$ (1.33)
Shares used in computing net loss per share available to common stockholders, basic and diluted	5,548	4,218	2,842

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

ALIGN TECHNOLOGY, INC. AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' DEFICIT
For the years ended December 31, 2000, 1999 and 1998 (in thousands)

	Common Stock		Additional Paid-In	Deferred Stock-based	Notes Receivable from	Accumulated Other Comprehensive	Accumulated	
	Shares	Amount	Capital	Compensation	Stockholders	Income	Deficit	Total
Balance at December 31, 1997	5,999	$ 1	$ 2	$ --	$ --	$ --	$ (664)	$ (661)
Net loss	--	--	--	--	--	--	(3,775)	(3,775)
Stock options exercised	92	--	5	--	--	--	--	5
Repurchase of common stock	(740)	--	(2)	--	--	--	--	(2)
Issuance of common stock	4	--	--	--	--	--	--	--
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)

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

ALIGN TECHNOLOGY, INC. AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Year Ended December 31,		
	2000	1999	1998
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net loss	$(88,748)	$(15,415)	$(3,775)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	2,513	559	115
Amortization of deferred stock-based compensation	13,372	394	--
Amortization of accelerated vesting of stock options	429	--	--
Gain on sale of property	--	--	32
Loss on retirement on fixed assets	98	--	--
Realized loss on marketable securities	10	--	--
Allowance for doubtful accounts	461	33	--
Amortization of capitalized financing costs and debt discount	834	984	--
Non-cash interest income on notes receivable from stockholders	(23)	--	--
Non-cash interest expense on convertible subordinated note	8,648	--	--
Changes in operating assets and liabilities:			
Accounts receivable	(4,612)	(347)	--
Deferred costs	(2,431)	--	--
Inventories	(1,658)	(366)	--
Other current assets	(1,425)	(187)	(415)
Accounts payable	4,401	672	167
Accrued liabilities	7,100	1,921	84
Deferred revenue	2,231	119	--
Net cash used in operating activities	(58,800)	(11,633)	(3,792)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchase of property and equipment	(13,571)	(2,463)	(973)
Increase in restricted cash	(15,646)	(340)	--
Purchase of marketable securities	(19,645)	(5,906)	(6,451)
Maturities of marketable securities	1,250	3,365	2,665
Proceeds from sale of marketable securities	7,827	1,740	804
Proceeds from sale of property	--	--	198
Change in other assets	(1,848)	--	--
Net cash used in investing activities	(41,633)	(3,604)	(3,757)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from issuance of common stock	1,037	42	5
Proceeds from issuance of convertible preferred stock, net of issuance costs	83,085	18,740	9,983
Proceeds from note receivable for preferred stock	--	76	--
Repurchase common stock	(48)	(2)	(2)
Proceeds from convertible subordinated notes	14,000	750	--
Payments for incurred IPO costs	(1,327)	--	--
Proceeds from draw down of line of credit	5,000	--	--
Repayment of line of credit	(5,000)	--	--
Payments on capital lease obligations	(318)	(8)	(3)
Net cash provided by financing activities	96,429	19,598	9,983
Net (decrease) increase in cash and cash equivalents	(4,004)	4,361	2,434
Cash and cash equivalents, beginning of year	6,832	2,471	37
Cash and cash equivalents, end of year	$ 2,828	$ 6,832	$ 2,471

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

ALIGN TECHNOLOGY, INC. AND SUBSIDIARY

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 the Invisalign System (the "System"), used for treating malocclusion, or the misalignment of teeth. The System 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.

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 financial statements have been restated to reflect the stock split.

On January 25, 2001, the Company launched its initial public offering of 10,000,000 shares of common stock at $13.00 per share. The aggregate proceeds of the offering amount to $120.9 million after deducting underwriting discounts and commissions and exclude expenses incurred in connection with the offering of approximately $2.3 million.

Note 2 Summary of Significant Accounting Policies

Basis of consolidation

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

Use of estimates

The preparation of financial statements in conformity with generally accepted accounting principles 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, 2000 is primarily comprised of $ 15.5 million held in escrow for deposits on future advertising (Note 4) and $533,000 for security on customer credit card transactions, on lease of manufacturing facility and others. Restricted cash as of December 31, 1999 primarily comprised amounts for security on customer credit card transactions 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' 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 $73,000 in unrealized gains as of December 31, 2000 included in the comprehensive income in stockholders' deficit and no unrealized gains or losses as of December 31, 1999.

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	

The cost and fair value of short-term available-for-sale securities at December 31, 1999 are as follows (in thousands):

	Cost	Fair Value
Commercial paper	$1,239	$1,239
Corporate notes	997	997
Medium term notes	3,017	3,017
	$5,253	$5,253

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

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

Inventory

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 range from three to seven years. 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 used 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." 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 $397,000 and $35,000 had been capitalized as of December 31, 2000 and 1999, respectively. Amortization of web site development costs commenced in July 2000 upon launch of the web site. Accumulated amortization as of December 31, 2000 amounted to $66,000.

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 Statement of Operations in accordance with SOP 98-1.

There was other software developed for internal use and capitalized as of December 31, 2000 in the amount of $111,000. Amortization has not yet been started as this software is not in use. No other software developed for internal use was capitalized and no amortization was needed in the year ended December 31, 1999.

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. The Company has also applied Emerging Issues Task Force Issue No. 00-10 "Accounting for Shipping and Handling Fees and Costs" retroactively to all periods presented.

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.

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 and December 2000 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 year ended December 31, 2000 and 1999 advertising costs totaled $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. In 2000, the effect of foreign currency exchange rate fluctuations on the Company's cash and cash equivalents denominated in foreign currencies was not material.

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 Employees" ("APB 25") and complies with the disclosure provisions of Statement of Financial Accounting Standards No. 123, "Accounting for Stock-Based Compensation" ("SFAS 123").

Under APB 25, compensation expense for grants to employees is based on the difference, if any, on the date of the grant, between the fair value of the Company's stock and the option's exercise price. SFAS 123 defines a "fair value" based method of accounting for an employee stock option or similar equity investment. 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 operates in one segment, using one measurement of profitability to manage its business. There were no export sales.

The Company maintains two facilities in Pakistan which generate no revenues and are comprised of $1,497,000 and $256,000 of identifiable assets as of December 31, 2000 and 1999, respectively.

Net loss and pro forma 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. 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.

Pro forma net loss per share for the year ended December 31, 2000 was computed using the weighted-average number of shares of common stock outstanding, including the pro forma effect of the automatic conversion of all of the Company's preferred stock into shares of the Company's common stock effective upon the closing of the Company's initial public offering as if such conversion occurred on January 1, 2000 or at the date of original issuance, if later.

In accordance with the Company's certificate of incorporation, as amended in connection with the Series D preferred stock sale, as of December 31, 2000, as the Company has issued 1,257,614 shares of common stock in excess of the 3,331,978 shares of common stock permitted, as defined in the certificate of incorporation, the Company will be required to issue additional 419,700 shares of common stock upon the conversion of the preferred stock.

The resulting pro forma adjustment includes an increase in the weighted-average shares used to compute pro forma basic net loss per share of total 21,269,000 shares for the year ended December 31, 2000.

The calculation of pro forma diluted net loss per share excludes warrants and stock options as their effect would be anti-dilutive.

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,		
	2000	1999	1998
Basic and diluted:			
Net loss available to common stockholders	$(142,264)	$(15,415)	$(3,775)
Weighted-average common shares outstanding	6,861	5,334	5,620
Less: Weighted-average shares subject to repurchase	1,313	1,116	2,778
Weighted-average shares used in basic and diluted net loss per share	5,548	4,218	2,842
Net loss per share available to common stockholders	$ (25.64)	$ (3.65)	$ (1.33)
Pro forma basic and diluted:			
Net loss	$ (88,748)		
Adjustments to reflect weighted-average effect of assumed conversion of preferred stock	21,269		
Weighted-average shares used in pro forma basic and diluted net loss per share	26,817		
Pro forma basic and diluted net loss per share	$ (3.31)		

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,		
	2000	1999	1998
Preferred stock (as if converted)	26,209	16,253	11,067
Options to purchase common stock	2,862	1,285	952
Common stock subject to repurchase	3,608	654	1,779
Warrants	646	533	--
	33,325	18,725	13,798

Recent accounting pronouncements

In June 1998, the FASB issued SFAS No. 133, "Accounting for Derivative Instruments and Hedging Activities." SFAS No. 133 establishes accounting and reporting standards for derivative investments, including certain derivative instruments embedded in other contracts, and for hedging activities. In July 1999, the FASB issued SFAS No. 137, "Accounting for Derivative and Hedging Activities--Deferral of the Effective Date of FASB Statement No. 133." SFAS No. 137 deferred the effective date of SFAS No. 133 until fiscal years beginning after June 15, 2000. The Company will adopt SFAS No. 133 during fiscal 2001. To date, the Company has not engaged in derivative or hedging activities and does not expect SFAS 133 to have a material impact upon financial results.

Note 3 Balance Sheet Components

Inventories consist of the following (in thousands):

	December 31,	
	2000	1999
Raw materials	$ 1,183	$ 73
Work in progress	294	--
Finished goods	547	293
	$2,024	$ 366

Other current assets consist of the following (in thousands):

	December 31,	
	2000	1999
Initial Public Offering costs	$1,884	$ --
Prepaid rent	245	175
Prepaid trade shows	420	--
Loan to officer	97	--
Notes receivable from stockholder of preferred stock	75	--
Other	1,274	494
	$3,995	$ 669

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

	December 31,	
	2000	1999
Clinical and manufacturing equipment	$12,372	$1,537
Computer hardware	4,809	1,580
Computer software	2,681	302
Furniture and fixtures	1,648	313
Leasehold improvements	2,580	275
	24,090	4,007
Less: Accumulated depreciation and amortization	(2,990)	(690)
	$21,100	$3,317

Property and equipment includes $2,220,040 and $18,957 of assets under capital leases at December 31, 2000 and 1999, respectively. Accumulated amortization of assets under capital leases totaled $333,862 and $9,607 at December 31, 2000 and 1999, respectively.

Depreciation expense was $2,513,000, $559,000 and $115,000 for the years ended December 31, 2000, 1999 and 1998, respectively.

Accrued liabilities consist of the following (in thousands):

	December 31,	
	2000	1999
Accrued marketing expenses	$ 5,592	$ 385
Accrued payroll and benefits	2,844	744
Accrued loss reserve on product sales	--	351
Accrued Initial Public Offering costs	557	--
Accrued costs for property and equipment acquired	5,046	--
Other	714	570
	$14,753	$2,050

Note 4 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 begins 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.

Total rent expense was $2,146,000, $295,000 and $147,000 for the years ended December 31, 2000, 1999 and 1998, 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 these leases as of December 31, 2000 are $3,112,000, $2,812,000, $2,268,000, $2,311,000, $1,177,000 and $66,000 for the years ended December 31, 2001, 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.

Software Development Commitments

In January 2001, the Company entered into a master software development and services agreement with Raindrop Geomagic, Inc. ("Raindrop"). Under the agreement, the Company will make non-refundable monthly payments of $250,000 to Raindrop in exchange for software development services, software source and object codes, documentation, software and other tangible and intangible work product. Additionally, at any time during the term of the agreement, the Company may obtain three fully paid-up, non-exclusive, non-terminable object code licenses for $240,000. The Company made an initial non-refundable payment of $600,000, of which $220,000 may be applied as a credit towards the $240,000 of license fees. The minimum term of the agreement is four months, after which the agreement may be terminated by either party without cause upon 30 days written notice.

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.

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

The Company is leasing equipment from a leasing company. Under the terms of the lease agreement, the capital lease obligation bears interest of 10.155% at December 31, 2000 and expires in October 2001.

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,	
2001	$ 579
2002	574
2003	574
2004	348
2005	130
Minimum lease payments	2,205
Less: Amount representing interest	(305)
Present value of minimum lease payments	1,900
Amount due within one year	(445)
Amount due after one year	$1,455

Note 5 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 (Note 6).

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 6). 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.

In August 1999, the Company entered into an agreement with a leasing company for a leasing line of credit of $1,000,000. Amounts borrowed under this agreement bear interest at a rate of 11.154% and are collateralized by leased assets. At December 31, 1999, the Company had not utilized this line of credit. At December 31, 2000, the Company leased one of the stereolithography machines against this leasing line of credit.

In August 1999, the Company entered into an agreement with a leasing company for a leasing line of credit of $2,000,000. Amounts borrowed under this agreement bear interest at a rate of 12.00% and are collateralized by leased assets. At December 31, 1999, the Company had not borrowed against this line of credit. The line of credit expired in June 2000.

Note 6 Convertible Preferred Stock

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.

Convertible preferred stock consists of the following (in thousands):

	December 31,	
	2000	1999
Series A: 4,350 shares authorized, issued and outstanding at December 31, 2000 and 1999 (liquidation preference at December 31, 2000 $2,175)	$ 2,164	$ 2,164
Series B: 7,650 shares authorized; 6,717 shares issued and outstanding at December 31, 2000 and 1999 (liquidation preference at December 31, 2000 $10,076)	10,059	10,059
Series C: 5,313 shares authorized; 5,186 shares issued and outstanding at December 31, 2000 and 1999 (liquidation preference at December 31, 2000 $20,745)	19,490	19,490
Series D: 9,898 shares and none authorized at December 31, 2000 and 1999, respectively, 9,535 shares and none issued and outstanding at December 31, 2000 and 1999, respectively (liquidation preference at December 31, 2000 $101,310)	97,160	--
	$128,873	$31,713

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." 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 ("Series D shares") 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.

In accordance with the Company's certificate of incorporation, as amended in connection with the Series D preferred stock sale, as of December 31, 2000, as the Company has issued 1,257,614 shares of common stock in excess of the 3,331,978 shares of common stock permitted, as defined in the certificate of incorporation, the Company will be required to issue additional 419,700 shares of common stock upon the conversion of the preferred stock. As a result, the additional shares issued upon conversion of Series D result in a beneficial conversion feature, calculated in accordance with Emerging Issues Task Force Issue No. 98-5. The Company recognized a deemed dividend based on the fair value of the common stock at the commitment date 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 previously converted.

As of January 25, 2001, because the Company has issued 3,591,458 shares of common stock in excess of the 3,331,978 shares of common stock permitted, as defined in the certificate of incorporation, the Company is required to issue 790,342 shares of common stock upon the conversion of the preferred stock in addition to 419,700 shares as of December 31, 2000. As a result, the Company recorded a deemed dividend based on the fair value of the common stock at the commitment date 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 previously converted, in January 2001.

Convertible subordinated note

During 1999, the Company issued $750,000 in convertible subordinated notes payable to certain preferred stockholders. The amount subsequently converted into 187,500 shares of Series C convertible preferred stock at $4.00 per share.

Convertible preferred stock

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

Voting rights

Holders of Series A, Series B, Series C and Series D preferred stock are 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, are 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 are 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, are 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 are 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, 2000.

Conversion rights

Shares of Series A, Series B, Series C and Series D preferred stock are convertible into common stock at the option of the holder or automatically upon a public offering of at least $75,000,000 of common stock or upon the written consent of the holders of more than two-thirds of the then outstanding shares of Series A, Series B, Series C and Series D preferred stock. The conversion rate is one share of common stock for one share of preferred stock (subject to certain adjustments). In the event of a sale of common stock below any preferred stock conversion price, such preferred stock conversion price shall be adjusted. In addition, in the event that the Company issues more than 3,331,978 additional shares of common stock, as defined, before the earlier of January 31, 2001, or the effectiveness of a registration statement, the Series D conversion price will be adjusted as of such date. As of December 31, 2000, the Company has issued 1,257,614 stock options above the 3,331,978 shares as defined above. As a result the Series D stockholders would receive an additional 419,700 shares of common stock upon conversion of the preferred stock.

Liquidation

In the event of liquidation or sale of the Company, each class of preferred stock shall be 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.

Holders of Series D preferred stock have preference over holders of Series A, Series B, Series C and common stockholders. Holders of Series C preferred stock have preference over holders of Series A and Series B preferred stock and common stockholders. Holders of Series B preferred stock have preference over holders of Series A preferred stock. Holders of Series A preferred stock have preference over common stockholders.

The remaining assets of the Company shall be distributed among all stockholders on an as-if-converted basis until such time as the Series D preferred stockholders have received $31.875 per share, Series C preferred stockholders have received $8.00 per share, the Series B preferred stockholders have received $4.50 per share and the Series A preferred stockholders have received $2.00 per share. The remaining assets of the Company shall then be distributed ratably to the common stockholders.

The following events are considered a liquidation: (i) any consolidation, merger or corporate reorganization in which the stockholders immediately prior to such transaction own less than 50% of the Company's voting power immediately after the transaction; or any transaction or series of related transactions in which in excess of 50% of the Company's voting power is transferred and (ii) a sale, lease or other disposition of all or substantially all of the Company's assets.

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 are exercisable for a period of ten years from the date of issuance or 5 years from the Company's initial public offering of common stock, whichever is shorter. 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 were 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 preferred stock at a price of $4.00 per share. The warrants are

exercisable for a period of ten years from the date of issuance or 5 years from the Company's initial public offering of common stock, whichever is shorter. 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.

Note 7 Common Stock

Common stock

The holders of common stock, voting as a separate class, may elect two members of the Board of Directors. Any additional members of the Board of Directors shall be elected by the holders of common stock and preferred stock voting together as a class.

The holders of common stock are also 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, 2000.

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 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, 2000 and 1999, 3,608,442 and 653,542 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.

Note 8 Stock Options

1997 Equity Incentive Plan

In April 1997, the Company adopted the 1997 Equity Incentive Plan (the "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.

Activity under the Plan is 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, 1997	1,335	195	$0.0451	9
Options granted	(1,009)	1,009	$0.1040	105
Options exercised	--	(92)	$0.0543	(5)
Options cancelled	160	(160)	$0.0500	(8)
Balances at December 31, 1998	486	952	$0.1061	101
Increase in pool	1,600	--	--	--
Options granted	(737)	737	$0.1953	144
Options exercised	--	(331)	$0.1269	(42)
Options cancelled	73	(73)	$0.1369	(10)
Balances at December 31, 1999	1,422	1,285	$0.1501	193
Increase in pool	5,600	--	--	--
Options granted	(5,890)	5,890	$0.8564	5,044
Options exercised	--	(4,121)	$0.6863	(2,828)
Options cancelled	192	(192)	$0.3345	(64)
Balances at December 31, 2000	1,324	2,862	$0.8194	2,345

The options outstanding and currently exercisable by exercise price at December 31, 2000 are as follows (in thousands, except per share data):

Options Outstanding and Exercisable		
Exercise Price	Number Outstanding and Exercisable	Weighted Average Remaining Contractual Life (Years)
$0.05	85	7.44
0.15	202	8.33
0.30	35	8.66
0.40	609	9.22
1.07	1,931	9.83
	2,862	

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 Incentive Stock Plan been determined based on the fair value at the grant date for awards during 2000, 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):

	December 31,		
	2000	1999	1998
Net loss available to common stockholders, as reported	$(142,264)	$(15,415)	$(3,775)
Net loss available to common stockholders, pro forma	$(142,363)	$(15,435)	$(3,777)
Net loss per share available to common stockholders, as reported, basic and diluted	$ (25.64)	$ (3.65)	$ (1.33)
Net loss per share available to common stockholders, pro forma, basic and diluted	$ (25.66)	$ (3.66)	$ (1.33)

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 with the following weighted assumptions:

	Year Ended December 31,		
	2000	1999	1998
Risk-free interest rate	5.17-6.71%	4.91-6.03%	4.22-5.63%
Expected life	5 years	5 years	5 years
Expected dividends	0%	0%	0%

Volatility was not included in the calculation of the fair value of options grants as the Company's equity securities were not publicly traded at the time of grant.

The weighted average per share fair values of options granted during the year ended December 31, 2000, 1999 and 1998 were $16.878, $3.285 and $0.06, respectively.

2001 Stock Incentive Plan

On January 4, 2001, the Board of Directors adopted the 2001 Stock Incentive Plan (the "2001 Plan"). 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. 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. No options have been granted under this plan as of December 31, 2000.

Employee Stock Purchase Plan

On January 4, 2001, the Board of Directors adopted the Employee Stock Purchase Plan (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. As of December 31, 2000, no shares of common stock have been purchased under the Purchase Plan.

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 will commence on January 25, 2001.

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 $87,687,000 related to options issued to employees to purchase common stock issued through December 31, 2000. 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, 2000 and 1999, the Company recorded amortization of stock-based compensation of $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 $4,065,000 related to options issued to consultants to purchase common stock issued through December 31, 2000. The compensation expense is being recognized over the option vesting period of four years, using the method presented by FIN 28. For the years ended December 31, 2000 and 1999, the Company recorded amortization of stock-based compensation of $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,	
	2000	1999
Cost of revenues	$ 2,939	$ 80
Sales and marketing	2,357	111
General and administrative	5,345	106
Research and development	2,731	97
	$13,372	$394

There was no amortization of deferred stock-based compensation for the year ended December 31, 1998.

From January 1, 2001 through January 25, 2001, the Company granted 333,844 options to purchase common stock under its 1997 Plan, and additional option grants outside of the 1997 Plan, which were approved by the stockholders prior to the Initial Public Offering, 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 granted under the 1997 Plan were issued at an exercise price of $1.07 per share, and as a result the Company will record gross incremental deferred stock-based compensation of $4.0 million in the first quarter of 2001.

Accelerated Vesting

During the fiscal 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 $429,000 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

No provision for federal or state income taxes has been recorded for the year ended December 31, 2000 and 1999 as the Company incurred net operating losses.

Deferred tax assets and liabilities consist of the following (in thousands):

	Year Ended December 31,		
	2000	1999	1998
Deferred tax assets:			
Start-up costs	$ 1,920	$ 2,514	$ 1,014
Net operating loss carryforwards	28,830	3,968	695
Research and development credit	1,128	606	219
Other	645	181	(4)
Deferred tax assets	32,523	7,269	1,924
Less: Valuation allowance	(32,523)	(7,269)	(1,924)
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 $25,254,000, $5,345,000 and $1,635,000 during 2000, 1999 and 1998, respectively.

At December 31, 2000, 1999 and 1998, the Company had federal and state net operating loss carry forwards of approximately $75,912,000, $11,531,000 and $1,700,000, 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, 2000, 1999 and 1998, the Company had federal and state research and experimentation tax credit carry forwards of approximately $1,128,000, $606,000 and $219,000, 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,		
	2000	1999	1998
Taxes paid	$ 1	$ 1	$ 4
Interest paid	$ 382	$ 614	$ --
Non-cash investing and financing activities:			
Note receivable for preferred stock	$ 75	$ --	$ 76
Note receivable for common stock	$ 1,791	$ --	$ --
Fixed assets acquired under capital lease	$ 2,209	$ --	$ 14
Fixed assets acquired with accounts payable or accrued liabilities	$ 5,257	$ 643	$ --
Accrual for IPO costs	$ 557	$ --	$ --
Issuance of warrants in conjunction with line of credit financing	$ 776	$1,042	$ --
Deferred stock-based compensation	$91,752	$2,174	$ --
Conversion of convertible subordinated notes into convertible preferred stock	$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 is due on demand, but in no event later than September 19, 2001. However, the Company plans to forgive the loan as of the first anniversary of the issuance date.

Employee Notes Receivable

In November through December 2000, the Company loaned $1,790,948 to certain employees and officers for the exercise of incentive stock options. All of the full recourse notes accrue interest at 9.5% and are due on the second anniversary of the issuance date. The notes are secured by the shares of common stock held by the employees.

Note 13 Subsequent Events

On March 15, 2001, the underwriters for the initial public offering exercised an overallotment option for 628,706 shares of common stock at a price $13.00 per share. The aggregate proceeds amount to approximately $7.6 million, after deducting underwriting discounts and commissions.

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.

(b) Reports on Form 8-K

None.

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.
21.1*	Subsidiaries of 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.

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 30, 2001.

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 30, 2001
/s/ Stephen Bonelli Stephen Bonelli	Chief Financial Officer and Vice President, Finance (Principal Accounting Officer)	March 30, 2001
/s/ Kelsey Wirth Kelsey Wirth	President and Director	March 30, 2001
/s/ Brian Dovey Brian Dovey	Director	March 30, 2001
/s/ Joseph Lacob Joseph Lacob	Director	March 30, 2001
/s/ Mark Logan Mark Logan	Director	March 30, 2001
/s/ H. Kent Bowen H. Kent Bowen	Director	March 30, 2001

EXHIBIT 23.1

CONSENT OF INDEPENDENT ACCOUNTANTS

We hereby consent to the incorporation by reference in the Registration Statement on Form S-8 (File No. 333-55020) of Align Technology, Inc. and subsidiary, of our report dated February 9, 2001, except for Note 13 which is as of March 15, 2001, relating to the consolidated financial statements, which appears in this Form 10-K. We also consent to the reference to us under the heading "Selected Consolidated Financial Data" in such Registration Statement.

PricewaterhouseCoopers LLP
San Jose, California
March 30, 2001