ALIGN TECHNOLOGY INC
Form 10-K
March 12, 2007

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, 2006
Or
o **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from to

Commission file number: 0-32259

ALIGN TECHNOLOGY, INC.

(Exact name of registrant as specified in its charter)

Delaware	**94-3267295**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)

881 Martin Avenue

Santa Clara, California 95050

(Address of principal executive offices, including Zip Code)

(408) 470-1000

Registrant s telephone number, including area code:

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Name of each exchange on which registered**
Common Stock, $0.0001 par value (Including associated Prefered Stock Purchase Rights)	The NASDAQ Stock Market LLC (NASDAQ Global Market)

Securities registered pursuant to Section 12(g) of the Act:

None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes o No x

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act. Yes o No x

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No o

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. x

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act.

Large accelerated filer o Accelerated filer x Non-accelerated filer o

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes o No x

The aggregate market value of the registrant s common stock held by non-affiliates of the registrant was $387,981,710 as of June 30, 2006 based on the closing sale price of the registrant s common stock on the NASDAQ Global Market on such date. Shares held by person who may be deemed affiliates have been excluded. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

On March 6, 2007, 65,837,621 shares of registrant s common stock were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of registrant s definitive Proxy Statement relating to its 2007 Annual Stockholders Meeting to be filed pursuant to Regulation 14A within 120 days after the registrant s fiscal year end of December 31, 2006 are incorporated by reference into Part III of this Annual Report on Form 10-K.

ALIGN TECHNOLOGY, INC.

FORM 10 K

For the Year Ended December 31, 2006

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In addition to historical information, this annual report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. These statements include, among other things, statements concerning our expectations regarding the anticipated benefit of increased collaboration between orthodontists and general practitioner dentists and the impact this collaboration will have on sales of Invisalign and on our revenue, our expectation that the percentage of revenue generated by general practitioner dentists will represent an increasingly larger percentage of our revenue, our intention to continue the integration of Invisalign into the curriculums of additional universities, our expectation regarding the benefits of new products, product features, and software enhancements, including ClinAdvisor, and the expected impact these new products and product enhancements will have on our market share, our expectations regarding product mix and Invisalign Express, our anticipated cost of the Patients First Program, our expectations regarding our average selling prices and gross margins in 2007, our expectations regarding the benefit of increased consumer marketing programs, our expectations regarding increased case shipment volume in 2007, our expectations regarding further expansion into North American and international markets, including Japan, our expectation regarding the anticipated level of our operating expenses in 2007, as well as other statements regarding our future operations, financial condition and prospects and business strategies. These statements may contain words such as expects, anticipates, intends, plans, believes, estimates, or other words indicating future results. These forward-looking statements are subject to certain risks and uncertainties that could cause actual results to differ materially from those reflected in the forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in Part II, Item 7 Management s Discussion and Analysis of Financial Condition and Results of Operations , and in particular, the risks discussed below in Item 1A Risk Factors . We undertake no obligation to revise or update these forward-looking statements. Given these risks and uncertainties, readers are cautioned not to place undue reliance on such forward-looking statements.

PART I

ITEM 1. BUSINESS

Our Company

Align Technology, Inc. was incorporated in April 1997 under the laws of the state of Delaware. We design, manufacture and market the Invisalign system, a proprietary method for treating malocclusion, or the misalignment of teeth. Invisalign corrects malocclusion using a series of clear, nearly invisible, removable appliances that gently move teeth to a desired final position. Because it does not rely on the use of metal or ceramic brackets and wires, Invisalign significantly reduces the aesthetic and other limitations associated with braces. Invisalign is appropriate for treating adults and teens with mature dentition. Align Technology received FDA clearance to market Invisalign in 1998.

Under the Corporate Information/Investor Relations section of our corporate website which can be accessed at either *www.aligntech.com* or *www.invisalign.com*, we make our Annual Report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, our proxy statement on Schedule 14A for our annual stockholders meeting and amendments to such reports available as soon as reasonably practicable after they are electronically filed with or furnished to the Securities and Exchange Commission, or SEC. All such filings are available free of charge. The information in, or that can be accessed through, our website is not part of this report.

Industry Background

Malocclusion

Malocclusion, the misalignment of teeth, is one of the most prevalent clinical dental conditions, affecting over 200 million individuals, or approximately 75% of the U.S. population. Approximately two million people annually elect treatment by orthodontists in the U.S. While most individuals seek

orthodontic treatment to improve their appearance, malocclusion may also be responsible for dental problems such as tooth decay, tooth loss, gum disease, jaw joint pain and headaches. Because of the compromised aesthetics, discomfort and other drawbacks associated with conventional orthodontic treatments, only a relatively small proportion of people with malocclusion seek traditional treatment.

Traditional Orthodontic Treatment

In the U.S., dental professionals treat malocclusion primarily with metal archwires and brackets, commonly referred to as braces. Occasionally, dental professionals attempt to improve treatment aesthetics by using ceramic, tooth-colored brackets or bond brackets on the inside, or lingual surfaces, of the patient s teeth. Dental professionals also augment braces with elastics, metal bands, headgear and other ancillary devices.

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

Fees for traditional orthodontic treatment typically range between U.S. $3,500 to $7,000 with a median fee of approximately $4,800; generally only a portion of the fees is reimbursed by insurance, if covered at all. In addition, dental professionals commonly charge a premium for lingual or ceramic alternatives. Fees are based on the difficulty of the particular case and on the dental professional s estimate of chair time, and are generally negotiated in advance. A treatment that exceeds the dental professional s estimate of chair time generally results in decreased fees per hour of chair time, and reduced profitability for the dental professional.

Limitations of Traditional Orthodontic Treatment

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

- *Unattractive appearance*. Braces call attention to the patient s condition and treatment. In addition, braces trap food, which can further compromise appearance. Braces can also result in permanent discoloration of teeth. Many adults associate braces with adolescence. As a result of these and other limitations, less than one percent of American adults with malocclusion elect traditional orthodontic treatment annually.

- *Oral discomfort*. Braces are sharp and bulky and can abrade and irritate the interior surfaces of the mouth. The tightening or adjustment of braces results in root and gum soreness and discomfort, especially in the few days immediately following an orthodontic visit.

- *Poor oral hygiene*. Braces compromise oral hygiene by making it more difficult to brush and floss. These problems can result in tooth decay and periodontal damage. Additionally, the bonding of brackets to teeth can cause permanent markings on the teeth.

- *Inability to project treatment*. Historically, dental professionals have not had a means to model the movement of teeth over a course of treatment. Accordingly, dental professionals must rely on intuition and judgment to plan and project treatment. As a result, they cannot be precise about the

direction or distance of expected tooth movement between patient visits. This lack of predictability may result in unwanted tooth movements and can limit the dental professional s ability to estimate the duration of treatment. Because most orthodontic treatment is performed on a fixed price basis, extended treatment duration reduces profitability for the dental professional.

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

- *Root resorption*. The sustained high levels of force associated with conventional treatment can result in root resorption, which is a shortening of tooth roots. This shortening can have substantial adverse periodontal consequences for the patient.

- *Emergencies*. At times, braces need to be repaired or replaced on an emergency basis. Such emergencies cause significant inconvenience to both the patient and the dental professional.

Due to the poor aesthetics, discomfort and other limitations of braces, relatively few people with malocclusion elect traditional orthodontic treatment. Accordingly, we believe there is a large unmet need for an orthodontic system that addresses these patient concerns. We also believe there is an unmet need among dental professionals for a treatment system that increases the predictability and efficiency of treatment and enhances practice profitability.

The Align Solution

Invisalign (which includes full Invisalign treatment and Invisalign Express discussed below under Our Products) is a proprietary system for treating malocclusion. The Invisalign treatment process is comprised of several phases, the principal steps of which are: the creation of electronic treatment plans using ClinCheck and the manufacturing of Invisalign aligners (referred to in this Form 10-K as Aligners). The complete Invisalign treatment process is described in greater detail under Business The Invisalign Treatment Process .

ClinCheck. ClinCheck is an internally developed computer modeling program that allows dental professionals to diagnose and plan treatments for their patients. We use a dental impression and a treatment form submitted by a dental professional to develop a customized, three-dimensional treatment plan that simulates appropriate tooth movement in a series of two-week increments. ClinCheck allows the dental professional to view this three-dimensional simulation with a high degree of magnification and from any angle. Accordingly, ClinCheck enables the dental professional to project tooth movement with a level of accuracy not previously possible.

Upon review of the ClinCheck simulation, the dental professional may immediately approve the projected treatment, or may provide us with feedback for modification. We reflect any requested adjustments in a modified simulation. Upon the dental professional s approval of the ClinCheck simulation, we use the data underlying the simulation, in conjunction with stereolithography technology, to manufacture Aligner molds. International Manufacturing Solutions Operaciones, S.R.L., or IMS, a third party shelter services provider in Juarez, Mexico, manufactures the molds and then uses these molds to fabricate the patient s Aligners.

Aligners. Aligners are custom-manufactured, thin, clear plastic, removable dental appliances that are manufactured in a series to correspond to each two-week stage of the ClinCheck simulation. Aligners are customized to perform the treatment prescribed for an individual patient by dental professionals using ClinCheck. 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 replaces them with the next pair in the series. This process is repeated until the final

Aligners are used and treatment is complete. Upon completion of the treatment, the dental professional may, at his or her discretion, have the patient use an Invisalign retainer or go directly to a conventional retainer.

Our Products

The vast majority of our revenue is generated from the sale of full Invisalign treatment and Invisalign Express treatment.

Full Invisalign Treatment. Commercial sales of full Invisalign treatment commenced in the U.S. in July 1999. Our traditional, full Invisalign treatment option is intended to be used as a complete treatment for a broad range of malocclusions. Each treatment plan is unique to the individual patient and will consist of as many Aligners as indicated by ClinCheck in order to achieve the doctor s treatment goals. In fiscal 2006, approximately 81% of our net revenue was generated by the sale of full Invisalign treatment.

Invisalign Express. In the third quarter of 2005, we launched Invisalign Express, a lower-cost solution for less complex orthodontic cases. Invisalign Express is a dual arch orthodontic treatment for cases that meet certain predetermined clinical criteria and consist of up to ten Aligners. Invisalign Express is intended to help a broader range of patients elect orthodontic treatment by providing a lower-cost option for adult relapse cases, for minor crowding and spacing, and as a pre-cursor to restorative or cosmetic treatments such as veneers. In fiscal 2006, approximately 13% of our net revenue was generated by the sale of Invisalign Express.

Ancillary and Other. The remaining 6% of our net revenue is generated by training fees and sales of ancillary products.

Benefits of Invisalign

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

Benefits to the dental professional

- *Ability to visualize treatment and likely outcomes*. ClinCheck enables dental professionals to preview a course of treatment and the likely outcome of treatment in an interactive three-dimensional computer model. ClinCheck allows dental professionals to analyze multiple treatment alternatives before selecting the course of action they feel is most appropriate for the patient.

- *Begin using Invisalign with minimal additional training*. The biomechanical principles that underlie treatment with the Invisalign system are consistent with those of traditional orthodontics. Dental professionals can complete our initial training within two days. We provide additional clinical support following the initial training and encourage dental professionals to attend continuing education classes, seminars and workshops.

- *Expanded patient base*. We believe that Invisalign has the potential to transform the practice of orthodontics. Currently, approximately two million people annually elect treatment by orthodontists in the U.S. These patients represent approximately 1 percent of the population of people with malocclusion. Of these, we estimate approximately 45 percent, or approximately 900,000 patients have mature dentition with mild to moderate malocclusion and are therefore potential candidates for Invisalign. We believe that Invisalign will allow dental professionals to attract patients who would not otherwise seek orthodontic treatment.

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

- *Practice productivity*. We believe that as dental professionals move to a higher volume of Invisalign patients, they will be able to better leverage their existing resources, including office space and staff time, resulting in an increase in daily patient appointments and practice productivity.

Benefits to the Patient

- *Excellent aesthetics*. Aligners are nearly invisible when worn, significantly reducing the aesthetic concerns associated with conventional braces.

- *Comfort*. By replacing the six-week adjustment cycle of traditional braces with two-week stages, Aligners move teeth more gently than conventional braces. Also, Aligners are thin, smooth and low in profile. As a result, Aligners are more comfortable and less abrasive than conventional braces.

- *Improved oral hygiene*. Patients can remove Aligners for tasks that are difficult with conventional braces, such as eating, brushing and flossing. We believe this feature has the potential to reduce tooth decay and periodontal damage during treatment, which may result from conventional braces.

- *Potentially reduced overall treatment time*. Aligners control force by distributing it broadly over the exposed surfaces of the teeth. In addition, the ClinCheck simulation from which Aligners are produced is designed to reduce unintended and unnecessary tooth movements. Together, these factors may reduce overall treatment time relative to conventional braces.

- *Potentially reduced root resorption*. We believe that controlling force and shortening treatment time has the potential to reduce the incidence of root resorption, which is the breakdown or destruction of root structure.

- *Reduced incidence of emergencies*. Typically, a lost or broken Aligner is simply replaced with the next Aligner in the treatment series, minimizing inconvenience to both patient and dental professional.

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

Limitations of Invisalign

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 dental professionals more than they generally pay for the supplies used in conventional treatment. Depending on the individual pricing policies of each dental professional, the cost of full Invisalign treatment to the patient may be greater than for conventional braces. Dental professionals must also incorporate our manufacturing cycle times into their overall treatment plan. Once a dental professional submits a case to us, there is generally a turn-around time of a month or more before the corresponding Aligners are delivered. Aligners may not be appropriate for all cases, such as severe malocclusion, which may require Aligners to be used in combination with conventional braces for optimal results. In addition, because Aligners are removable, treatment using Invisalign depends on patients wearing their Aligners as recommended. Some patients may experience a temporary period of adjustment to wearing Aligners that may mildly affect speech. In some instances, patients have experienced scratched or irritated gums, cheeks and lips and in some rare instances allergic reactions have occurred. We believe that these limitations are generally outweighed by the many benefits of Invisalign to both patients and dental professionals.

Our Target Market and Patient Base

We currently market Invisalign to treat patients with mature dentition. Individuals with mature dentition have fully erupted second molars and substantially completed jaw growth, which typically occurs between the ages of 11 and 15 years. We do not treat children whose teeth and jaws are still developing, as the effectiveness of Invisalign relies on our ability to accurately predict the movement of teeth over the course of treatment. Based on our clinical studies to date, we recommend that dental professionals use Invisalign as a complete treatment for a broad range of malocclusions and as a component of treatment for severe malocclusions. We estimate 45 percent of the people who annually elect treatment by orthodontists in the U.S., or more than 900,000 patients, have mature dentition and are therefore potential candidates for Invisalign. Our market research indicates that the vast majority of people with malocclusion who desire treatment do not elect traditional treatment because of its many limitations. We believe that, since Invisalign addresses the primary limitations of braces, persons with malocclusion will be more likely to seek treatment. We believe that adults, who are particularly sensitive to the aesthetic limitations of traditional treatment, represent our most immediate and significant market expansion opportunity.

In an effort to more fully penetrate our target market, in August 2005, we launched Invisalign Express, a lower-cost solution for less complex cases. Invisalign Express is a simple, dual arch orthodontic treatment for cases that meet certain predetermined clinical criteria and consist of up to ten Aligners. We expect Invisalign Express will increase the overall market for Invisalign, as patients who would not have otherwise sought orthodontic treatment due to its relatively high cost are introduced to this lower-cost treatment option. We continue to market and sell our traditional full Invisalign treatment option for more complex cases.

As of December 31, 2006, approximately 529,000 patients worldwide have started treatment using Invisalign. Internationally, we operate in the geographic regions of Europe, Asia-Pacific, Japan and Latin America. In 2006, international sales accounted for 16% of our net revenues. A geographic breakdown of our net revenues is summarized in Note 15 Segments and Geographic Information in the Notes to our Consolidated Financial Statements.

In each of fiscal 2006, 2005 and 2004, no single customer accounted for 10% or more of our total net revenues.

Business Strategy

Our objective is to establish Invisalign as the standard method for treating orthodontic malocclusion through customer responsiveness, product leadership and operational effectiveness. Key elements of our strategy include the following.

Customer Responsiveness

Focus on education and customer support. In order to build long-term relationships with our customers, we focus on delivering superior training, support and services. Each year, we provide numerous clinical education and training programs, which include certification classes, conference calls, seminars and workshops. By participating in these events, we believe that our customers will emerge with a better understanding of the product and its applicability, and with a greater awareness for starting and finishing Invisalign cases. We also maintain an online clinical education center which is intended to augment our training workshops, conference calls and seminars by enabling Invisalign-trained doctors to obtain continuing education credits and access a full range of case studies and best practices. As of December 31, 2006, we had trained approximately 40,800 dental professionals worldwide on the use and benefits of Invisalign.

Educate future orthodontists and general practitioners. By educating dental students and orthodontic residents on the benefits of the Invisalign technique, we believe they will be more likely to use this technology in their future practices and offer Invisalign as a treatment option. Currently, we have incorporated the Invisalign technique into the curriculum of 38 university programs. We expect additional dental schools to integrate the Invisalign technique into their curricula in the future.

Stimulate demand for Invisalign treatment. Our market research indicates that the vast majority of people with malocclusion who desire treatment do not elect traditional treatment because of its many limitations, such as compromised aesthetics and oral discomfort. By communicating the benefits of Invisalign to both dental professionals and consumers, we intend to increase the number of patients who seek orthodontic treatment annually. In 2007, we expect to increase the overall marketing spending in the United States with a focus on programs designed to raise the profile of Invisalign and drive more consumers to our most experienced doctors. We also intend to initiate similar consumer marketing efforts, but on a smaller scale, in key European countries. We believe that this increased consumer awareness of Invisalign will increase the market for our products.

Penetration into our domestic market. We have two customer channels: the orthodontist and the general practitioner dentist, or GP. As specialists, orthodontists are a critical part of our business, and we expect that orthodontists will continue to treat the majority of complex cases and continue to drive research for expanding Invisalign applications. However, there exists a significantly greater number of GPs in North America than orthodontists. As the primary care dental provider, GPs have access to a greater number of patients than orthodontists, and possess a unique opportunity to educate these patients and introduce them to Invisalign. GPs also have the ability to refer appropriate cases to orthodontists and, in certain instances, may choose to treat less complex cases themselves. We are committed to improving the collaboration and referral relationships between orthodontists and GPs. We continue to support study clubs, which pair experienced orthodontists with less experienced GPs. These orthodontists act as mentors to the GPs and lend them support and guidance in their Invisalign practice. Through these study clubs, GPs are introduced to an experienced Invisalign practitioner and are able to refer appropriate cases to these orthodontists. In 2007, we expect that revenue generated by GPs will represent an increasingly larger percentage of our revenue, largely due to the fact that there are significantly more GPs than orthodontists. We believe that by focusing on increasing utilization rates among our existing GP customers, the overall market for Invisalign will increase, as patients that would not have otherwise sought orthodontic treatment are introduced to Invisalign by their GPs. Information regarding risks related to our expectation that orthodontists and GPs will collaborate may be found in Part I, Item 1A of this Annual Report on Form 10-K under the heading Risk Factors.

Product Leadership

New products and enhancements to products. Our strategy for ensuring product leadership focuses on delivering new products and product features as well as enhancing the user experience. In 2005 we launched Invisalign Express, a lower-cost solution for less complex cases, allowing the dental professional to treat a broader range of patients. In the second half of 2006, we began a phased rollout of ClinAdvisor, a new suite of software tools designed to make Invisalign case selection and submission processes more efficient for doctors. During 2007, we expect to extend the product features and functionality of ClinAdvisor to an increasing number of practices. In addition, we plan to introduce a further series of software enhancements that will evolve Invisalign into distinct suites of software tools for the orthodontist and GP. Software enhancements for the orthodontist are intended to provide a more robust set of tools for greater predictability, wider applicability and more flexibility in the use of the Invisalign system. Software enhancements targeting the GP will focus on ease of diagnosis, guidance through the case set-up process and self-help tools designed to simplify treatment of cases of mild to moderate malocclusion. We continue to focus research and development efforts on next generation Aligner material and a compliance indicator,

which efforts we expect to extend at least through 2008. Next generation Aligner material is intended to consistently deliver force to the teeth over a longer period of time. The compliance indicator is intended to help the dental professional and the patient understand if the patient has worn their Aligner for enough time to effectively move their teeth. We believe continuing to introduce new products and product features as well as enhancing the user experience will keep us at the forefront of the market and increase demand for Invisalign.

Extend and defend technology leadership. Invisalign represents a significant technological advancement in orthodontics. Our issued U.S. patents broadly cover the Invisalign system, including digital modeling and manipulation of scanned patient data, treatment planning, and fabrication of dental appliances, among others. 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. Nonetheless, our intellectual property rights may not be successfully asserted in the future or may be invalidated, circumvented or challenged. In addition, the laws of various countries where the Invisalign system is distributed do not protect our intellectual property rights to the same extent as U.S. laws. Information regarding risks associated with failure to protect our proprietary technology and our intellectual property rights may be found in Part I, Item 1A of this Annual Report on Form 10-K under the heading Risk Factors. *See also Part I, Item 3 of this Annual Report on Form 10-K under the heading Legal Proceedings.*

Operational Effectiveness

Expand and enhance manufacturing capability. Our manufacturing operations are designed to produce large numbers of custom Aligners at a high level of quality. To improve cost efficiency, we conduct labor intensive processes in relatively low-wage countries. We believe that our existing facilities are adequate to meet current requirements and that additional or substitute space will be available as needed to accommodate any expansion of operations. 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.

The Invisalign Treatment Process

The Invisalign treatment process comprises the following five stages:

Orthodontic diagnosis and transmission of treatment data to us. In an initial patient visit, the dental professional determines whether Invisalign is an appropriate treatment. The dental professional then prepares a treatment data package which consists of a polyvinyl-siloxane, or PVS, impression of the relevant dental arches, x-rays of the patient s dentition, photographs of the patient, a bite impression depicting the relationship between the patient s upper and lower dental arches and an Invisalign treatment planning form, or prescription. The impression is a critical component of Invisalign as it depicts the three-dimensional geometry of the patient s teeth and hence forms the basis for our computer models. An impression requires the patient to bite into a viscous material. This material hardens, capturing the shape of the patient s teeth. The prescription is also a critical component of Invisalign, describing the desired positions and movement of the patient s teeth. The dental professional sends the treatment data to our Santa Clara, California facility.

Preparation of three-dimensional computer models of the patient s initial malocclusion. Upon receipt, we use the treatment data to construct digital models of the patient s dentition. Using CT scanning, we scan the PVS impression to develop a digital, three-dimensional computer model of the patient s current dentition. We then transmit this initial computer model together with the dental professional s prescription and supplemental materials electronically to our facilities in Costa Rica.

Preparation of computer-simulated treatment and viewing of treatment using ClinCheck. In Costa Rica we transform this initial digital model into a customized, three-dimensional treatment plan that simulates appropriate tooth movement in a series of two-week increments. This simulation is then reviewed for adherence to prescribed clinical, treatment and quality standards. Upon passing review, the simulation is then made available to the prescribing dental professional via Virtual Invisalign Practice (VIP), our proprietary customer interfacing software, which is available on our websites located at *www.invisalign.com* and *www.aligntech.com*. The dental professional then reviews the ClinCheck simulation and determines whether to ask us to make adjustments. By reviewing and amending the treatment simulation, the dental professional retains control over the treatment plan and, thus, participates in the customized design of the Aligners. At this point, the dental professional may also invite the patient to review ClinCheck, allowing the patient to see the projected course of treatment. The dental professional then approves the proposed treatment and, in doing so, engages us for the manufacture of corresponding Aligners.

Construction of molds corresponding to each step of treatment. We use the approved ClinCheck simulation to construct a series of molds of the patient s teeth. Each mold is a replica of the patient s teeth at each two-week stage of the simulated course of treatment. These molds are fabricated by IMS, a third party shelter services provider based in Juarez, Mexico.

Manufacture of Aligners and shipment to the dental professional. From these molds, IMS fabricates Aligners by pressure-forming polymeric sheets over each mold. The Aligners are then trimmed, polished, cleaned and packaged. Following final inspection, the Aligners are shipped directly to the prescribing dental professional. We ship all of the Aligners in a single batch. In certain cases, dental professionals may use Invisalign in conjunction with tooth-colored attachments bonded to the patient s teeth. These attachments are used to increase the force applied to a tooth or teeth in circumstances where the Aligners alone may have difficulty in effecting the desired movement. In certain cases, we provide an aligner-like template to the dental professionals to aid the placement of bonding attachments to the patient s teeth. Also, in cases where interproximal reduction, or IPR, is requested by the dental professional, we provide an IPR treatment form, quantifying the amount of space to be created through enamel reduction, location, and timing of IPR.

Manufacturing

To produce our highly customized, highly precise, medical quality products in volume, we have developed a number of proprietary processes and technologies. These technologies include complex software solutions, computed tomography, known as CT scanning, stereolithography and automated Aligner fabrication.

We rely on two vendors who are each the sole source of the polymer and resin used in our manufacturing process. In the event that either of these vendors become unable for any reason to supply us with their respective products, we would experience a manufacturing disruption while we qualify and obtain an alternate source.

As of December 31, 2006, our manufacturing and operations staff in the U.S. and Costa Rica consisted of 672 people. Manufacturing is coordinated in Santa Clara, California. Digital dental modeling is processed in our 63,000 square foot facility in San Jose, Costa Rica. The operations team in Costa Rica creates ClinCheck treatments using simulation software. In anticipation of increased capacity demands primarily resulting from the Patients First Program, we hired approximately 100 new dental technicians in Costa Rica in the fourth quarter of 2006. *For a more complete discussion of the Patients First Program, please see Part I, Item 7 of this Annual Report on Form 10-K under the heading Management s Discussion and Analysis Overview* . In the second quarter of 2006, in an effort to optimize operations, improve efficiency and reduce operating costs, we relocated our streolithography (SLA) mold fabrication operations from our Santa Clara, California facility to IMS, a third party shelter services provider based in Juarez, Mexico. We

also use IMS for the fabrication and packaging of Aligners. Information regarding risks associated with our manufacturing process and foreign operations may be found in Part I, Item 1A of this Annual Report on Form 10-K under the heading Risk Factors.

Throughput Management

Because we manufacture each case on a build-to-order basis, we must conservatively build manufacturing capacity for anticipated demand. To increase throughput, we must improve the efficiency and increase the scale of our manufacturing processes.

In order to increase the efficiency of our manufacturing processes, we focus our efforts on software development and the improvement of rate-limiting processes, or bottlenecks. We continue to upgrade our proprietary, three-dimensional treatment-planning software to enhance computer analysis of treatment data and to reduce time spent on manual and judgmental tasks for each case, thereby increasing the efficiency of our technicians in Costa Rica. During the first half of 2007, as a result of the increase in demand for Invisalign case volume primarily due to of the Patients First Program (discussed in Part I, Item 7 Managements Discussion and Analysis Overview), we will monitor our capacity in Costa Rica to ensure a sufficient number of technicians have been hired. We are also continuing the development of automated systems for the fabrication and packaging of Aligners manufactured in Juarez, Mexico. In order to scale our manufacturing capacity, we expect that we will continue to invest in capital equipment.

Quality Assurance

Align s quality system is in compliance with Food & Drug Administration s Medical Device regulations, 21CFR Part 820, and Health Canada s Medical Device Regulations. We are certified to EN ISO 13485:2003, internationally recognized standards for Medical Device manufacturing and of the Council of Canada. Align has a formal, documented quality system by which quality objectives are defined, understood and achieved. Systems, processes and procedures are implemented to ensure high levels of product and service quality. We monitor the effectiveness of the quality system based on internal data and direct customer feedback and strive to continually improve our systems and processes, taking corrective action, as needed.

Since we custom manufacture Aligners on a build-to-order basis, we do not offer refunds on our products. Because each ClinCheck and each Aligner is unique, we inspect 100% of the product at various points in the manufacturing process, to ensure that the product meets our customers expectations. Aligners are subject to the Invisalign product warranty, which covers defects in materials and workmanship. Our materials and workmanship warranty is in force until the Invisalign case is completed. In the event the Aligners fall within the scope of the Invisalign product warranty, we will replace the Aligners at our expense. Our warranty is contingent upon proper use of the Aligners for the purposes for which they are intended. If a patient chooses not to wear the Aligners, and as a result, requests additional Invisalign treatment, the dental professional pays the additional expense of the replacement Aligners.

The Invisalign product warranty does not provide any assurances regarding the outcome of treatment using Invisalign. Actual treatment results may deviate significantly from the approved ClinCheck treatment plan. Deviations not covered under warranty have typically been the result of unpredictable biological factors, such as variations in bone density or tooth topography and abnormal jaw growth. Warranty treatment requires that the dental professional submit new impressions of the patient s dentition to us. We use the impressions to create a new ClinCheck treatment plan for the dental professional to approve, from which a successive series of Aligners will be produced that will allow the patient to finish treatment.

Sales and Marketing

We market Invisalign by communicating Invisalign s benefits directly to dental professionals through our training, certification programs and direct mail campaigns and to consumers with a nationwide advertising campaign. Based on our experience with advertising and commercial sales, we believe that making consumers aware of Invisalign as a new treatment alternative generates significant demand for Invisalign. In order to serve anticipated demand, we are training a broad base of dental professionals.

Professional Marketing

Our sales and support staff has been engaged in marketing Invisalign to orthodontists since July 1999. In 2001, we began marketing Invisalign to general practitioner dentists in our domestic market. As of December 31, 2006 our North America sales organization consisted of 130 people of which 109 were direct sales representatives and 21 were sales administration and management. Internationally, we have approximately 40 people engaged in sales and sales support as December 31, 2006. We provide training, certification, marketing and clinical support to orthodontists and general practitioner dentists in the U.S. and Canada, which we consider our domestic market, and internationally.

As of December 31, 2006, we had trained approximately 40,800 dental professionals worldwide to use Invisalign. Of those trained dental professionals, approximately 73% are dental professionals in our domestic market (United States and Canada). Within our domestic market, we have trained approximately 8,000 orthodontists and approximately 22,000 active general practitioner dentists.

Invisalign relies on the same orthodontic principles that apply to traditional treatment. Our sales and orthodontic teams conduct training primarily in a workshop format. The key topics covered in training include Invisalign applicability, instructions on filling out the Invisalign treatment form, clinical tips and techniques, guidance on pricing and instructions on interacting with our ClinCheck software and the many other features of our website.

After training, sales representatives follow up with the dental professional to ensure that their staff is prepared to handle Invisalign cases. Such follow up may include assisting the dental professional in taking dental impressions, establishing an Internet connection and familiarizing them with our website. Sales representatives may also provide practice-building assistance, including helping the dental professional to market Invisalign to prospective patients through direct mail or other forms of media. Many dental professionals have commenced promotional activity in their local region with our assistance.

Consumer Marketing

Our experience indicates that prospective patients seek information from six primary sources:

- an orthodontist;
- a general practice dentist;
- consumer marketing and advertising;
- our website, which can be accessed at either *www.invisalign.com* or *www.aligntech.com;*
- direct-to-consumer mail advertising and public relations efforts; and
- other Invisalign patients.

In 2007, we expect to increase the overall marketing spend in the United States with a focus on programs designed to raise the profile of Invisalign and drive more consumers to our most experienced doctors. We believe that this increased consumer awareness of Invisalign will increase demand for our product.

Research and Development

Our research and development effort is focused on extending the range of dental applicability of Invisalign, enhancing the software used in the manufacturing process and enhancing our Invisalign system product lines. Our research and development expenses were $18.5 million for fiscal 2006, $18.6 million for fiscal 2005 and $15.8 million for fiscal 2004.

In an effort to demonstrate Invisalign s broad treatment capabilities, various clinical case studies and articles have been published that highlight the applicability of Invisalign to malocclusion cases, including those of severe complexity. We are also undertaking post-marketing studies and making additional technological improvements to the product and manufacturing process. We have recently started a phased roll out of ClinAdvisor, a new suite of software tools, designed to make Invisalign case selection and submission processes more efficient and predictable for our doctors. In addition, we plan to introduce a further series of software enhancements that will evolve Invisalign into distinct suites of software tools for the orthodontist and GP. Software enhancements for the orthodontist are intended to provide a more robust set of tools for greater predictability, wider applicability and more flexibility in the use of the Invisalign system. Software enhancements targeting the GP will focus on ease of diagnosis, guidance through the case set-up process and self-help tools designed to simplify treatment of cases of mild to moderate malocclusion. We continue to focus research and development efforts on next generation Aligner material and a compliance indicator, which efforts we expect to extend at least through 2008.

Intellectual Property

We believe our intellectual property position represents a substantial business advantage. As of December 31, 2006, we had 85 issued U.S. patents, 120 pending U.S. patent applications, and numerous foreign issued patents, as well as pending foreign patent applications. *See Part I, Item 3 Legal Proceedings for a discussion on Reexamination Proceedings pending with the United States Patent and Trademark Office.*

We continue to pursue further intellectual property protection through U.S. and foreign patent applications and non-disclosure agreements. We also seek to protect our software, documentation and other written materials under trade secret and copyright laws. We cannot be certain that patents will be issued as a result of any patent application or that patents that have been issued to us or that may be issued in the future will be found to be valid and enforceable and sufficient to protect our technology or products. Our intellectual property rights may not be successfully asserted in the future or may be invalidated, circumvented or challenged. In addition, the laws of various foreign countries where Invisalign is distributed do not protect our intellectual property rights to the same extent as U.S. laws. Our inability to protect our proprietary information could harm our business. Information regarding risks associated with failure to protect our proprietary technology and our intellectual property rights may be found in Part I, Item IA of this Annual Report on Form 10-K under the heading Risk Factors.

Competition

We compete for the attention of dental professionals with manufacturers of traditional orthodontic appliances (or wires and brackets), which include 3M Company, Sybron Dental Specialties and Dentsply International, Inc. We also compete directly with established companies that manufacture and distribute products that are similar in use to Invisalign, including the product called Red, White & Blue manufactured and distributed by Ormco Orthodontics, a division of Sybron Dental Specialties. In May 2006, Danaher Corporation purchased Sybron Dental Specialties. *See Part I, Item 3 Legal Proceedings for a summary of our litigation with Ormco.* In May 2005, OrthoClear, Inc. announced the commercial launch of the OrthoClear system, a product that was intended to compete directly with our Invisalign system. On October 13, 2006, we entered into a formal agreement with OrthoClear, Inc., OrthoClear Holdings, Inc., and OrthoClear Pakistan Pvt. Ltd. (OrthoClear), together with certain

individuals associated with OrthoClear to end all pending litigation between the parties. In addition, OrthoClear agreed, among other things, to stop accepting new patient cases for treatment, consent to the entry of an exclusion order by the ITC prohibiting the importation of OrthoClear aligners into the United States, assign and transfer to Align all intellectual property rights with application to the correction of malocclusion and to discontinue all design, manufacture, marketing and sales of removable dental aligners worldwide. *See Part I, Item 3 Legal Proceedings for a summary of our litigation with OrthoClear.* In the future, we may face further competition from other early stage and more mature companies who enter our target markets to manufacture and distribute products that are similar in use to Invisalign. Information regarding risks associated with increased competition may be found in Part I, Item IA of this Annual Report on Form 10-K under the heading Risk Factors.

We believe that in addition to price, the principal competitive factors in the market for orthodontic appliances include the following:

- aesthetic appeal of the treatment method;
- effectiveness of treatment;