

ALIGN TECHNOLOGY INC
Form 424B3
February 05, 2004
Table of Contents

Filed Pursuant to Rule 424(b)(3)

Registration Statement No. 333-109800

ALIGN TECHNOLOGY, INC.

9,578,943 SHARES

COMMON STOCK

This prospectus relates to 9,578,943 shares of our common stock that may be offered and sold from time to time by certain of our stockholders identified in this prospectus. See Selling Stockholders. These shares were issued to the selling stockholders in connection with a private placement financing pursuant to a common stock purchase agreement with Align Technology, Inc. (the Financing). Our common stock issued to the selling stockholders in the Financing was issued pursuant to an exemption from the registration requirements of the Securities Act of 1933, as amended (the Securities Act), provided by Section 4(2) thereof.

The selling stockholders will receive all of the net proceeds from the sale of the shares under this prospectus and will pay all brokerage fees and selling commissions, if any, applicable to the sale of the shares. We will not receive any proceeds from the sale of shares by the selling stockholders.

Our common stock is listed on The Nasdaq National Market under the symbol ALGN. On February 3, 2004, the closing sales price of our common stock as reported by The Nasdaq National Market was \$20.81 per share.

You should consider carefully the risk factors beginning on page 2 of this prospectus before purchasing any of our common stock offered under this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities, or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is February 4, 2004

Table of Contents

TABLE OF CONTENTS

	Page
<u>Summary</u>	1
<u>Risk Factors</u>	2
<u>Where to Find Additional Information About Align</u>	12
<u>Information Incorporated By Reference</u>	12
<u>Forward-Looking Information</u>	13
<u>Use of Proceeds</u>	13
<u>Selling Stockholders</u>	13
<u>Plan of Distribution</u>	15
<u>Legal Matters</u>	16
<u>Experts</u>	16

You should rely only on the information contained in this prospectus. We have not authorized anyone to provide you with information different from that contained in this prospectus. The selling stockholders are offering to sell, and seeking offers to buy, our shares of common stock only in jurisdictions where offers and sales are permitted. The information contained in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or of any sale of the shares.

In this prospectus, **Align**, **we**, **us**, and **our** refer to Align Technology, Inc. and its subsidiaries.

Table of Contents

SUMMARY

Align Technology, Inc.

Since our inception in April 1997, we have been engaged in the design, manufacture and marketing of Invisalign, a proprietary system for treating malocclusion, or the misalignment of teeth. The Invisalign product has two components: ClinCheck and Aligners. ClinCheck is an Internet-based application that allows dental professionals to simulate treatment, in three dimensions, by modeling two-week stages of tooth movement. Aligners are thin, clear plastic, removable dental appliances that are manufactured in a series to correspond to each two-week stage of the ClinCheck simulation. Aligners are customized to perform the treatment prescribed for an individual patient by dental professionals using ClinCheck.

2002 Private Placement Transaction

On November 14, 2002, we entered into a Stock Purchase Agreement to sell 9,578,943 shares of our common stock at a per share purchase price of \$1.90 to a group of institutional investors led by existing stockholders in a private placement. The shares sold are unregistered and were issued pursuant to the private placement exemption from the registration requirements of Section 5 of the Securities Act. In accordance with the terms of the Stock Purchase Agreement, we are obligated to file this registration statement registering the shares for resale at least 30 days prior to November 20, 2003, and to use our reasonable best efforts to cause this registration statement to become effective as soon thereafter as practicable but not prior to November 20, 2003. We will not receive any proceeds from the sale of the shares by the selling stockholders. All net proceeds from the sale of our common stock will go to the stockholders who offer and sell their shares.

Table of Contents

RISK FACTORS

Before you invest in any of our securities, you should be aware of various risks, including those described below. The following lists some, but not all, of these risks and uncertainties which may have a material adverse effect on our business, financial condition or results of operations. You should carefully consider these risk factors, together with all of the other information included or incorporated by reference in this prospectus and in the prospectus supplement, before you decide whether to purchase any of our securities. The risks set out below are not the only risks we face.

If any of the following risks occur, our business, financial condition and results of operations could be materially adversely affected. In such case, the trading price of our securities could decline, and you may lose all or part of your investment.

Since we have a history of losses and negative operating cash flows, we expect our operating losses to continue throughout fiscal 2003 and we may not achieve or maintain profitability in the future.

You should consider our business and prospects in light of the risks, expenses and difficulties encountered by a company in an early stage of development. Since inception, we have incurred significant operating losses and we have not yet achieved profitability. From inception through July 2000, we spent significant funds on organizational and start-up activities, recruiting key managers and employees, developing Invisalign and developing our manufacturing and customer support resources. We also spent significant funds on clinical trials and training programs to train dental professionals in the use of Invisalign.

We continue to incur significant operating expenses to:

develop new software and increase the automation of our manufacturing processes;

execute our consumer advertising campaign and dental professional marketing efforts;

increase the size of our sales force and dental professional training staff;

execute clinical research and education plans;

develop technological improvements to our products;

continue our international sales and marketing efforts; and

undertake quality assurance and improvement initiatives.

Edgar Filing: ALIGN TECHNOLOGY INC - Form 424B3

As a result, we will need to increase our revenue significantly, while controlling our expenses, to achieve profitability. Only recently, beginning in the third quarter of 2003, have we generated positive cash flow from operations, and we cannot be certain that we will be able to sustain or increase such positive cash flow from operations, from period to period, in the future. It is possible that we will not achieve profitability in the future, if at all, and even if we do achieve profitability, we may not be able to sustain or increase profitability in future periods.

We have a limited operating history and expect our future financial results to fluctuate significantly, which may cause our stock price to decline.

We were incorporated in April 1997 and began sales of Invisalign in July 1999. Thus, we have a limited operating history, which makes an evaluation of our future prospects and your investment in our stock difficult. In addition, we expect our future quarterly and annual operating results to fluctuate as we increase our commercial sales. These fluctuations could cause our stock price to decline. Some of the factors that could cause our operating results to fluctuate include:

changes in the timing of product orders;

Table of Contents

unanticipated delays in production caused by insufficient capacity, any disruptions in the manufacturing process or the introduction of new production processes;

inaccurate forecasting of revenue, production and other operating costs; and

the development and marketing of directly competitive products by potential competitors.

To respond to these and other factors, we may need to make business decisions that could adversely affect our operating results. Most of our expenses, such as employee compensation and lease payment obligations, are relatively fixed in the short term. Moreover, our expense levels are based, in part, on our expectations regarding future revenue levels. As a result, if our revenue for a particular period falls below our expectations, we may be unable to adjust spending quickly enough to offset any unexpected shortfall in revenue growth or any decrease in revenue levels.

Due to these and other factors, we believe that quarter-to-quarter comparisons of our operating results may not be meaningful. You should not rely on our results for any one quarter as an indication of our future performance.

We have limited product offerings, and if demand for Invisalign declines or fails to develop as we expect, our revenue will decline.

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

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

Our success depends upon increasing acceptance of Invisalign by dental professionals. Invisalign requires dental professionals and their staff to undergo special training and learn to interact with patients in new ways. In addition, because Invisalign has only been in clinical testing since July 1997 and commercially available only since July 1999, dental professionals may be reluctant to adopt it until more historical clinical results are available. Also, increasing adoption and cumulative use by dental professionals will depend on factors such as the capability, safety, efficacy, ease of use, price, quality and reliability of our products and our provision of effective sales support, training and service. In the future, unanticipated poor clinical performance of Invisalign could result in significant adverse publicity and, consequently, reduced acceptance by dental professionals. If Invisalign does not achieve growing acceptance in the orthodontic and dental communities, our operating results will be harmed.

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

Invisalign represents a significant change from traditional orthodontic treatment, and patients may be reluctant to accept it or may not find it preferable to conventional treatment. In addition, patients may not comply with recommended treatment guidelines for Invisalign, which could compromise the effectiveness of their treatment. We have generally received positive feedback from both dental professionals and patients regarding Invisalign as both an alternative to braces and as a clinical method for treatment of malocclusion, but a number of dental professionals believe that Invisalign is appropriate for only a limited percentage of their patients. Our success will depend upon the acceptance of Invisalign

Edgar Filing: ALIGN TECHNOLOGY INC - Form 424B3

by a substantially larger number of dental professionals and potential patients to whom we are now actively marketing. We have had a limited number of complaints from patients and prospective patients generally related to shipping delays and minor manufacturing irregularities. Market acceptance will depend in part upon the recommendations of dental professionals, as well

Table of Contents

as other factors including effectiveness, safety, reliability, improved treatment aesthetics and greater comfort and hygiene compared to conventional orthodontic products. Furthermore, consumers may not respond to our direct marketing campaigns or we may be unsuccessful in reaching our target audience. Adoption by consumers may also be impacted by general macroeconomic conditions, including the economic downturn and increased unemployment levels in the United States of America, levels of consumer confidence and consumer spending, all of which fluctuate and could be affected by unstable global economic, political or other conditions. If orthodontists and dentists experience a reduction in consumer demand for orthodontic services or consumers prove unwilling to adopt Invisalign as rapidly as we anticipate or in the volume that we anticipate, our operating results will be harmed.

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

Currently, two of our key production steps are performed in operations located outside of the U.S. At our facility in Costa Rica, technicians use a sophisticated, internally developed computer-modeling program to prepare electronic treatment plans, which are transmitted electronically back to the U.S. These electronic files form the basis of our ClinCheck product and are used to manufacture Aligner molds. A third party manufacturer in Mexico fabricates Aligners and ships the completed products to our customers. Our costs associated with these operations are denominated in Costa Rican colons, Mexican pesos and U.S. dollars.

Our reliance on international operations exposes us to risks and uncertainties that may affect our business or results of operation, including:

political, social and economic instability;

acts of terrorism and acts of war;

difficulties in staffing and managing international operations;

controlling quality of the manufacturing process;

interruptions and limitations in telecommunication services;

product or material transportation delays or disruption;

burdens of complying with a wide variety of local country and regional laws;

trade restrictions and changes in tariffs;

import and export license requirements and restrictions;

fluctuations in currency exchange rates; and

potential adverse tax consequences.

If any of these risks materialize in the future, our operating results may be harmed.

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

Our success will depend in part on our ability to maintain existing intellectual property and to obtain and maintain further intellectual property protection for our products, both in the U.S. and in other countries. Our inability to do so could harm our competitive position. We believe our intellectual property position represents a substantial business advantage. As of October 31, 2003, we had 39 issued U.S. patents, 70 pending U.S. patent applications, and numerous foreign issued patents, as well as 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

Table of Contents

pending or future patent filings may not issue as patents. Additionally, any patents issued to us may be challenged, invalidated, held unenforceable, circumvented, or may not be sufficiently broad to prevent third parties from producing competing products similar in design to our products. In addition, any protection afforded by foreign patents may be more limited than that provided under U.S. patents and intellectual property laws. We also rely on protection of our copyrights, trade secrets, know-how and proprietary information. We generally enter into confidentiality agreements with our employees, consultants and our collaborative partners upon commencement of a relationship with us. However, these agreements may not provide meaningful protection against the unauthorized use or disclosure of our trade secrets or other confidential information, and adequate remedies may not exist if unauthorized use or disclosure were to occur. Our inability to maintain the proprietary nature of our technology through patents, copyrights or trade secrets would impair our competitive advantages and could have a material adverse effect on our operating results, financial condition and future growth prospects. In particular, a failure of our proprietary rights might allow competitors to copy our technology, which could adversely affect pricing and market share.

If we infringe the patents or proprietary rights of other parties or are subject to a patent infringement claim, our ability to grow our business will be severely limited.

Extensive litigation over patents and other intellectual property rights is common in the medical device industry. We have been sued for infringement of another party's patent in the past and, while that action has been dismissed, we may be the subject of patent or other litigation in the future.

On January 6, 2003, Ormco Corporation filed suit against us in the United States District Court for the Central District, Orange County Division, asserting infringement of U.S. Patent Nos. 5,447,432, 5,683,243 and 6,244,861. The complaint seeks unspecified monetary damages and injunctive relief. On February 18, 2003, we answered the complaint and asserted counterclaims seeking a declaration by the Court of invalidity and non-infringement of the asserted patents. In addition, we counterclaimed for infringement of its U.S. Patent No. 6,398,548, seeking unspecified monetary damages and injunctive relief. Ormco filed a reply to our counterclaims on March 10, 2003 and asserted counterclaims against us seeking a declaration by the Court of invalidity and non-infringement of U.S. Patent No. 6,398,548. We responded to Ormco's counterclaims on April 2, 2003. At a Scheduling Conference held on June 30, 2003, the Court set a January 2, 2004, discovery cutoff and a May 2004 trial date. The Court also granted leave for us to amend our counterclaim to add Allesee Orthodontic Appliances, Inc. (AOA), a wholly-owned subsidiary of Ormco, as a defendant in regard to our claim of infringement of U.S. Patent No. 6,398,548. We filed our amended answer and counterclaim on July 7, 2003.

On June 11, 2003, Ormco's wholly-owned subsidiary, AOA, filed a declaratory judgment action against us in the Eastern District of Wisconsin, seeking a determination that U.S. Patent No. 6,398,548 (the same patent the Company is asserting against Ormco and AOA in the Central District of California) is invalid and/or not infringed. On July 9, 2003, we answered the Wisconsin complaint and counterclaimed for infringement of U.S. Patent No. 6,398,548, seeking unspecified monetary damages and injunctive relief. On July 7, 2003, Ormco filed a motion in the Central District of California to sever our counterclaims and a motion to transfer those counterclaims to the Eastern District of Wisconsin. Also on July 7, 2003, we filed a motion in the Central District of California to enjoin Ormco and AOA from proceeding with the action filed in the Eastern District of Wisconsin. The Central District of California denied Ormco's motion to sever, did not decide Ormco's motion to transfer and found our counterclaims were properly filed in the Central District of California, but denied our motion to enjoin without prejudice to renew, deferring to the Eastern District of Wisconsin to stay or dismiss the case pending in that District. Shortly thereafter, the parties stipulated to the dismissal of AOA's Wisconsin action. Currently pending before the Court is Ormco's motion to amend its complaint to add its newly-issued U.S. Patent No. 6,616,444 to this case. We also seeks to add U.S. Patent No. 6,554,611 to this case.

Three years ago, Ormco filed suit against us asserting infringement of U.S. Patent Nos. 5,447,432 and 5,683,243. In June 2000, the parties entered into a Stipulation of Dismissal with Ormco. Ormco agreed for a

Table of Contents

period of at least two years not to pursue litigation with respect to these patents, except as set forth below. Further, Ormco agreed that it would not bring any patent action against us for at least a period of one year with respect to any as yet unissued patents. If Ormco were to bring such an action concerning as yet unissued patents after one year, the Stipulation of Dismissal would allow Ormco to include in such an action claims involving U.S. Patent Nos. 5,447,432 and 5,683,243. In August 2001, Ormco notified us of the issuance of U.S. Patent No. 6,244,861 and offered a license for this patent. We did not take a license to this patent. Five months after Ormco's notification, it filed the lawsuit that is currently pending.

The claims in U.S. Patent Nos. 5,447,432 and 5,683,243 relate to methods and systems for forming and manufacturing custom orthodontic appliances. The relevant claims are limited to computerized methods and algorithms for determining the final positioning of a patient's teeth based upon a derived or ideal dental archform of the patient. The claims in U.S. Patent No. 6,244,861 are more generic claims relating to the methods and systems for forming and manufacturing custom orthodontic appliances. Based on the disclosure in the patent, however, the relevant claims also appear to be limited to computerized methods and algorithms for determining the final positioning of a patient's teeth based upon a derived or ideal dental archform of the patient. The treatment plan simulation developed in our facilities determines the final positioning of a patient's teeth but is not based on a derived or ideal dental archform of the patient.

The claims in our U.S. Patent No. 6,398,548 relate to methods and systems for incrementally moving teeth using a series of appliances designed to be placed successively on the patient's teeth.

We strongly believe that Ormco's claims of infringement lack merit and that Align's counterclaim of infringement will be successful. However, the outcome of a lawsuit is inherently unpredictable. Should our technology be found to infringe any one of Ormco's asserted patents, 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 its business.

From time to time, we have received and may in the future receive letters from third parties drawing our attention to their patent rights. While we do not believe that we infringe upon any valid and enforceable rights that 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.

Pending or Future Litigation Could Have a Material Adverse Impact on Our Results of Operation and Financial Condition.

We are currently a party to various legal proceedings and claims. Management does not believe that the ultimate outcome of these legal proceedings and claims will have a material adverse effect on our financial position or results of operations. However, litigation is subject to inherent uncertainties and unfavorable rulings could occur. An unfavorable ruling could include monetary damages or, in cases where injunctive relief is sought, an injunction prohibiting us from selling our products. If an unfavorable ruling were to occur in any specific period, there exists the possibility of a material adverse impact on the results of operations of that period or future periods.

On April 9, 2002, we exercised our right to terminate an Exclusive Marketing Agreement dated October 18, 2001 with Discus Dental Impressions, Inc. pursuant to the express terms of the Agreement and issued a press release reporting this termination. On or about May 14, 2002

we received a demand for arbitration submitted by

Table of Contents

Discus Dental with the American Arbitration Association in San Jose, California. In its arbitration demand, Discus Dental sought damages of approximately \$30 million, including commissions and bonus payments it claims it would have allegedly received under the Agreement as well as other expenses, attorneys' fees and injunctive relief to prevent us from selling Invisalign to dentists in the U.S. and Canada. Based on a review of the factual and legal issues, we deny all claims made by Discus Dental in its demand and contend that such claims are entirely without merit. In addition, on or about June 13, 2002 we submitted a counter-claim against Discus in the arbitration seeking damages of approximately \$40 million arising out of our claims for misrepresentation, breach of confidentiality provisions, and unfair competition, among others. Three arbitrators were selected, and the arbitration hearing commenced in San Francisco on August 18, 2003. The parties completed presenting witness testimony on September 9, 2003. The parties completed all post-hearing legal briefing on October 10, 2003, and the closing argument was heard on October 29, 2003. Discus now seeks lost profit damages of \$46.5 million or loss of goodwill/out of pocket damages of \$13.5 million. We previously and voluntarily dismissed our damage counter-claims but maintained our counter-claim for declaratory relief, seeking a judicial declaration that we properly terminated the Agreement with Discus. The arbitrators are expected to issue a ruling by the end of November, 2003.

We currently rely on third parties to provide key inputs to our manufacturing process, and if our access to these inputs is diminished, our business may be harmed.

We currently outsource key portions of our manufacturing process. We rely on a third party manufacturer in Mexico to fabricate Aligners and to ship the completed product to customers. As a result, if this third party manufacturer fails to deliver its components or if we lose its services, we may be unable to deliver our products in a timely manner and our business may be harmed. This third party manufacturer was recently acquired by a larger company in its industry. Any difficulties encountered by the acquiring company with respect to assimilating personnel and operations, and maintaining acceptable manufacturing standards, controls, procedures and policies could disrupt our ability to deliver our products in a timely manner. Finding a substitute manufacturer may be expensive, time-consuming or impossible.

In addition, we are highly dependent on manufacturers of specialized scanning equipment, rapid prototyping machines, resin and other advanced materials. We maintain single supply relationships for many of these machines and materials technologies. Our growth may exceed the capacity of one or more of these manufacturers to produce the needed equipment and materials in sufficient quantities to support our growth. In the event of delivery delays or shortages of these items, our business and growth prospects may be harmed.

We have experienced rapid growth, and our failure to manage this growth could harm our business.

We have expanded rapidly since we commenced commercial sales in 1999. Our headcount increased from approximately 50 employees as of September 30, 1999 to approximately 716 employees as of September 30, 2003. This expansion will continue to place significant demands on our management and other resources and will require us to continue to develop and improve our operational, financial and other internal controls, both in the U.S. and internationally. In particular, rapid growth increases the challenges involved in a number of areas, including recruiting and retaining sufficient skilled personnel, providing adequate training and supervision to maintain our high quality standards, and preserving our culture and values. Our inability to effectively manage this level of growth could harm our business.

If we lose our key personnel or are unable to attract and retain key personnel, we may be unable to pursue business opportunities or develop our products.

We are highly dependent on the key employees in our clinical engineering and management teams. The loss of the services of those individuals may significantly delay or prevent the achievement of our product development and other business objectives and could harm our business. Our future success will also depend on our ability to identify, recruit, train and retain additional qualified personnel. In addition, few orthodontists

are

7

Table of Contents

accustomed to working in a manufacturing environment since they are generally trained to work in private practices, universities and other research institutions. Thus, we may be unable to attract and retain personnel with the advanced qualifications necessary for the further development of our business. Furthermore, we may not be successful in retaining our key personnel or their services. If we are unable to attract and retain key personnel, our business could be materially harmed.

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

Currently, our Invisalign product competes directly against a product called Red, White and Blue, which is manufactured and distributed by Ormco, a subsidiary of Sybron Dental Specialties. In addition, manufacturers of traditional braces, such as 3M Company, Sybron Dental Specialties and Dentsply International, Inc. have substantially greater financial resources and manufacturing and marketing experience than we do and may, in the future, attempt to develop an orthodontic system similar to ours. Large consumer product companies may also enter the orthodontic supply market. Furthermore, we may face competition in the future from new companies that may introduce new technologies. We may be unable to compete with these competitors and one or more of these competitors may render our technology obsolete or economically unattractive. If we are unable to compete effectively with existing products or respond effectively to any products developed by our competitors, our business could be harmed.

We may be unable to raise additional capital if it should be necessary, which could harm our ability to compete.

We have incurred significant operating losses and negative operating cash flows since inception and have not yet achieved profitability. As of September 30, 2003, we had an accumulated deficit of approximately \$301.0 million.

We expect to expend significant capital to continue to build our national brand, expand our dental professional channels, automate our manufacturing processes and develop both product and process technology. In November 2002, we completed a private placement of common stock to a group of investors led by existing stockholders, raising \$18.1 million, net of issuance costs. In December 2002, we secured an accounts receivable-based revolving line of credit of up to \$10.0 million and an equipment-based term loan of \$5.0 million, which was fully drawn down in December 2002. As of September 30, 2003, we had not utilized the accounts receivable-based revolving line of credit. Accessing the accounts receivable-based revolving line of credit is restricted based on qualifying accounts receivable and compliance with customary loan covenants. There can be no assurance that such financing will be adequate for us to avoid reducing operating expenses by, among other things, reducing planned capital expenditures relating to enhancing our manufacturing process and reducing worldwide staff.

Complying with the Food and Drug Administration (FDA) and other regulations is an expensive and time-consuming process, and any failure to comply could result in substantial penalties.

Our products are medical devices and are subject to extensive regulation in the U.S. and internationally. FDA regulations are wide ranging and govern, among other things:

product design, development, manufacture and testing;

product labeling;

product storage;

pre-market clearance or approval;

advertising and promotion; and

product sales and distribution.

Table of Contents

Noncompliance with applicable regulatory requirements can result in enforcement action which may include recalling products, ceasing product marketing, and paying significant fines and penalties. One or more of these enforcement actions could limit product sales, delay product shipment and adversely affect our profitability.

We must comply with facility registration and product listing requirements of the FDA and adhere to applicable Quality System regulations. The FDA enforces its Quality System regulations through periodic unannounced inspections, which we have yet to undergo. If we or any third party manufacturer of our products do not conform to applicable Quality System regulations, we may be required to find alternative manufacturers, which could be a long and costly process.

Before we can sell a new medical device in the U.S., we must obtain FDA clearance or approval, which can be a lengthy and time-consuming process. Even though the devices we market have obtained the necessary clearances from the FDA through the pre-market notification provisions of Section 510(k) of the federal Food, Drug, and Cosmetic Act, we may be unable to maintain the necessary clearances in the future. Furthermore, we may be unable to obtain the necessary clearances for new devices that we market in the future. Our inability to maintain or obtain regulatory clearances or approvals could materially harm our business.

If the security of our customer and patient information is compromised, patient care could suffer, we could be liable for related damages, and our reputation could be impaired.

We retain confidential customer and patient information in our processing centers. Therefore, it is critical that our facilities and infrastructure remain secure and that our facilities and infrastructure are perceived by the marketplace and our customers to be secure. Despite the implementation of security measures, our infrastructure may be vulnerable to physical break-ins, computer viruses, programming errors, attacks by third parties or similar disruptive problems. If we fail to meet our clients' expectations, we could be liable for damages and our reputation could be impaired. In addition, patient care could suffer and we could be liable if our systems fail to deliver correct information in a timely manner. Our insurance may not protect us from this risk.

If compliance with government regulations of healthcare becomes costly and difficult for our customers or for us, we may not be able to grow our business.

Participants in the healthcare industry are subject to extensive and frequently changing regulations under numerous laws administered by governmental entities at the federal, state and local levels, some of which are, and others of which may be, applicable to our business. Furthermore, our healthcare service provider, payor and plan customers are also subject to a wide variety of laws and regulations that could affect the nature and scope of their relationships with us.

The healthcare market itself is highly regulated and subject to changing political, economic and regulatory influences. Regulations implemented pursuant to the Health Insurance Portability and Accountability Act (HIPAA) may require us to make unplanned enhancements of software applications or services, result in delays or cancellations of orders, or result in the revocation of endorsement of our products and services by healthcare participants. The affect of HIPAA on our business is difficult to predict, and there can be no assurance that we will adequately address the business risks created by HIPAA and its implementation or that we will be able to take advantage of any resulting business opportunities.

Extensive and changing government regulation of the healthcare industry may be expensive to comply with and exposes us to the risk of substantial government penalties.

In addition to medical device laws and regulations, numerous state and federal healthcare-related laws regulate our business, covering areas such as:

storage, transmission and disclosure of medical information and healthcare records;

Table of Contents

prohibitions against the offer, payment or receipt of remuneration to induce referrals to entities providing healthcare services or goods;
and

the marketing and advertising of our products.

Complying with these laws and regulations could be expensive and time-consuming, and could increase our operating costs or reduce or eliminate certain of our sales and marketing activities or our revenues.

We face risks related to our international sales, including the need to obtain necessary foreign regulatory clearance or approvals.

Sales of our products outside the U.S. are subject to foreign regulatory requirements that vary widely from country to country. The time required to obtain clearances or approvals required by other countries may be longer than that required for FDA clearance or approval, and requirements for such approvals may differ from FDA requirements. We may be unable to obtain regulatory approvals in one or more of the other countries in which we do business or in which we may do business in the future. We may also incur significant costs in attempting to obtain and maintain foreign regulatory approvals. If we experience delays in receipt of approvals to market our products outside of the U.S., or if we fail to receive these approvals, we may be unable to market our products or enhancements in international markets in a timely manner, if at all. We currently sell our product in Europe, the United Kingdom, Mexico, Brazil, Australia and Hong Kong, and may expand into other countries from time to time. We do not know whether orthodontists, dentists and consumers outside our domestic market will adopt Invisalign in sufficient numbers or as rapidly as we anticipate.

Our business exposes us to potential product liability claims, and we may incur substantial expenses if we are subject to product liability claims or litigation.

Medical devices involve an inherent risk of product liability claims and associated adverse publicity. We may be held liable if any product we develop or any product that uses or incorporates any of our technologies causes injury or is otherwise found unsuitable. Although we intend to continue to maintain product liability insurance, adequate insurance may not be available on acceptable terms, if at all, and may not provide adequate coverage against potential liabilities. A product liability claim, regardless of its merit or eventual outcome, could result in significant legal defense costs. These costs would have the effect of increasing our expenses and diverting management's attention away from the operation of our business, and could harm our business.

In fiscal 2002, the market price for our common stock declined significantly and was highly volatile. Although the market price for our common stock has increased during fiscal 2003, the market price of our common stock could be subject to wide price fluctuations in response to various factors, many of which are beyond our control.

In fiscal 2002, market price of our common stock declined and was highly volatile. Although the market price for our common stock has increased during fiscal 2003, the market price of our common stock could be subject to wide price fluctuations in response to various factors, many of which are beyond our control, including:

quarterly variations in our results of operations and liquidity;

Edgar Filing: ALIGN TECHNOLOGY INC - Form 424B3

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

speculation in the press or investment community concerning our business and results of operations;

strategic actions by our competitors, such as product announcements or acquisitions; and

announcements of technological innovations or new products by us, our customers or competitors; and general market conditions.

Table of Contents

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, class action litigation has often been brought against the issuing company following periods of volatility in the market price of a company's securities. If a securities class action suit is filed against us in the future, 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.

Future sales of significant amounts of our common stock may depress our stock price.

A large percentage of our outstanding common stock is currently owned by a small number of significant stockholders. These stockholders have sold in the past, and may sell in the future, large amounts of common stock over relatively short periods of time. Sales of substantial amounts of our common stock in the public market by our existing stockholders may adversely affect the market price of our common stock. Such sales could create public perception of difficulties or problems with our business. In addition, certain of our current stockholders have registration rights in connection with a private placement sale of approximately 9.6 million shares of our common stock that occurred in November 2002. As a result of these registration rights, we were required to file a registration statement under the Securities Act at our expense to register the securities sold in the November 2002 private placement. We filed this registration statement with the SEC on October 17, 2003. As soon as this registration statement is effective, our stock price could fluctuate significantly if the holders of these shares sell them or are perceived by the market as intending to sell them. These sales may also make it more difficult for us to sell securities in the future at a time and at a price we deem appropriate.

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

The interests of our management could conflict with those of our other stockholders. As of September 30, 2003, our executive officers, directors and principal stockholders beneficially owned an aggregate of approximately 52.6% of our outstanding common stock. These stockholders, if acting together, would be able to influence significantly all matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. This could have the effect of delaying or preventing a change of control of us, which in turn could reduce the market price of our stock.

Table of Contents

WHERE TO FIND ADDITIONAL INFORMATION ABOUT ALIGN

We have filed reports, proxy statements and other information with the Securities and Exchange Commission, or SEC. You may read and copy any document we file with the SEC at the SEC's Public Reference Room at 450 Fifth Street, N.W., Washington, D.C. 20549. You may obtain information on the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC maintains a website that contains the reports, proxy statements and other information we file with the SEC. The address of the SEC website is <http://www.sec.gov>.

INFORMATION INCORPORATED BY REFERENCE

The SEC allows us to incorporate by reference the information we file with it, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is considered to be part of this prospectus, and later information that we file with the SEC will automatically update and supersede the information contained in this prospectus, including the information incorporated by reference in this prospectus. We incorporate by reference the documents listed below, and any future filings we may make with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act of 1934, as amended (the Exchange Act) prior to the termination of this offering. This prospectus is part of a registration statement we filed with the SEC. The documents we incorporate by reference include:

1. Our Annual Report on Form 10-K for the fiscal year ended December 31, 2002 filed with the SEC on March 27, 2003.
2. Our Annual Report on Form 10-K/A for the fiscal year ended December 31, 2002 filed with the SEC on August 13, 2003.
3. Our Definitive Proxy Statement on Schedule 14A filed on April 14, 2003.
4. Our Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2003 filed with the SEC on May 13, 2003.
5. Our Quarterly Report on Form 10-Q/A for the fiscal quarter ended March 31, 2003 filed with the SEC on August 13, 2003.
6. Our Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2003 filed with the SEC on August 13, 2003.
7. Our Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2003 filed with the SEC on November 12, 2003.

Each of these filings is available from the SEC as described above. You may request, and we will provide at no cost, a copy of these filings, including any exhibits to such filings, by writing or telephoning us at the following address:

Barbara Domingo Investor Relations

Align Technology, Inc.

881 Martin Avenue

Edgar Filing: ALIGN TECHNOLOGY INC - Form 424B3

Santa Clara, California 95050

(408) 470-1000

12

Table of Contents

FORWARD-LOOKING INFORMATION

This prospectus, including the information incorporated by reference herein, contains forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act. These forward-looking statements include, but are not limited to, statements about our plans, objectives, expectations and intentions and other statements contained in this prospectus that are not historical facts. When used in this prospectus, the words *expects*, *anticipates*, *estimates* and similar expressions are intended to identify forward looking statements. Because these forward looking statements involve risks and uncertainties, there are important facts that could cause our actual results to differ materially from those expressed or implied by these forward looking statements, including statements under the caption *Risk Factors*. Please review these risk factors carefully. In addition, please review the sections captioned *Factors Affecting Future Operating Results* under *Management's Discussion and Analysis of Financial Condition and Results of Operations* in our annual report on Form 10-K for the fiscal year ended December 31, 2002, as amended and filed on Form 10-K/A on August 13, 2003, and our quarterly report on Form 10-Q for the fiscal quarter ended September 30, 2003. In connection with forward looking statements which appear in these disclosures, you should carefully consider the risk factors set forth in this prospectus under *Risk Factors* and under the caption *Factors Affecting Future Operating Results* in the *Management's Discussion and Analysis* section of any subsequent annual or quarterly report we file with the SEC.

USE OF PROCEEDS

We will not receive any proceeds from the sale of the shares by the selling stockholders. The selling stockholders will receive all of the net proceeds from the sale of the shares under this prospectus.

SELLING STOCKHOLDERS

The following table sets forth information with respect to:

the number of shares and percentage of our common stock beneficially owned by each selling stockholder prior to this offering;

the amount to be offered for each selling stockholder's account; and

the amount and percentage to be held by each selling stockholder assuming the sale of all shares offered under this prospectus.

The information in the table below is current as of the date of this prospectus. The percentage ownership is based on shares of common stock outstanding as of October 31, 2003.

Some of the selling stockholders listed below may distribute their respective shares to their general or limited partners. Any shares so distributed may be offered hereunder by the general or limited partners of the distributing selling stockholders. Each general or limited partner distributee will be deemed to be a selling stockholder for purposes of this prospectus with respect to the distributed shares.

Table of Contents

The shares offered by this prospectus may be offered from time to time by the selling stockholders named below:

Selling Stockholder	Shares Beneficially		Number of Shares Being Offered	Shares Beneficially	
	Owned Prior			Owned After Offering	
	to Offering			Number	Percent
	Number	Percent		Number	Percent
Carlyle Partners III, L.P. (1).	3,510,804	6.0%	2,565,457	945,347	1.6%
CP III Coinvestment, L.P. (1)	90,486	*	66,121	24,365	*
Dionis Trust (2)	2,285,872	3.9%	1,052,632	1,233,240	2.1%
Gordon Gund Grant Gund Generation Skipping Trust (3)	839,473	1.4%	789,473	50,000	*
Gordon Gund G. Zachary Gund Skipping Trust (4)	839,473	1.4%	789,473	50,000	*
Kleiner Perkins Caufield Byers VIII, L.P. (5)	5,222,718	8.9%	1,492,421	3,730,297	6.4%
KPCB VIII Founders Fund, L.P. (5)	305,181	*	86,526	218,655	*
Oak Hill Capital Management Partners, L.P. (6)	81,097	*	65,789	15,308	*
Oak Hill Capital Partners, L.P. (6)	3,163,582	5.4%	2,565,789	597,793	1.0%
Thomas M. Prescott	84,681	*	52,631	32,050	*
Warren Thaler	94,584	*	52,631	41,953	*

* Less than 1% of the outstanding shares of common stock.

- (1) TC Group III, L.P., the general partner of Carlyle Partners III, L.P. and CP III Coinvestment, L.P., exercises sole voting or investment power over the shares.
- (2) Gordon Gund and Llura Gund exercise shared voting or investment power over the shares. Each of these individuals are co-trustees of Dionis Trust.
- (3) Grant Gund, Richard T. Watson, Rebecca Dent and George Gund, III exercise shared voting or investment power over the shares. Each of these individuals are co-trustees of Gordon Gund Grant Gund Generation Skipping Trust.
- (4) G. Zachary Gund, Richard T. Watson, Rebecca Dent and George Gund, III exercise shared voting or investment power over the shares. Each of these individuals are co-trustees of Gordon Gund G. Zachary Gund Skipping Trust.
- (5) KPCB VIII Associates, L.P., the general partner of Kleiner Perkins Caufield and Byers VIII, L.P. and KPCB VIII Founders Fund, L.P., exercises sole voting or investment power over the shares.
- (6) OHCP GenPar, L.P., the general partner of Oak Hill Capital Management Partners, L.P. and Oak Hill Capital Partners, L.P., exercises sole voting or investment power over the shares.

Table of Contents

PLAN OF DISTRIBUTION

We will not receive any proceeds from the sale of the shares by the selling stockholders. The selling stockholders will receive all of the net proceeds from the sale of the shares under this prospectus. The shares may be sold or distributed from time to time by the selling stockholders or by pledgees, donees, transferees of, or other successors in interest to, the selling stockholders directly to one or more purchasers (including pledgees) or through brokers, dealers or underwriters who may act solely as agents or may acquire shares as principals at market prices prevailing at the time of sale, at prices related to such prevailing market prices, at negotiated prices or at fixed prices, all of which may be changed. The distribution of the shares may be effected in one or more transactions that may take place through the Nasdaq National Market, including block trades or ordinary broker's transactions, or through privately negotiated transactions, through put or call options transactions relating to the shares, through short sales of the shares or through a combination of any such methods of sale, at market prices prevailing at the time of sale, at prices related to such prevailing market prices or negotiated prices. Usual and customary or specifically negotiated brokerage fees or commissions may be paid by the selling stockholders in connection with such sales.

The aggregate proceeds to the selling stockholders from the sale of the shares will be the purchase price of the common stock sold less the aggregate agents' commissions, if any, and other expenses of issuance and distribution not borne by us. The selling stockholders and any dealers or agents that participate in the distribution of the shares may be deemed to be underwriters within the meaning of the Securities Act, and any profit on the sale of the shares by them and any commissions received by any such dealers or agents might be deemed to be underwriting discounts and commissions under the Securities Act.

The selling stockholders or the successors in interest to the selling stockholders may enter into hedging transactions with broker-dealers who may engage in short sales of shares in the course of hedging the positions they assume with the selling stockholders. The selling stockholders or the successors in interest to the selling stockholders may also enter into option or other transactions with the broker-dealers that require the delivery to such broker-dealers of the shares, which shares may be resold thereafter by such broker-dealer pursuant to this prospectus. We have informed the selling stockholders that the anti-manipulative provisions of Regulation M promulgated under the Exchange Act may apply to their sales in the market.

To the extent required, the specific shares to be sold, the names of the selling stockholders, the purchase price, the public offering price, the names of any such agent, dealer or underwriter and any applicable commission or discount with respect to a particular offering will be set forth in an accompanying prospectus supplement.

Pursuant to the Stock Purchase Agreement entered into in connection with the Financing, the selling stockholders have agreed that they will not, prior to the earlier of (i) November 20, 2003 and (ii) the effectiveness of this registration statement, sell, offer to sell, solicit offers to buy, dispose of, loan, pledge or grant any right, or take any action with respect to any shares of common stock acquired in the Financing except with the written consent of Align. This prohibition on the sale of the shares acquired in the Financing includes short sales of the shares and any other hedging or other transaction that is designed to or could reasonably be expected to lead to or result in the sale of the shares by the selling stockholder or any other person or entity.

We have agreed to bear certain expenses of registration of the shares under federal and state securities laws and other expenses related to the registration of shares hereunder excluding expenses associated with the actual sale of such shares, such as commissions of dealers or agents and related fees. We have agreed to indemnify the selling stockholders against certain liabilities, including certain potential liabilities under the Securities Act. The selling stockholders have also agreed to indemnify us against certain liabilities, including certain potential liabilities under the Securities Act arising from information provided by them for inclusion in this prospectus.

Edgar Filing: ALIGN TECHNOLOGY INC - Form 424B3

We may suspend the effectiveness of the registration statement of which this prospectus is part upon the happening of any event that we believe, in our reasonable judgment, requires additional disclosure of material,

Table of Contents

non-public information and that immediate disclosure of such information would be materially detrimental to us. We cannot exercise this right to suspend more than three (3) occasions of not more than 30 calendar days each in any 12-month period, unless, in the good faith judgment of our Board of Directors, the sale of our common stock under this registration statement would reasonably likely to cause a violation of the Securities Act or the Exchange Act and result in potential liability to us. During any period of suspension or deferral, we are required to use our reasonable best efforts to amend the registration statement and/or amend or supplement the related prospectus if necessary and to take all other actions necessary to allow the proposed sale to take place as soon as reasonably practicable, and in any event within 30 days after delivery of a suspension notice to the selling stockholders, subject, to our right to delay further sales of our common stock until the material, non-public information has been disclosed.

We are required to maintain the effectiveness of the registration statement of which this prospectus is part, until the earlier of:

the second anniversary of the closing date of the Financing (November 20, 2004);

the date on which the selling stockholders may sell all the shares of common stock purchased by them in the Financing without restriction by the volume limitations of Rule 144(e) promulgated under the Securities Act; or

such time as all the shares of common stock purchased by the selling stockholders in the Financing have been sold pursuant to this registration statement.

There can be no assurance that the selling stockholders will sell any or all of the shares offered by them under this prospectus.

LEGAL MATTERS

The validity of the shares offered under this prospectus has been passed upon for us by Wilson Sonsini Goodrich & Rosati, Professional Corporation, Palo Alto, California.

EXPERTS

The consolidated financial statements of Align incorporated in this prospectus by reference to the Annual Report on Form 10-K/A for the year ended on December 31, 2002, have been incorporated in reliance on the report of PricewaterhouseCoopers LLP, independent accountants, given on the authority of said firm as experts in auditing and accounting.