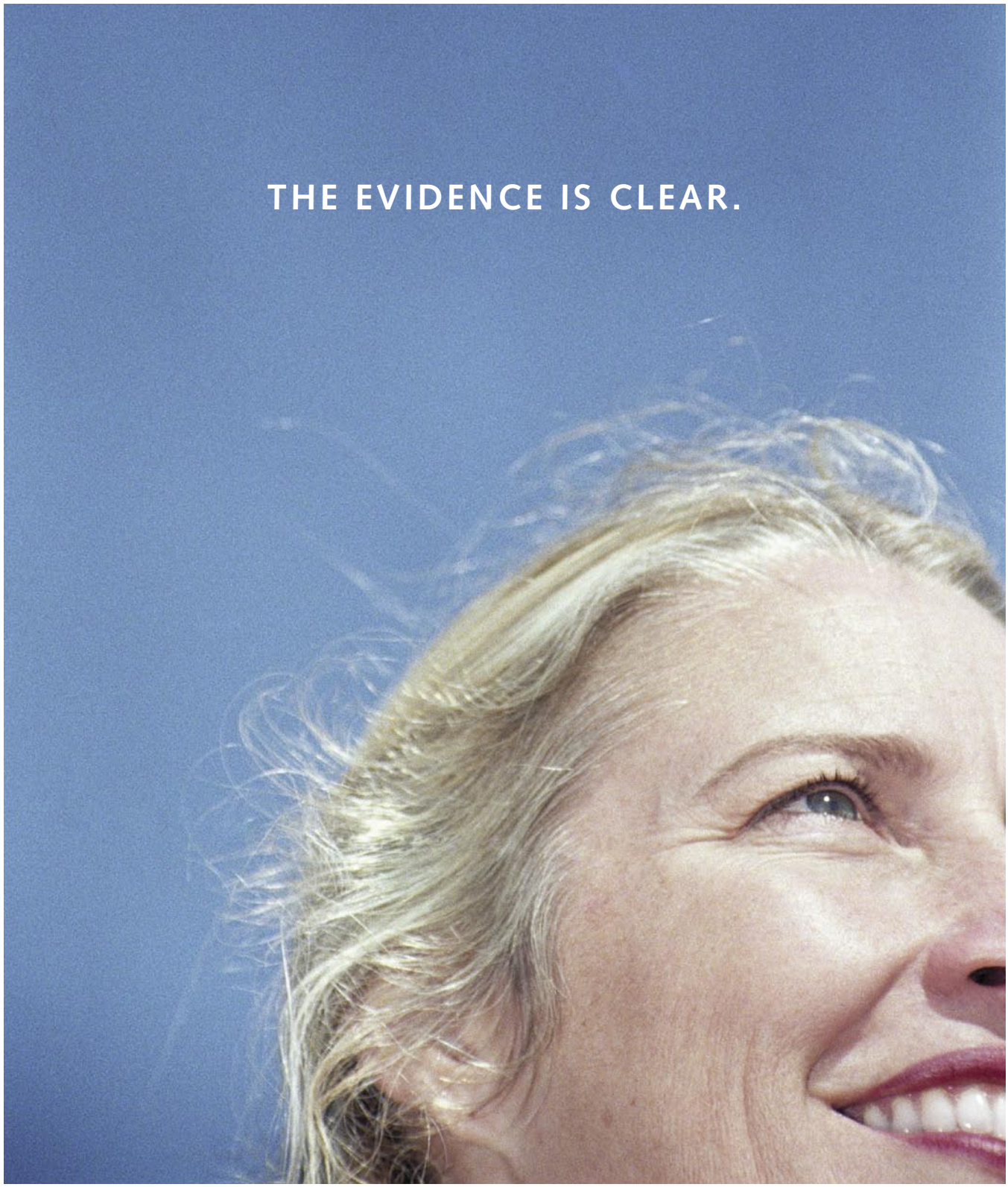


ALIGN

ALIGN TECHNOLOGY, INC.

2003 Annual Report

Financial Highlights

in thousands, except per share data	2003	2002	2001
Income Statement			
Total Revenues	$ 122,725	$ 69,698	$ 44,808
Gross Profit (Loss)	71,160	24,707	(2,022)
Total Operating Expense	91,097	97,642	98,747
Net Loss	$ (20,122)	$ (72,819)	$ (110,240)
Net Loss Per Share	$ (0.35)	$ (1.52)	$ (2.61)
Shares Used in Computing Net Loss Per Share	57,758	47,878	42,247
Balance Sheet			
Cash, Cash Equivalents and Marketable Securities	$ 47,670	$ 41,506	$ 66,394
Working Capital	39,737	41,160	62,172
Total Assets	102,202	92,856	118,218
Total Long-Term Liabilities	1,849	3,837	980
Stockholder's Equity	62,976	64,347	97,827
Reconciliation of GAAP to Non-GAAP Financials ($ per share, basic)			
Net Loss	$ (20,122)	$ (72,819)	$ (110,240)
Stock-based Compensation Included in:			
Cost of Revenues	2,560	3,399	4,602
Operating Expenses	12,471	16,886	17,831
Restructuring Costs Included in:	—	—	—
Cost of Revenues	—	559	—
Operating Expenses	507	4,635	—
Preferred Stock and Litigation Settlement Charges	—	—	13,394
Non-GAAP Net Loss	$ (4,584)	$ (47,340)	$ (74,413)
Non-GAAP Net Loss Per Share	$ (0.08)	$ (0.99)	$ (1.76)

WE'RE GETTING RESULTS.

1.

Our business model is working

Align's business model is built on three programs: enhancing automation, supporting customers through clinical education, and becoming an important and integral part of customers' practices. Successful execution of programs leads to increases in cases received and, therefore, revenues.

2.

We're creating opportunities for orthodontists and dentists

The opportunities for Align and its customers are great. Align aims to generate product awareness of Invisalign, giving customers an esthetic option for treating malocclusion. Orthodontists and GP dentists working together foster excellent treatment outcomes and satisfied patients.

3.

Invisalign applications continue to expand

Research and development are critical to creating a quality product that doctors want to recommend. With ongoing clinical research, Align's customers will be able to treat a greater number of patients using Invisalign.

Dear Fellow Shareholders:

2003 was a great year for Align. In addition to achieving the financial goals we set for the Company, we made significant progress in improving our operating performance, expanding our community of orthodontists and dentists, and increasing the use and applicability of our product.

Record Financial Performance.* Align reported record revenues of $122.7 million for 2003, an increase of 76% over 2002. The Company also reported 60% gross margins and decreased operating expenses to $78.1 million. By increasing our sales and managing our operations, we were able to decrease our net loss significantly – to $4.6 million, from $47.3 million in 2002. Our sales increased each quarter, we reported two quarters of non-GAAP profitability and we increased our cash position by $6.2 million, ending 2003 as a strong and financially stable company.

We continued to make strides in improving our manufacturing and operating costs through improvements in technology, automation and operating efficiency. These accomplishments have given us the solid financial foundation we need to continue capitalizing on the extraordinary growth opportunities that exist for Align both in the United States and abroad. All of us at Align are proud of our Company's performance in 2003 and excited about the opportunity to build on our success in the coming years.

Align's performance in 2003 reflects the hard work, dedication and commitment we have to exceeding customers' expectations. I am proud that our collective efforts to strengthen the Align brand and continue enhancing the quality of our product have won recognition from others, including our industry peers. This past year, Align was awarded the "Phoenix Emerging Growth Company Award" for our outstanding achievements in the medical device and diagnostic industries.

Investing in Education and Customer Support. Being a successful company is about more than just selling great products. At Align, we also believe that building long-term relationships with our customers requires delivering superior training, support and services at every step along the way. Last year, we conducted more than 350 clinical education events teaching our customers more about our product and increasing their confidence in getting great outcomes – leading to increases in case submissions. Approximately 155,000 people have experienced treatment using Invisalign. We also completed the move to our new 63,000-square-foot facility in Costa Rica. This facility serves as the headquarters for our digital dental lab, where we use patented, state-of-the-art 3-D modeling technology to create individualized treatments for each Invisalign case. Going forward, this investment will allow us to significantly expand our operations and capacity as demand for Invisalign grows.

Expanding the Invisalign Community. We continued to train doctors in record numbers in 2003. Approximately 24,000 doctors worldwide are now trained in Invisalign.

LETTER TO OUR SHAREHOLDERS

** Financial performance throughout this Annual Report is discussed on a non-GAAP basis. See the reconciliation of GAAP to non-GAAP financials on the "Financial Highlights" page.*

We made progress in increasing utilization in orthodontic practices and expanding the community of Invisalign-trained dentists, and these will remain important goals for us in 2004. We believe that the key to increasing the number of cases generated by doctors hinges on three important factors: providing superior training and ongoing education, supporting doctors' efforts to grow their practices and fostering greater collaboration between orthodontists and dentists. Last spring we launched the Online Clinical Education Center, which augments our training workshops, study clubs and doctor calls by enabling Invisalign-trained doctors to obtain continuing education credits and access a full range of case studies and best practices. We are confident that these initiatives, coupled with our ongoing direct-marketing efforts to stimulate consumer demand for Invisalign, will be increasingly powerful drivers of new case submissions.

We are excited about the rapidly growing acceptance of Invisalign by academicians, as evidenced by the New York University College of Dentistry's decision to incorporate Invisalign into its undergraduate curriculum. Working with Align, the College, which graduates more than 8% of all U.S. dentists each year, plans to train and certify all graduating students in Invisalign.

Poised for the Future. Invisalign is among the most innovative and potentially lucrative new orthodontic products since the advent of traditional wire-and-bracket teeth-straightening methods. Based on conservative estimates, we believe the existing orthodontic market for Invisalign in the U.S. alone is approximately $1 billion. The additional market opportunity of patients who would not seek treatment without the Invisalign option is even greater. Now, on the strength of our solid 2003 performance, Align is better-positioned than ever to attract new consumers and expand market share both in the U.S. and abroad.

As we execute our proven business strategy, prudent financial management will remain a primary focus. Our goals for 2004 are clear: continue growing our revenues and improving our gross margins by enhancing productivity through automation; enlarge the Invisalign community and become a more important part of our customers' practices; and selectively expand our presence in high-potential international markets, especially in Europe. We are confident that our market leadership, together with the competitive edge our patented technology gives us, will enable us to build value for our investors, customers and employees in 2004 and beyond.

I am grateful to all of our stakeholders for the unwavering support they have given us during this critical stage in our Company's development. The resulting strength and stability will be invaluable assets as we expand Align's market reach … one smile at a time.

Sincerely,

Thomas M. Prescott
President and Chief Executive Officer

Thomas M. Prescott
President and Chief Executive Officer

Q&A WITH

Eldon M. Bullington
VP, Finance and CFO

Thomas M. Prescott
President and CEO

What will drive future growth for Align? Align has two customers: the orthodontist and the general practice (GP) dentist. As specialists, orthodontists will always be Align's most important customers because they will continue to drive the research needed to push the envelope of Invisalign applications. On the other hand, GP dentists will eventually treat more patients, due to their greater numbers and their role as primary dental care providers. We believe that collaboration between our two types of customers is ideal. When an orthodontist and a GP dentist in a particular area work together and expand their referral relationship, the number of case referrals from GP dentists to orthodontists can increase – increasing the total number of cases we receive and, therefore, increasing our revenues. It is really a combination of orthodontists treating more patients, more GP dentists identifying additional cases to be treated, and the increased collaboration between the two practices that will accelerate growth in Invisalign cases and revenues for Align.

What are your goals for your customers? Our goal is to provide a quality product and excellent customer support – helping our customers get fantastic results. Their success comes from great clinical outcomes, happy patients and terrific financial rewards. As we enable expansion of their practices with Invisalign, we believe they will treat more patients with our system.

Does Align have competition? We view Invisalign as an additional product line for orthodontists and GP dentists, not as a replacement for braces. While we do compete indirectly with wire and bracket manufacturers, our intellectual property has made us the only provider of mass-customized invisible appliances used to treat malocclusion. In a broader sense, we also face competition for alternative uses of disposable income. Patients have a decision to make when considering Invisalign treatment – should they correct their malocclusion or should they spend their money elsewhere?

Is Invisalign being used for a greater variety of cases today than in previous years? When Align initially launched Invisalign, it was primarily used to treat adult patients with mild to moderate crowding. Thanks to good product development and clinical research, we have expanded the application of Invisalign significantly. Invisalign is now used to treat a wide range of malocclusions and is an important part of treatment for some surgical cases and other complex treatments. In addition, as doctors see great clinical results in their practices, they gain confidence with Invisalign and begin to treat a broader range of patients.

Why is there an increased focus on clinical education at Align? Clinical education and ongoing training are critical to our customers' success with Invisalign. In addition to certifying thousands of new doctors to use Invisalign each year, we have a responsibility to share product enhancements, treatment tips and techniques, and clinical research data with our customers. This information ensures that they

TOM PRESCOTT, CEO, AND ELDON BULLINGTON, CFO

understand Invisalign's expanding applications and best uses, and that they feel confident about treating more of their patients with Invisalign.

Many people believe that Invisalign is best-suited to adult patients. Is Invisalign effective for adolescents as well? Invisalign is an effective treatment option for adults and adolescents. The only age-related requirement is that patients have fully erupted second molars. A recent study based on orthodontic practices found that teen patients are compliant with Invisalign and respond well to treatment. Many are very excited about Invisalign treatment because of the "cool factor" involved in having clear, removable appliances. You can see great examples of teen treatments online at the Invisalign Clinical Education Center.

Why are Align's customers so loyal to the Company and to the Invisalign product? We believe that Align's customers are loyal for two reasons. First, Align provides customers with a product that helps them deliver great clinical results and very happy patients. Second, we share a common goal with our customers, and that is to make a difference in patients' lives. It is very rewarding to talk with a patient who has new confidence or the smile they've always wanted as a result of Invisalign treatment. Our customers help patients achieve important personal goals, and we appreciate being a part of that process.

Will Align ever be a global company? The opportunities we have in North America are outstanding. As you can see from the charts on page nine, we have barely penetrated the North American market. As we establish a strong foothold in our backyard, we will look into expanding the product on an international level. We currently have patients in treatment in over 30 countries. In 2004, we expect to increase our infrastructure and support in key countries in Europe and initiate important strategic moves in Asia in order to take advantage of the emerging opportunities.

Do you believe that Align operates with integrity and accountability? Align believes that communication is one of the keys to creating shareholder value. We will do our best to communicate Company news and events, both positive and negative, with integrity and in a timely manner. We will also commit to ensuring that shareholders can trust us to manage the Company with their interests in mind, and to operate a Company that is fully compliant with all regulations required by the Securities and Exchange Commission and The NASDAQ Stock Market.

OUR BUSINESS MODEL IS WORKING

In the 2002 Align Annual Report, the Company delivered its goals for 2003: increase sales each quarter; foster a growing, cooperative and energized community of Invisalign orthodontists and dentists; continue to expand consumer recognition and understanding of the power of the product; and exit 2003 a profitable organization. Align achieved all of these goals because our business model is working.

The foundation of Align's business model for generating growth and increasing shareholder value is built on three programs: enhancing automation, supporting customers through clinical education, and becoming an important and integral part of our customers' practices.

Automation Drives Case Volume and Gross Margins. In 2003, several enhancements in manufacturing technology enabled increases in case volume and gross margins. Align shipped almost 74,000 cases worldwide, bringing the total number of patients experiencing treatment to more than 155,000. Doubling production and, ultimately, the patient base in one year was made possible by improvements in the manufacturing process.

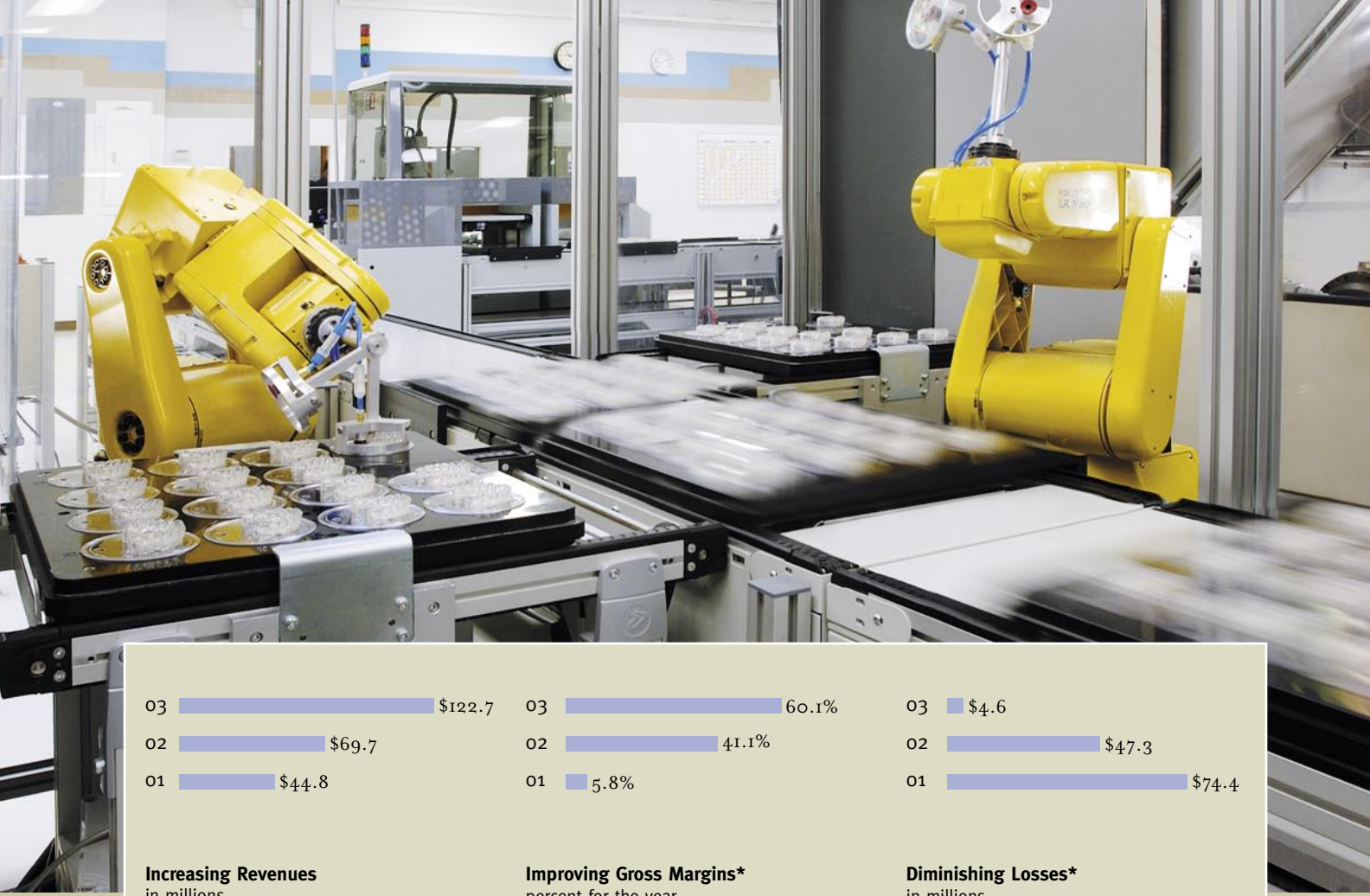
Align has introduced automation into many key steps of what was previously an extremely labor-intensive process. This eliminates countless man-hours, and enables Align to produce Aligners with accuracy and consistency. From creating 3-D digital models using advanced CT scanning, to high-volume rapid production of Aligner molds using stereo-lithography, and introducing a FlexLink material handling system to efficiently move Aligners through production, Align has re-invented the meaning of mass customization. While constantly improving the technology and consistency of the product, Align has reduced manufacturing time and, consequently, increased gross margins by 19 percentage points.

Educating Our Customers. During 2003, Align supported over 350 clinical education events. These events included certification classes, conference calls, seminars and workshops – all designed to teach customers more about Invisalign, increase their confidence in achieving great outcomes, and as a direct result, lead to increases in case submissions and, therefore, revenue.

The effort Align has made in making clinical education a cornerstone of our business plan has led to a customer base with confidence in our product.

Making Our Customers Happy. We are honored that 13,400 doctors around the world have selected Invisalign as a treatment option for their patients. As Align's most important customers, we value the time and effort that orthodontists have spent researching and defining Invisalign's reach and applicability, and we encourage them to continue defining the product range by submitting more cases and cases with a higher degree of difficulty. General practice (GP) dentists are also helping Align grow, but in a different way. As Align trains and educates more GP dentists, they can identify additional cases that are treatable with Invisalign in their own practices or by an orthodontist in their area.

With a product that is consistent and accurate, and a customer base that is growing in both size and number of cases started, Align expects to continue growing revenues and profit for many years to come.



Increasing Revenues
in millions

Over the last three years, Align has significantly improved its manufacturing process, clinical education, and customer support. These efforts have led to doctors with increased confidence in the product and in the Company – leading to healthier case submissions and revenues.

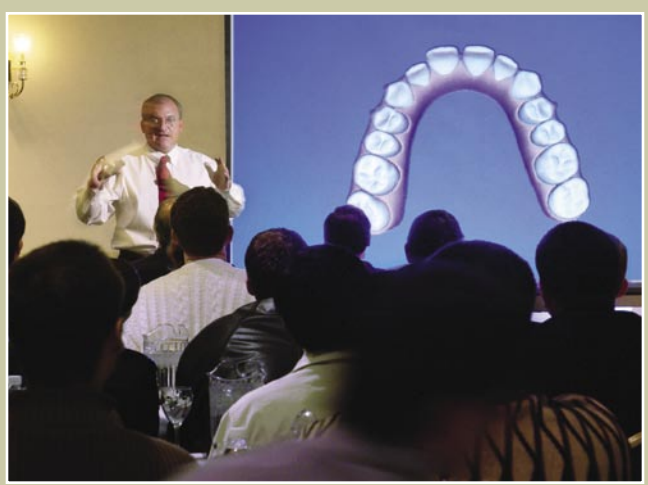
Improving Gross Margins*
percent for the year

Align has greatly improved the technology we use to manufacture Aligners. We are currently on our fourth generation scanning technology and have continuously made improvements in material handling and treatment planning – leading to gross margin improvements over the last three years.

Diminishing Losses*
in millions

Align's bottom line has improved as a result of increases in case submissions, improvements in gross margins and decreases in operating expenses. We expect to continue providing bottom-line improvement for our shareholders for many years to come.

** For a reconciliation of GAAP to non-GAAP financials, please refer to the financial highlights section.*



Clinical education events give our customers the knowledge they need to feel more confident about treating their patients with Invisalign. Dr. Perry Jones helps Align make every effort to keep our customers abreast of the latest applications of Invisalign.

Straightening teeth – the Invisalign way.

Dr. Robert Fry
Orthodontist

Dr. Anthony Marengo and Dr. Thelma Frankum
Referring dentists

WE'RE CREATING OPPORTUNITIES

FOR ORTHODONTISTS AND DENTISTS

Align is committed to maximizing Invisalign treatment opportunities for our customers. By generating brand awareness among consumers, supporting doctors' practice development efforts and encouraging doctor-to-doctor collaboration, Align helps doctors reach and treat a wide range of patients.

Align's consumer marketing is designed to increase national awareness of Invisalign and its treatment benefits, while resources such as the Invisalign Co-Op Marketing Program give doctors tools to reach potential patients in their area. With Invisalign, doctors have an esthetic option for existing patients, and a vehicle for reaching new ones.

Orthodontists are the foundation of Invisalign adoption and expertise. Great clinical results and practice growth have led thousands of orthodontists to make Invisalign a bigger part of their practices. In the U.S., orthodontists have begun to launch Invisalign-only centers to focus exclusively on Invisalign treatment. Around the world, orthodontists are the driving force behind Invisalign research and education.

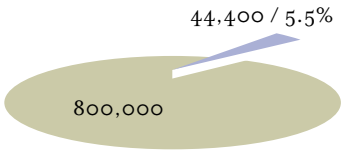
As primary care providers, general practice (GP) dentists have access to the greatest number of potential patients. In 2003, approximately 4,300 new GP dentists embraced this opportunity by becoming Invisalign certified. Invisalign enables GP dentists to expand their existing services with a higher-margin product and by coupling limited orthodontics with cosmetic treatment options.

Orthodontists and GP dentists can make the most of their Invisalign opportunities by working together. Experienced orthodontists often serve as mentors to GP dentists. In this collaborative model, orthodontists and GP dentists, together, help ensure that patients have excellent treatment outcomes.

Dr. Anthony Marengo, Jr. has one of the most successful dental practices in Olathe, Kansas, a suburb of Kansas City. Since becoming certified last year, Dr. Marengo and his associate Dr. Thelma Frankum have been offering Invisalign as a complement or alternative to cosmetic dentistry. "I have never been as excited about treatment as I am with Invisalign," says Dr. Marengo. He has an ideal referral relationship with Dr. Robert Fry, one of the first orthodontists to see Invisalign's potential and make it a significant part of his orthodontic practice. Dr. Fry serves as a mentor and Invisalign "coach" to Dr. Marengo, providing encouragement and treatment advice.

Orthodontists

Annual U.S. Market Potential

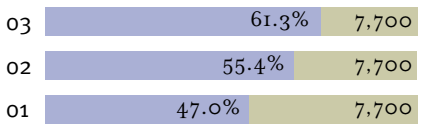


Orthodontic patients treatable with Invisalign

2003 Invisalign patients

Less than 6% of potential U.S. orthodontic patients began Invisalign treatment in 2003.

U.S. Market Penetration

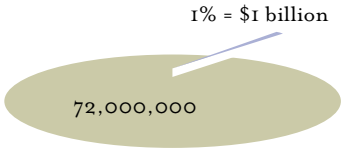


Trained and certified orthodontists

Percent submitting cases since inception

As their confidence in using the product grows, we expect more orthodontists to treat more patients with Invisalign.

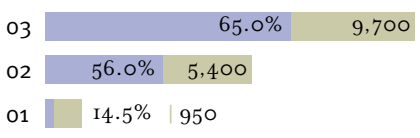
General Practitioners



Dental patients treatable with Invisalign

Potential revenues

Millions of people who would not otherwise treat their malocclusion now have an esthetic option for straightening their teeth.



Trained and certified dentists

Percent submitting cases since inception

With 130,000 GP dentists in the U.S., Align expects to continue training GP dentists to identify and treat minor malocclusion.

INVISALIGN APPLICATIONS CONTINUE TO EXPAND

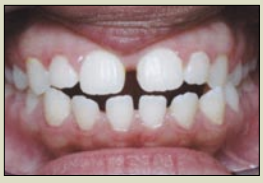
Align is committed to responsible clinical research and ongoing product development. Our goals are to contribute to the general body of orthodontic knowledge and to test and challenge the practical limits of the appliance.

Through Align's own research and the efforts of doctors around the world, the use and application of Invisalign have progressed significantly. Doctors now treat adults and adolescents with equal confidence and use Invisalign for a wide range of malocclusions, including extraction and surgical cases.

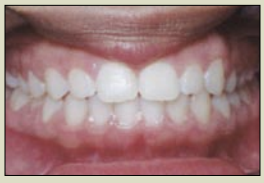
In 2003, 11 clinical papers on Invisalign were published, and five new research studies were launched in major universities around the world. In the coming year, we will increase our investment in research and development for software product improvements, product and materials research, and data mining.

Research feeds our clinical education programs. Last year, we demonstrated our commitment to Invisalign clinical education and advanced training with more than 350 workshops, seminars and doctor conference calls to help doctors and their staffs increase their confidence with Invisalign. We launched the online Invisalign Clinical Education Center, providing our customers with online access to detailed case studies and published valuable resources such as the *Clinical Monitoring Guide.* These courses and tools are designed to accelerate doctors' understanding of Invisalign and to pave the way for optimal patient outcomes.

Through education and understanding of Invisalign applications, our customers' practices can expand and prosper, and more patients can benefit from orthodontic treatment.

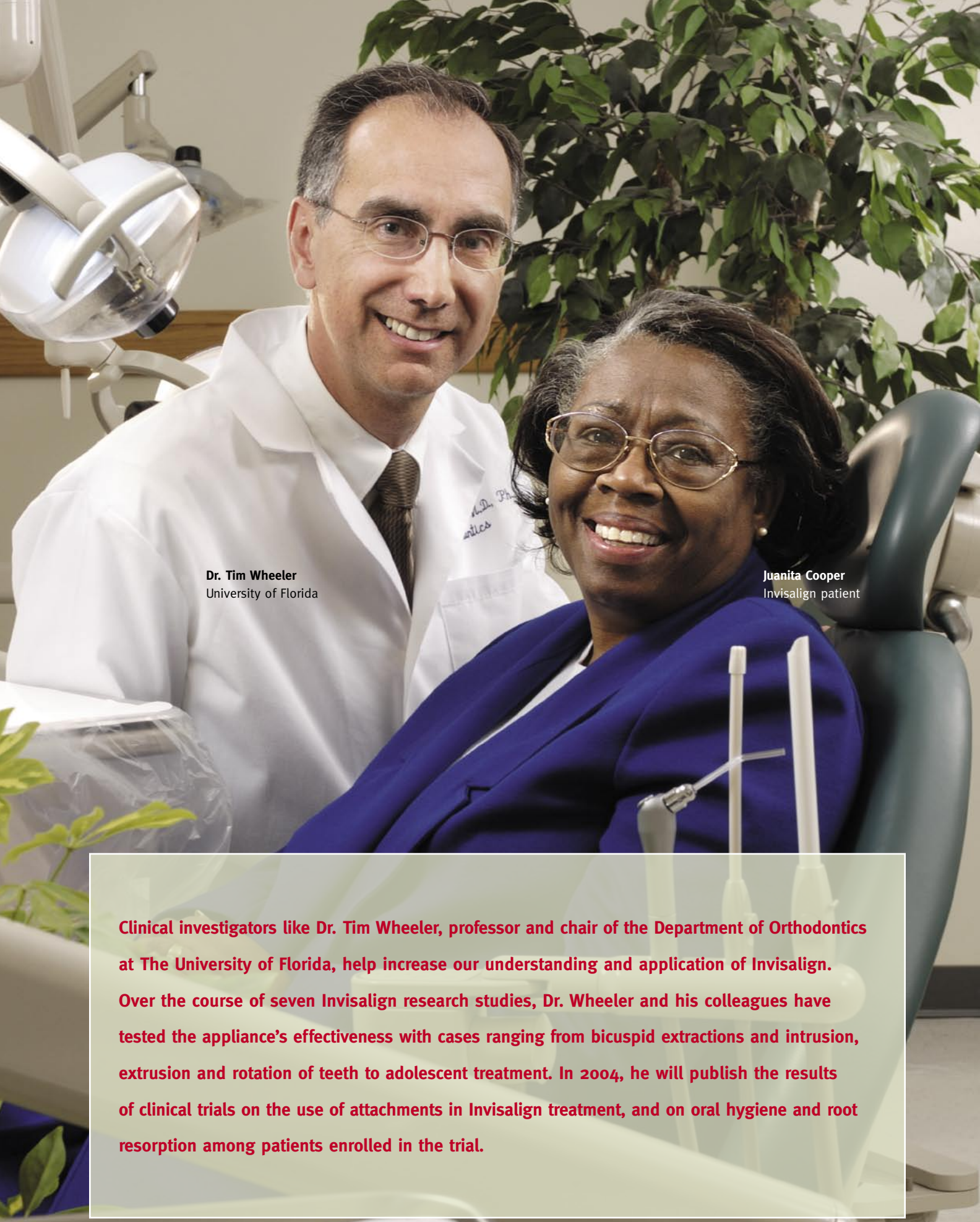


Before



After

Thanks to research and clinical education, Invisalign doctors now treat adolescents with confidence. This case demonstrates closure of an anterior openbite by relative and absolute extrusion of the incisors. The 17-year-old was diagnosed as Class I spaced malocclusion with anterior openbite, and insisted on esthetic treatment with Invisalign. Treatment time was 12 months using 22 upper Aligners and 21 lower.



Dr. Tim Wheeler
University of Florida

Juanita Cooper
Invisalign patient

Clinical investigators like Dr. Tim Wheeler, professor and chair of the Department of Orthodontics at The University of Florida, help increase our understanding and application of Invisalign. Over the course of seven Invisalign research studies, Dr. Wheeler and his colleagues have tested the appliance's effectiveness with cases ranging from bicuspid extractions and intrusion, extrusion and rotation of teeth to adolescent treatment. In 2004, he will publish the results of clinical trials on the use of attachments in Invisalign treatment, and on oral hygiene and root resorption among patients enrolled in the trial.

OFFICERS AND DIRECTORS

EXECUTIVE TEAM

Thomas M. Prescott
President and Chief Executive Officer

Eldon M. Bullington
Vice President, Finance and
Chief Financial Officer

Amir Abolfathi
Vice President, Research and Development

Jon Fjeld
Vice President, Engineering

Roger E. George
Vice President, Legal Affairs and
General Counsel

Len Hedge
Vice President, Operations

David S. Thrower
Vice President, Global Marketing

Patricia Wadors
Vice President, Human Resources

BOARD OF DIRECTORS

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Administration
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Johnson & Johnson

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Domain Associates, L.L.C.

Joseph S. Lacob
Partner
Kleiner Perkins Caufield & Byers

Greg J. Santora
Chief Financial Officer
Shopping.com

Thomas M. Prescott
President and Chief Executive Officer
Align Technology, Inc.

C. Raymond Larkin, Jr.
Chairman and Chief Executive Officer
Eunoe, Inc.

Kelsey Wirth
Former President and Co-Founder
Align Technology, Inc.

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2003

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the Transition Period from _____ to _____

Commission file number: 0-32259

ALIGN TECHNOLOGY, INC.

(Exact name of Registrant as Specified in its Charter)

Delaware	**94-3267295**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification Number)**

881 Martin Avenue
Santa Clara, California 95050
(Address of Principal Executive Offices, including Zip Code)

(408) 470-1000
(Registrant's Telephone Number, Including Area Code)

Securities registered pursuant to Section 12(b) of the Act:
None

Securities registered pursuant to Section 12(g) of the Act:
Common Stock, $0.0001 par value

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

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

Indicate by check mark whether Registrant is an accelerated filer (as defined in Rule 12b-2 of the Securities Exchange Act of 1934). Yes ☒ No ☐

As of December 31, 2003, the end of the Registrant's last fiscal year, there were 58,752,655 shares of Registrant's common stock outstanding, and the aggregate market value of such shares held by non-affiliates of Registrant (based upon the closing sale price of such shares on the NASDAQ National Market on June 30, 2003) was approximately $356,139,063. Shares of Registrant's common stock held by each executive officer and director and by each entity that owns 5% or more of Registrant's outstanding common stock have been excluded in that such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

On February 27, 2004, 59,490,105 shares of Registrant's common stock were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of Registrant's definitive Proxy Statement relating to its Annual Stockholders' Meeting to be held on May 19, 2004 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, 2003

TABLE OF CONTENTS

PART I

The statements contained below and elsewhere in this Annual Report on Form 10-K that are not purely historical are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 and Section 21E of the Securities Exchange Act of 1934, including, without limitation, statements regarding our expectations, hopes, beliefs, anticipations, commitments, intentions and strategies regarding the future. Actual results could differ from those projected in any forward-looking statements for the reasons, among others, detailed below. The fact that some of the risk factors may be the same or similar to our past filings means only that the risks are present in multiple periods. We believe that many of the risks detailed here are part of doing business in the industry in which we compete and will likely be present in all periods reported. The fact that certain risks are characteristic to the industry does not lessen the significance of the risk. The forward-looking statements are made as of the date of this Annual Report on Form 10-K, and we assume no obligation to update the forward-looking statements or to update the reasons why actual results could differ from those projected in the forward-looking statements.

ITEM 1. BUSINESS.

Overview

Since 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™.

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 ClinCheck™ and are used in conjunction with stereolithography technology to manufacture Aligner molds. A third party manufacturer in Mexico fabricates Aligners from the molds and ships the completed products to our customers.

Revenue from the sale of Invisalign and ancillary products is recognized upon product shipment, provided that no significant obligations remain, transfer of title has occurred and collection of the receivable is deemed probable. The costs of producing the ClinCheck™ treatment plan, which are incurred prior to the production of Aligners, are deferred and recognized as related revenues are earned, i.e. upon shipment of the Aligners.

In cases where the dental professional elects to finish the treatment plan using Invisalign, the dental professional orders case refinement. From June 2001 through April 2003, we offered our dental professionals the opportunity to purchase case refinement in advance at a discount. The advance purchase price was non-refundable. Revenue, in the amount of the stand-alone sales price of the undelivered element, is deferred until the earlier of shipment of the case refinement or case expiration. In cases where the dental professional did not purchase case refinements in advance, case refinement revenues are recognized when the new Aligners are shipped.

In May 2003, we updated our domestic pricing policy to include the future delivery of one case refinement in the price of each case and to offer additional case refinements at a price of $125 each, which we believe represents its fair value based on competitive product offerings. Revenue deferrals associated with future case refinement sales are $125 per case. This revenue deferral amount represents the fair value of a case refinement as determined in accordance with the Emerging Issues Task Force Issue No. 00-21, Accounting for Revenue Arrangements with Multiple Deliverables (EITF 00-21), which addresses the issue of accounting for

arrangements that involve the delivery of multiple products or services. These revenue deferrals will be recognized when the case refinement has been utilized or upon case expiration, which ever is earliest.

Service revenues earned for training of dental professionals and staff for Invisalign are recorded as the services are performed. Service revenues earned under agreements with third parties are based on negotiated rates, which are intended to approximate a mark-up on our anticipated costs.

We estimate and record a provision for amounts of estimated losses on sales, if any, in the period such sales occur. Provisions for discounts and rebates to customers are provided for in the same period that the related product sales are recorded based upon historical discounts and rebates.

Industry Background

Malocclusion

Malocclusion, 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., generating industry revenues of approximately $7 billion. While most individuals seek orthodontic treatment to improve their appearance, malocclusion may also be responsible for dental problems such as tooth decay, tooth loss, gum disease, jaw joint pain and headaches. Because of the compromised aesthetics, discomfort and other drawbacks associated with conventional orthodontic treatments, only a relatively small proportion of people with malocclusion seek traditional treatment.

Traditional Orthodontic Treatment

Currently, dental professionals apply traditional techniques and principles of orthodontic treatment developed in the early 20th century. In the U.S., dental professionals treat malocclusion primarily with metal archwires and brackets, commonly referred to as braces. Occasionally, 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.

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

Limitations of Traditional Orthodontic Treatment

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

- *Unattractive appearance*. Braces call attention to the patient's condition and treatment. In addition, braces trap food, which can further compromise appearance. Braces can also result in permanent discoloration of teeth. Many adults associate braces with adolescence. As a result of these and other limitations, less than one half of one percent of American adults with malocclusion elect traditional orthodontic treatment annually.
- *Oral discomfort*. Braces are sharp and bulky and can abrade and irritate the interior surfaces of the mouth. The tightening or adjustment of braces results in root and gum soreness and discomfort, especially in the few days immediately following an orthodontic visit.
- *Poor oral hygiene*. Braces compromise oral hygiene by making it more difficult to brush and floss. These problems can result in tooth decay and periodontal damage. Additionally, the bonding of brackets to teeth can cause permanent markings on the teeth.
- *Inability to project treatment*. Historically, dental professionals have not had a means to model the movement of teeth over a course of treatment. Accordingly, dental professionals must rely on intuition and judgment to plan and project treatment. As a result, they cannot be precise about the direction or distance of expected tooth movement between patient visits. This lack of predictability may result in unwanted tooth movements and can limit the dental professional's ability to estimate the duration of treatment. Because most orthodontic treatment is performed on a fixed price basis, extended treatment duration reduces profitability for the dental professional.
- *Physical demands on dental professional*. The manipulation of wires and brackets requires sustained manual dexterity and visual acuity, and may place other physical burdens on the dental professional.
- *Root resorption*. The sustained high levels of force associated with conventional treatment can result in root resorption, which is a shortening of tooth roots. This shortening can have substantial adverse periodontal consequences for the patient.
- *Emergencies*. At times, braces need to be repaired or replaced on an emergency basis. Such emergencies cause significant inconvenience to both the patient and the dental professional.

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

The Align Solution

Invisalign is a proprietary system for treating malocclusion. Invisalign consists of two components: ClinCheck™ and Aligners.

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

Upon review of the ClinCheck™ simulation, the dental professional may immediately approve the projected treatment, or may provide us with feedback for modification. We reflect any requested adjustments in a modified simulation. Upon the dental professional's approval of the ClinCheck™ simulation, we use the data underlying the simulation to manufacture the patient's Aligners.

Aligners. Aligners are custom-manufactured, clear, removable dental appliances that, when worn in a prescribed series, provide orthodontic treatment. Each Aligner covers a patient's teeth and is nearly invisible when worn. Aligners are commonly worn in pairs, over the upper and lower dental arches. Aligners are generally worn for consecutive two-week periods which correspond to the approved ClinCheck™ treatment simulation. After two weeks of use, the patient discards the Aligners and replaces them with the next pair in the series. This process is repeated until the final Aligners are used and treatment is complete. Upon completion of the treatment, the dental professional may, at his or her discretion, have the patient use Invisalign Aligners as a retainer or go directly to a conventional retainer.

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 Invisalign are consistent with those of traditional orthodontics. Although dental professionals can complete our initial training within two days, Invisalign provides additional education and clinical support.
- *Ease of use*. When treating patients with Invisalign, dental professionals do not spend their time manipulating wires and brackets. This allows them to spend proportionately more time diagnosing and interacting with their patients.
- *Expanded patient base*. We believe that Invisalign has the potential to transform the practice of orthodontics. Currently, less than one percent of the over 200 million people with malocclusion in the U.S. enter treatment each year. We believe that Invisalign will allow dental professionals to attract patients who would not otherwise seek orthodontic treatment.
- *Decreased dental professional and staff time*. We believe that Invisalign reduces both the frequency and length of patient visits. Invisalign eliminates the need for time-intensive processes such as bonding appliances to the patient's teeth, adjusting archwires during the course of treatment and removing the appliances at the conclusion of treatment. As such, use of Invisalign reduces dental professional and staff chair time and can increase practice throughput.
- *Practice productivity*. We believe that as dental professionals move to a higher volume of Invisalign patients, the dental professionals will be able to better leverage their existing resources, including office space and staff time, resulting in an increase in daily patient appointments and practice productivity.

Benefits to the Patient

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

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

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

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

- *Potentially reduced root resorption*. We believe that controlling force and shortening treatment time has the potential to reduce the incidence of root resorption.

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

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

Limitations of Invisalign

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

Our Target Market and Patient Base

Medical devices are classified into one of three classes based on the controls necessary to reasonably assure their safety and effectiveness. Class I or II devices require the manufacturer to submit a pre-market notification to the Food and Drug Administration, or the FDA, requesting permission for commercial distribution, which is known as 510(k) clearance. We obtained our 510(k) clearance in September 1998. Our 510(k) clearance allows us to market Invisalign to treat patients with any type of malocclusion with mature dentition. We voluntarily restrict the use of Invisalign to adults and adolescents with mature dentition. Individuals with mature dentition have fully erupted second molars and substantially complete jaw growth. This group represents approximately 160 million people in the U.S. Typically, permanent dentition are fully erupted between the ages of 11 and 15 years. Currently, we do not treat children whose teeth and jaws are still developing, as the effectiveness of Invisalign relies on our ability to accurately predict the movement of teeth over the course of treatment. Based on our clinical studies to date, we recommend that dental professionals use Invisalign as a complete treatment for a broad range of malocclusions and as a component of treatment for severe malocclusions.

Approximately two million people annually elect treatment by orthodontists in the U.S. These patients represent approximately one percent of the population of people with malocclusion. Of these, we estimate 50%, or more than one million patients, have mature dentition and are therefore potential candidates for Invisalign.

In addition, we believe that we have an immediate and substantial market expansion opportunity. Our market research indicates that the vast majority of people with malocclusion who desire treatment do not elect traditional treatment because of its many limitations. We believe that, since Invisalign addresses the primary limitations of braces, persons with malocclusion will be more likely to seek treatment. We believe that adults, who are particularly sensitive to the aesthetic limitations of traditional treatment, represent our most significant market expansion opportunity.

Commercial sales of Invisalign commenced in the U.S. in July 1999. As of December 31, 2003 approximately 155,000 patients worldwide had entered treatment using Invisalign. Internationally, the Company operates through three business segments divided among the geographic regions of Europe, Asia-Pacific and Latin America. In 2003, international sales accounted for approximately 9% of the Company's net sales.

In each of fiscal 2003, 2002 and 2001, no single customer accounted for 10% or more of our total revenues.

We continue to focus on the domestic market opportunity and on selected international markets.

Business Strategy

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

Educate dental professionals and stimulate demand for Invisalign treatment. Our market research indicates that the vast majority of people with malocclusion who desire treatment do not elect traditional treatment because of its many limitations. By communicating the benefits of Invisalign to both dental professionals and consumers, we intend to increase the number of patients who seek orthodontic treatment annually. We advertise nationally using a broad marketing mix to drive consumer and dental professional demand and to reinforce the breadth of applicability of Invisalign. In October 2001, we expanded our training of dental professionals in our domestic market to include general practitioner dentists. As of December 31, 2003, we had trained approximately 24,000 dental professionals worldwide on the use and benefits of Invisalign.

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.

Extend and defend technology leadership. Invisalign represents a significant technological advancement in orthodontics. We believe that our issued patents, multiple pending patents and other intellectual property provide us with a substantial lead over potential competitors. 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.

Expand number of clinicians and utilization within their practices. Invisalign can provide complete treatment for patients with mature dentition and a broad range of malocclusion. In addition, we believe that Invisalign can provide partial treatment of severe malocclusion. In an effort to demonstrate Invisalign's ability to comprehensively treat such cases, we have published a series of clinical case studies and articles that highlight the applicability of Invisalign to malocclusion cases of severe complexity. We have also launched new studies in fiscal 2003 with universities worldwide and we are making additional improvements to our product. We are also expanding the clinical education and training sessions for our customers.

Manufacturing

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

We believe the complexity inherent in producing such highly customized devices in high volumes is a barrier to potential competitors. Furthermore, we believe the sophisticated software we use to guide a custom manufacturing process on a high volume was not available until we developed it. We rely on two vendors who are each the sole source of the polymer and resin used in our manufacturing process. In the event that either of these vendors becomes unable for any reason to supply us with their respective products, we would experience a manufacturing disruption while we qualify and obtain an alternate source.

Manufacturing is coordinated in Santa Clara, California. Digital dental modeling is processed in our 63,000 square foot facility in San Jose, Costa Rica. As of December 31, 2003, we employed a manufacturing staff in the U.S. and Costa Rica of approximately 427 people. The operations team in Costa Rica creates ClinCheck™ treatments using simulation software. We outsource the fabrication and packaging of Aligners to a contract manufacturer based in Juarez, Mexico. Information regarding risks associated with our foreign operations may be found in Part II, Item 7 of this Report on Form 10-K under the heading "Risk Factors."

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 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 delivered to the prescribing dental professional via ClinCheck™, which is available on our website at www.invisalign.com and www.aligntech.com. The dental professional then reviews the ClinCheck™ simulation and, on occasion, asks us to make adjustments. By reviewing and amending the treatment simulation, the dental professional retains control over the treatment plan and, thus, participates in the customized design of the Aligners. At this point, the dental professional may also invite the patient to review ClinCheck™, allowing the patient to see the projected course of treatment. The dental professional then approves the proposed treatment and, in doing so, engages us for the manufacture of corresponding Aligners.

Construction of molds corresponding to each step of treatment. We use the approved ClinCheck™ simulation to construct a series of molds of the patient's teeth. Each mold is a replica of the patient's teeth at each two-week stage of the simulated course of treatment. These molds are fabricated at our Santa Clara, California manufacturing facility using custom manufacturing techniques, including stereolithography, that we have adapted for use in orthodontic applications.

Manufacture of Aligners and shipment to the dental professional. From these molds, our contract manufacturer in Mexico fabricates Aligners by pressure-forming polymeric sheets over each mold. The Aligners are then trimmed, polished, cleaned and packaged. Following final inspection, the Aligners are shipped directly to the prescribing dental professional. We ship all of the Aligners in a single batch. In certain cases, dental professionals may use Invisalign in conjunction with clear attachments bonded to the patient's teeth. These attachments are used to increase the force applied to a tooth or teeth in circumstances where the Aligners alone may have difficulty in effecting the desired movement.

In certain cases, we provide an aligner-like template to the dental professionals to aide the placement of bonding attachments to the patient's teeth. These attachments are used to optimize the force applied to a tooth or teeth in circumstances where the Aligners alone may have difficulty in effecting the desired movements. Also, in cases where interproximal reduction, or IPR, is requested by the dental professional, we provide an IPR prescription form, quantifying the amount of space to be created through enamel reduction, location, and timing of IPR.

Throughput Management

Because we manufacture each case on a build-to-order basis, we do not build inventories. As a result, we must conservatively build manufacturing throughput for anticipated demand. To increase throughput, we must improve the efficiency and increase the scale of our manufacturing processes.

In order to increase the efficiency of our manufacturing processes, we focus our efforts on software development and the improvement of rate-limiting processes, or bottlenecks. We continue to upgrade our proprietary, three-dimensional treatment-planning software to enhance computer analysis of treatment data and to reduce time spent on manual and judgmental tasks for each case, thereby increasing the efficiency of our technicians in Costa Rica. We are also continuing the development of automated systems for the fabrication of Aligners currently conducted in Mexico. In order to scale our manufacturing capacity, we continue to invest in facilities and capital equipment.

Quality Assurance

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 ISO 9001:1994, internationally recognized quality system standards, and ISO 13485:1996, internationally recognized standards for Medical Device manufacturing. Align has a formal, documented quality system by which quality objectives are understood and achieved. Our quality system defines processes and procedures to ensure product and service quality, and includes methods to monitor levels of quality, based on internal data and direct customer feedback. We utilize this data to continuously improve our systems and processes, taking corrective action as required.

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.

In the event that a dental professional wishes to effect additional adjustments to a patient's treatment when the actual treatment results are in accordance with the approved ClinCheck™ treatment plan, the dental professional may request a case refinement or additional Aligners. Our pricing policy includes the future delivery of one case refinement in the price of each case and offers additional case refinements at the dental professional's expense. In addition, should a dental professional request a replacement for a lost Aligner, we charge the dental professional for the cost of the replacement Aligner.

Sales and Marketing

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

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. 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, 2003, we had trained approximately 24,000 dental professionals worldwide to use Invisalign. Of those dental professionals trained, approximately 70% are dental professionals in our domestic market. Within our domestic market, we have trained approximately 7,700 orthodontists and approximately 9,700 general practitioner dentists. Our sales and orthodontic teams conduct training primarily in a workshop format. The key topics covered in training include Invisalign applicability, instructions on filling out the Invisalign prescription form, clinical tips and techniques guidance on pricing and instructions on interacting with our ClinCheck™ software and the many other features of our website.

Invisalign relies on the same orthodontic principles that apply to traditional treatment, and we present our training material in a manner consistent with dental professionals' training and experience. Our success in training a large number of dental professionals confirms our belief that training represents a minimal barrier to adoption for most dental professionals.

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

General practitioner dentists play an important role in informing their patients about orthodontics and are a key source of both referrals to orthodontists and Invisalign case submissions. There are over 130,000 active general practice dentists in the U.S. and Canada.

Consumer Marketing

Our national consumer marketing efforts primarily focus on television advertising and are supported by other advertising media and public relations. We advertise nationally using a broad marketing mix to drive consumer and dental professional demand.

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

- an orthodontist;
- a general practice dentist;
- direct-to-consumer mail advertising and public relations efforts;
- other Invisalign patients;
- our toll-free support line (1-800-INVISIBLE); and
- our website, which can be accessed at either www.invisalign.com or www.aligntech.com.

Our marketing efforts have generated substantial consumer interest directed toward our telephone support line and our website. Our telephone support line and our website not only provide consumers with information on Invisalign, but also allow us to channel consumer interest to dental professionals. We have outsourced the telephone support function to a national call center operator.

Research and Development

Prior to commercial launch in July 1999, our research and development strategy had three primary objectives: developing the Invisalign product, establishing the ability of Invisalign to treat malocclusion and developing software and processes to enable the manufacture of Aligners in volume. Since our commercial launch, our research and development effort has focused on extending the range of dental applicability of Invisalign, enhancing the software used in the manufacturing process and enhancing our Invisalign system product lines. Our research and development expenses were $13.1 million for fiscal 2003 and 2002, and $15.6 million in fiscal 2001.

In an effort to demonstrate Invisalign's broad treatment capabilities, we have published a series of clinical case studies and articles that highlight the applicability of Invisalign to malocclusion cases, including those of severe complexity. We are also undertaking post-marketing studies and making additional technological improvements to the product and manufacturing process. Our product development team is testing enhanced materials and a number of complementary products that we expect will provide additional revenue opportunities.

In fiscal 2003, we continued to enhance our proprietary, three-dimensional treatment-planning software primarily to increase our manufacturing capacity and efficiency.

Intellectual Property

We believe our intellectual property position represents a substantial business advantage. As of December 31, 2003, we had 41 issued U.S. patents, 73 pending U.S. patent applications, and numerous foreign issued patents, as well as pending foreign patent applications.

We continue to pursue further intellectual property protection through U.S. and foreign patent applications and non-disclosure agreements. We also seek to protect our software, documentation and other written materials under trade secret and copyright laws. We cannot be certain that patents will be issued as a result of any patent application or that patents that have been issued to us or that may be issued in the future will be found to be valid and enforceable and sufficient to protect our technology or products.

Competition

We compete directly with companies such as Ormco Orthodontics, a wholly owned subsidiary of Sybron Dental Specialties, which manufactures and distributes a product called Red, White & Blue, that is similar in use to Invisalign. We compete for the attention of dental professionals with manufacturers of other orthodontic products. These manufacturers of traditional orthodontic appliances include 3M Company, Ormco Orthodontics and Dentsply International, Inc.

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

- aesthetic appeal of the treatment method;
- comfort associated with the treatment method;
- oral hygiene;
- effectiveness of treatment;
- ease of use; and
- dental professionals' chair time.

We believe that Invisalign compares favorably with our competitors' products with respect to each of these factors.

Government Regulation

FDA's Quality System Regulation for Medical Devices. Invisalign is regulated as a Class I medical device by Food and Drug Administration. Accordingly, our product development, manufacturing processes, packaging, labeling, handling, storage and distribution activities are subject to extensive review by National and State government agencies to ensure that our devices are safe and effective.

The Aligners are manufactured by The TECMA Group, LLC, formerly known as Elamex S.A. de C.V., a contract manufacturer based in Mexico. As a medical device company, we are required to ensure that our contract manufacturer complies with FDA's Quality System regulations. As a result, we have ensured that TECMA is registered with the FDA as a medical device manufacturer. In addition, TECMA is certified to ISO 9000 requirements and is subject to inspection by an independent ISO agency. We have also ensured that our quality system procedures and processes are set up at TECMA to comply with all FDA regulations. TECMA has dedicated an area in its facilities and trained personnel for the manufacture and distribution of Invisalign. We conduct frequent visits to the Mexico facility to monitor TECMA's performance and its compliance with our requirements and also perform independent audits of their quality system.

In November 1998, Invisalign received 510(k) Pre-Market clearance by the FDA, allowing us to market Invisalign in the U.S. The manufacture and distribution of Invisalign are subject to continuing regulations by the FDA. We are subject to routine inspections by the FDA and State agencies to determine compliance with Quality System requirements. Our facility is registered with the State of California as a medical device manufacturer.

During inspections of our facility, if FDA determines that we have failed to comply with the applicable FDA regulations, it can institute a wide variety of enforcement actions against us, ranging from a public Warning Letter to more severe sanctions, including but not limited to financial penalties, withdrawal of our right to market products and criminal prosecution.

Health Canada's Medical Device Regulations. In Canada, we comply with the Health Canada's Medical Device Regulations and as such Align's facility and products are registered with Health Canada. We are in compliance with their regulations and have been granted permission to market our products in Canada.

European Union's MDD Requirements & ISO 9000 and ISO 13485. In Europe, Invisalign is regulated as a custom device and as such, we follow the Medical Device Directives requirements and are registered with the Competent Authority in Europe. The fact that we are ISO 9000 and ISO 13485 certified facilitates commercialization of Invisalign outside the United States and especially in Europe.

Health Insurance Portability and Accountability Act of 1996. Under the Health Insurance Portability and Accountability Act of 1996, or HIPAA, Congress mandated a package of interlocking administrative simplification rules to establish standards and requirements for electronic transmission of certain health information. Confidentiality of patient records and the circumstances under which these records may be released are subject to substantial regulations under the HIPAA Standards for Privacy of Individually Identifiable Health Information, referred to as the Privacy Standard, and other state laws and regulations. The Privacy Standard governs both the disclosure and the use of confidential patient medical information. Although compliance is principally the responsibility of the hospital, physician or other healthcare provider, our agreements with orthodontists and other healthcare professionals require that we comply with the Privacy Standard when providing technical services and when handling patient information and records. We have designed our product and service offerings to enable compliance with HIPAA and applicable corresponding state laws and regulations. Compliance with these laws and regulations is costly and could require complex changes in our systems and services. Additionally, our success may be dependent on the success of healthcare participants in dealing with HIPAA requirements and the Privacy Standard.

Other Federal and State Laws. As a participant in the health care industry we are subject to extensive and frequently changing regulation under many other laws administered by governmental entities at the federal, state and local levels, some of which are, and others of which may be, applicable to our business. Furthermore, our health care service provider customers are also subject to a wide variety of laws and regulations that could affect the nature and scope of their relationships with us.

Laws regulating medical device manufacturers and health care providers cover a broad array of subjects. For example, the confidentiality of patient medical information and the circumstances under which such information may be released for inclusion in our databases, or released by us to third parties, are subject to substantial regulation by state governments. These state laws and regulations govern both the disclosure and the use of confidential patient medical information and are evolving rapidly. In addition, provisions of the Social Security Act prohibit, among other things, paying or offering to pay any remuneration in exchange for the referral of patients to a person participating in, or for the order, purchase or recommendation of items or services that are subject to reimbursement by, Medicare, Medicaid and similar other federal or state health care programs. Most states have also enacted illegal remuneration laws that are similar to the federal laws. These laws are applicable to our financial relationships with, and any marketing or other promotional activities involving, our dental professional customers. Finally, various states regulate the operation of an advertising and referral service for dentists, and may require registration of such services with a state agency as well as compliance with various

requirements and restrictions on how they conduct business and structure their relationships with participating dentists. Violations of any of these laws or regulations could subject us to a variety of civil and criminal sanctions.

Employees

As of December 31, 2003, we had approximately 741 employees, approximately 341 of whom were employed in the U.S., 338 in Costa Rica, 44 in Europe, 9 in Latin America, 8 in Asia/Pacific and 1 in the United Arab Emirates, or the U.A.E. As of December 31, 2003, of our U.S. employees, approximately 89 were employed in manufacturing, 73 were employed in various management, administrative and support positions, 69 were marketing and customer support staff, 63 were employed in sales, 33 were employed in engineering and 14 were employed in research and development.

Executive Officers

The following table sets forth certain information regarding our executive officers as of March 9, 2004:

Name	Age	Position
Thomas M. Prescott	48	President and Chief Executive Officer
Eldon M. Bullington	52	Vice President, Finance and Chief Financial Officer
Amir Abolfathi	39	Vice President, Research and Development
Jon Fjeld	52	Vice President, Engineering
Roger E. George	38	Vice President, Legal Affairs, and General Counsel
Len M. Hedge	46	Vice President, Operations
David S. Thrower	39	Vice President, Global Marketing
Patricia L. Wadors	39	Vice President, Human Resources

Thomas M. Prescott has served as our President and Chief Executive Officer and as a member of our Board of Directors since March 27, 2002. Prior to joining us, Mr. Prescott was President and Chief Executive Officer of Cardiac Pathways, Inc., a publicly-traded medical device company, from May 1999 until its acquisition by Boston Scientific in August 2001. Mr. Prescott then worked as a consultant for Boston Scientific Corporation until January 2002. Prior to working at Cardiac Pathways, Mr. Prescott held various sales, general management and executive roles at Nellcor Puritan Bennett, Inc. from April 1994 to May 1999. Mr. Prescott serves as a director of R2 Technologies, Inc. and Interventional Rhythm Management, Inc., both privately held companies.

Eldon M. Bullington has served as our Vice President of Finance and Chief Financial Officer since October 2002. Mr. Bullington was previously Vice President, Finance and Chief Financial Officer of Milpitas, CA-based Verplex Systems, Inc, an electronic design automation company, from January 2002 until October 2002. Prior to that, Mr. Bullington spent two years as the Vice President and Chief Financial Officer at Cardiac Pathways, Inc., until it was acquired by Boston Scientific in August 2001. Prior to Cardiac Pathways, Mr. Bullington was Vice President and Chief Financial Officer at Saraide, Inc. from September 1998 to March 1999. He also served in executive financial management roles at Verifone, Inc. and Radius, Inc.

Amir Abolfathi has served as our Vice President of Research and Development since March 2000. From November 1999 to March 2000, Mr. Abolfathi served as our Senior Director of Planning. Prior to joining us, Mr. Abolfathi served as a consultant for a number of medical device companies from February 1999 through November 1999, including Embolic Protection, Inc. and Novasys Medical, Inc. From April 1995 through January 1999, Mr. Abolfathi served as Senior Director of Research and Development and Vice President of Research and Development for EndoTex Interventional Systems, Inc., a company focused on the treatment of neurovascular diseases that he co-founded.

Jon Fjeld has served as our Vice President of Engineering since December 2000. Prior to joining us, Mr. Fjeld was the President and Chief Executive Officer of Raindrop Geomagic, Inc., a software company. From January 1998 through June 1998, Mr. Fjeld served as Vice President of Larscom, Inc., a networking company. From August 1995 through December 1997, Mr. Fjeld served as Vice President of Marketing and later as President and Chief Executive Officer at Netedge Systems, Inc., a networking company.

Roger E. George has served as Vice President, Legal Affairs, and General Counsel since July 2002. Prior to joining Align, Mr. George was the Chief Financial Officer, Vice President of Finance and Legal Affairs and General Counsel of SkyStream Networks, a privately held broadband and broadcast network equipment company. Prior to SkyStream, Mr. George was a partner at Wilson Sonsini Goodrich & Rosati, P.C. in Palo Alto, California.

Len M. Hedge has served as our Vice President, Operations since March 2002, having served as our Vice President of Manufacturing from January 1999 to March 2002. Mr. Hedge served as Vice President of Operations for Plynetics Express Corporation, a rapid-prototyping and stereolithography services supplier, from December 1996 to December 1998. From October 1991 to December 1996, Mr. Hedge worked at Beckman Instruments Corporation as Manager for Prototype Manufacturing and Process Development.

David S. Thrower has served as our Vice President, Global Marketing since August 2002. Prior to joining Align, Mr. Thrower served as Senior Vice President of Global Marketing and Sales BioSource International, a publicly-held life science reagent company, from October 2000 until July 2002. Prior to BioSource, Mr. Thrower served as Senior Vice President, Global Marketing at GN ReSound, Inc. a hearing and communications device company, from July 1998 until December 1999. Mr. Thrower also has previous experience in large and small independent management consulting firms, including five years with Boston-based Bain & Company.

Patricia L. Wadors has served as our Vice President, Human Resources since January 2004. Prior to joining Align, Ms. Wadors spent 8 years at San Jose, CA-based Applied Materials in both Human Resources and Operations. Her last position at Applied Materials was Senior Director of Human Resources for the PDC Product Group. Prior to Applied Materials, Ms. Wadors held Human Resources positions at Merck Pharmaceutical, Viacom International and Calvin Klein Cosmetics.

Our executive officers are elected by the Board of Directors and serve until their successors have been duly elected and qualified. There are no family relationships among any of our directors or executive officers.

Web Site Postings

We make our annual report on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K, and amendments to such reports, available free of charge through our web site at the following addresses: www.aligntech.com and www.invisalign.com. The information in, or that can be accessed through, our web site is not part of this report.

ITEM 2. PROPERTIES.

Our headquarters are located in Santa Clara, California. We lease approximately 90,000 square feet of space where we house our manufacturing, customer support, software engineering and administrative personnel. We lease our Santa Clara facilities under two leases, both of which expire in 2005. The combined monthly rent for the Santa Clara facilities is approximately $230,000.

We also operate a facility in San Jose, Costa Rica. The main facility comprises approximately 63,000 square feet of manufacturing and office space. The monthly rent for the Costa Rica facility is approximately $51,000. The lease for this facility expires at the end of 2008.

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.

ITEM 3. LEGAL PROCEEDINGS.

On January 6, 2003, Ormco Corporation ("Ormco") 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 our 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. We amended our counterclaim to add Allesee Orthodontic Appliances, Inc. ("AOA"), a wholly-owned subsidiary of Ormco, as a counterdefendant in regard to our counterclaim of infringement of U.S. Patent No. 6,398,548. The Court then permitted Ormco to amend its Complaint and permitted us to amend our counterclaim to add an additional patent each. Ormco filed a first amended complaint for infringement of U.S. Patent No. 6,616,444 on October 15, 2003. On October 27, 2003, we filed an answer to Ormco's first amended complaint and a counterclaim for invalidity and non-infringement of U.S. Patent No. 6,616,444 and for infringement of U.S. Patent No. 6,554,611.

At a Scheduling Conference held on November 24, 2003, the Court set a June 10, 2004 discovery cutoff and an October 2004 trial date.

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 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 Nos. 6,244,861 and 6,616,444 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 Nos. 6,398,548 and 6,554,611 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 our 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 might not be available on commercially reasonable terms or at all. In that event, we could be subject to damages or an injunction, which could materially adversely affect our business.

On April 9, 2002, we exercised our right to terminate an Exclusive Marketing Agreement dated October 18, 2001 with Discus Dental Impressions, Inc. (the "Agreement") 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 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 claimed 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 denied all claims made by Discus Dental in its demand and contended that such claims were entirely without merit. In addition, on or about June 13, 2002, we submitted a counter-claim against Discus Dental 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 (the "Panel"), 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 closing argument was heard on October 29, 2003. At the closing argument before the Panel, Discus Dental sought lost profit damages of $46.5 million and loss of good will/out of pocket damages of $13.5 million. We 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 Dental.

On February 9, 2004, the Panel issued its final arbitration award which concluded the arbitration proceedings initiated by Discus Dental. Under the final arbitration award, Discus Dental is entitled to a judgment in the amount of $1.00 in damages and reasonable attorney fees and costs in the amount of $2.1 million. In reaching their decision, the arbitrators found that Align's termination of its marketing agreement with Discus Dental in April of 2002 was wrongful. We included the $2.1 million charge relating to the final arbitration award in general and administrative expenses for the year ended December 31, 2003.

From time to time, we have received, and may again receive, letters from third parties drawing our attention to their patent rights. While we do not believe that we infringe any such rights that have been brought to our attention, there may be other more pertinent proprietary rights of which we are presently unaware.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS.

There were no matters submitted to a vote of security holders during the fourth quarter of fiscal 2003.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY AND RELATED STOCKHOLDER MATTERS.

(a) Price Range of Common Stock

Our common stock is listed on The NASDAQ National Market under the symbol "ALGN." Public trading of our common stock commenced on January 26, 2001. Prior to that date, there was no public market for our common stock. The following table shows, for the periods indicated, the high and low per share closing prices of common stock, as reported by The NASDAQ National Market:

	High	Low
Year Ended December 31, 2003:		
Fourth quarter	$18.61	$12.85
Third quarter	$14.30	$10.45
Second quarter	$12.60	$ 5.75
First quarter	$ 6.13	$ 2.63
Year Ended December 31, 2002:		
Fourth quarter	$ 3.59	$ 1.30
Third quarter	$ 3.50	$ 1.70
Second quarter	$ 5.48	$ 3.32
First quarter	$ 5.98	$ 4.05

On February 27, 2004, the last reported sale price of our common stock on The NASDAQ National Market was $19.67 per share. As of February 27, 2004 there were approximately 417 holders of record of our common stock.

We have never declared or paid any cash dividends on our common stock. We currently intend to retain any future earnings to fund the development and growth of our business and do not anticipate paying any cash dividends in the foreseeable future.

(b) Sales of Unregistered Securities

In November 2002, we completed a financing deal for a private placement of 9,578,944 shares of common stock to a group of institutional investors led by existing shareholders, raising $18.1 million, net of issuance costs. The investors include Dionis Trust, Gordon Gund-Grant Gund Generation Skipping Trust, Gordon Gund-G. Zachary Gund Generation Skipping Trust, Kleiner Perkins Caulfield Byers VIII, L.P., KPCB VIII Founders Fund, L.P., Carlyle Partners III, L.P., CP III Coinvestment, L.P., Warren Thaler, Thomas M. Prescott, Oak Hill Capital Partners, L.P. and Oak Hill Capital Management Partners, L.P. 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 of 1933. We filed an S-3 Registration Statement registering the shares for resale and it was declared effective by the SEC on November 20, 2003.

(c) Use of Proceeds from Sales of Registered Securities

We did not issue any registered securities during the fiscal year ended December 31, 2003.

The information required by this item regarding equity compensation plans is incorporated by reference to the information set forth in Item 12 of this Report on Form 10-K.

ITEM 6. SELECTED FINANCIAL DATA.

The following discussion and analysis of our selected consolidated financial data should be read together with our consolidated financial statements and related notes included elsewhere in this Annual Report on Form 10-K.

The following tables set forth the selected consolidated financial data for each of the years in the five-year period ended December 31, 2003. The selected consolidated financial data is qualified in its entirety and should be read in conjunction with our consolidated financial statements as of December 31, 2003 and notes thereto set forth on pages 46 to 64 and "Management's Discussion and Analysis of Financial Condition and Results of Operations" beginning on page 19. The historical results presented below are not necessarily indicative of future results.

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

	Year Ended December 31,				
	2003	2002	2001	2000	1999
Consolidated Statement of Operations Data:					
Total revenues	$122,725	$ 69,698	$ 44,808	$ 6,741	$ 411
Cost of revenues	51,565	44,991	46,830	20,251	1,754
Loss from operations	(19,937)	(72,935)	(100,769)	(81,115)	(14,705)
Other income (expense), net	(101)	116	1,730	(7,633)	(710)
Net loss before provision for income taxes	(20,038)	(72,819)	(99,039)	(88,748)	(15,415)
Provision for income taxes	84	—	10	—	—
Net loss	(20,122)	(72,819)	(99,049)	(88,748)	(15,415)
Dividend related to beneficial conversion feature of preferred stock	—	—	(11,191)	(53,516)	—
Net loss available to common stockholders	$ (20,122)	$(72,819)	$(110,240)	$(142,264)	$(15,415)
Net loss per share available to common stockholders, basic and diluted	$ (0.35)	$ (1.52)	$ (2.61)	$ (25.64)	$ (3.65)
Shares used in computing net loss per share available to common stockholders, basic and diluted	57,758	47,878	42,247	5,548	4,218

	December 31,				
	2003	2002	2001	2000	1999
Consolidated Balance Sheet Data:					
Working capital	$ 39,737	$ 41,160	$ 62,172	$ 18,273	$ 10,027
Total assets	102,202	92,856	118,218	70,561	17,091
Total long-term liabilities	1,849	3,837	980	1,455	3
Convertible preferred stock and preferred stock warrants	—	—	—	130,691	32,755
Stockholders' equity (deficit)	62,976	64,347	97,827	(84,674)	(19,414)

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

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 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 the following sections entitled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations." We undertake no obligation to revise or publicly release the results of any revision to these forward-looking statements. Given these risks and uncertainties, readers are cautioned not to place undue reliance on such forward-looking statements.

The following discussion and analysis of our financial condition and results of operations should be read together with "Selected Consolidated Financial Data" and our consolidated financial statements and related notes included elsewhere in this Annual Report on Form 10-K.

Overview

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™.

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 ClinCheck™ and are used in conjunction with stereolithography technology to manufacture Aligner molds. A third party manufacturer in Mexico fabricates Aligners from the molds and ships the completed products to our customers.

Revenue from the sale of Invisalign and ancillary products is recognized upon product shipment, provided that no significant obligations remain, transfer of title has occurred and collection of the receivable is deemed probable. The costs of producing the ClinCheck™ treatment plan, which are incurred prior to the production of Aligners, are deferred and recognized as related revenues are earned, i.e. upon shipment of the Aligners.

In cases where the dental professional elects to finish the treatment plan using Invisalign, the dental professional orders case refinement. From June 2001 through April 2003, we offered our dental professionals the opportunity to purchase case refinement in advance at a discount. The advance purchase price was non-refundable. Revenue, in the amount of the stand-alone sales price of the undelivered element, is deferred until the earlier of shipment of the case refinement or case expiration. In cases where the dental professional did not purchase case refinements in advance, case refinement revenues are recognized when the new Aligners are shipped.

In May 2003, we updated our domestic pricing policy to include the future delivery of one case refinement in the price of each case and to offer additional case refinements at a price of $125 each, which we believe represents its fair value based on competitive product offerings. Revenue deferrals associated with future case refinement sales

are $125 per case. This revenue deferral amount represents the fair value of a case refinement as determined in accordance with the newly adopted rules contained in EITF 00-21, which addresses the issue of accounting for arrangements that involve the delivery of multiple products or services. These revenue deferrals will be recognized when the case refinement has been utilized or upon case expiration, which ever is earliest.

Service revenues earned for training of dental professionals and staff for Invisalign are recorded as the services are performed. Service revenues earned under agreements with third parties are based on negotiated rates, which are intended to approximate a mark-up on our anticipated costs.

We estimate and record a provision for amounts of estimated losses on sales, if any, in the period such sales occur. Provisions for discounts and rebates to customers are provided for in the same period that the related product sales are recorded based upon historical discounts and rebates.

We have incurred significant operating losses and negative operating cash flows since inception and have achieved profitability for the first time in the fourth quarter of fiscal 2003. As of December 31, 2003, we had an accumulated deficit of approximately $300.6 million.

We expect to expend significant capital to continue to build consumer demand, expand our dental professional channel, 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 shareholders, 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 in December 2003 negotiated more favorable terms and increased the line of credit up to $15 million. In December 2002, we also secured an equipment-based term loan of $5.0 million, which was fully drawn down in December 2002. As of December 31, 2003, we had not utilized the accounts receivable-based revolving line of credit. As of December 31, 2003, the equipment-based term loan had an outstanding balance of $3.3 million. Accessing the accounts receivable-based revolving line of credit is restricted based on qualifying accounts receivable and compliance with certain loan covenants. However, 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.

Litigation settlement included in general and administrative expenses. 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 Discus Dental with the American Arbitration Association in San Jose, California. On February 9, 2004, the Panel issued its final arbitration award which concluded the arbitration proceedings initiated by Discus Dental. Under the final arbitration award, Discus Dental is entitled to a judgment in the amount of $1.00 in damages and attorney fees and costs in the amount of $2.1 million. In reaching their decision, the arbitrators found that Align's termination of its marketing agreement with Discus Dental in April of 2002 was wrongful. We included the $2.1 million charge relating to the final arbitration award in general and administrative expenses for the year ended December 31, 2003.

In July 2002, we announced a plan to streamline worldwide operations. The plan included closing our facilities in Pakistan and the U.A.E. We transitioned the operations performed at these facilities to the United States and Costa Rica. For the period ending December 31, 2002, we recorded severance charges of $2.3 million, facility closure charges of $0.9 million, a loss on disposal of fixed assets of $1.1 million and an impairment charge of $0.9 million related to the land in Pakistan. The land was written down to a zero value to reflect its fair value as estimated by our management. Approximately $0.1 million of accrued charges related to professional fees were included in accrued liabilities as of December 31, 2002. We discontinued operations at our facilities in Pakistan and the U.A.E in October and December 2002, respectively. We concluded the remainder of indirect operational activities related to the Costa Rica transition in January 2003. We will cease non-operational closing activities in Pakistan when the land is disposed of and in the U.A.E. when the necessary statutory filings have been completed.

Comparison of Years Ended December 31, 2003 and 2002:

Revenues. Revenues for the year ended December 31, 2003 increased 76% to $122.7 million from $69.7 million for the year ended December 31, 2002. Revenues derived from the sale of Invisalign were $115.3 million for the year ended December 31, 2003 compared to Invisalign revenues of $63.7 million for the year ended December 31, 2002. The increase in Invisalign revenues for the year ended December 31, 2003 as compared to the year ended December 31, 2002 was primarily the result of an increase in the domestic orthodontic channel of $23.4 million, the domestic general practitioner channel of $22.0 million and the international channel of $6.2 million. For the year ended December 31, 2003, growth in the domestic orthodontic and general practitioner channels resulted primarily from an increase in a growing number of participating clinicians and utilization within their practices. All channels benefited from Invisalign marketing promotion programs conducted during the year ended December 31, 2003. The balance of our revenues represented sales of training and ancillary products of $7.4 million for the year ended December 31, 2003 and $6.0 million for the year ended December 31, 2002.

Cost of revenues. Cost of revenues for the year ended December 31, 2003 was $51.6 million compared to $45.0 million for the year ended December 31, 2002. Cost of revenues include the salaries for staff involved in production, the cost of materials and packaging, shipping costs, depreciation on the capital equipment used in the production process, under/over absorbed manufacturing capacity, training costs and the cost of facilities. Included in cost of revenues are stock-based compensation expenses of $2.5 million and $3.4 million for the year ended December 31, 2003 and 2002, respectively. The year ended December 31, 2002 included restructuring charges of $0.6 million. Gross profit for the year ended December 31, 2003 was $71.2 million or 58% of revenue, compared to a gross profit of $24.7 million or 35% of revenue for the year ended December 31, 2002. The higher gross profit for the year ended December 31, 2003 as compared to fiscal 2002 is primarily attributable to a combination of manufacturing process efficiencies, and improved fixed cost absorption related to increasing volumes. We believe that the gross profit percentage for fiscal 2004 will continue to improve based on manufacturing process improvements and absorption of costs from higher volumes.

Sales and marketing. Sales and marketing expenses for the year ended December 31, 2003 were $43.7 million compared to $45.3 million for the year ended December 31, 2002. Sales and marketing expenses include sales force compensation (combined with expenses for professional marketing programs), conducting workshops and market surveys, advertising and attending dental professional trade shows. Sales and marketing expenses for the year ended December 31, 2003 and 2002 include stock-based compensation expenses of $2.2 million and $3.0 million, respectively. The decrease in sales and marketing expenses for the year ended December 31, 2003 as compared to the year ended December 31, 2002 resulted primarily from a decrease in spending of $2.3 million for international media and advertising and $1.7 million related to our restructuring of and reductions in our international sales and marketing work force. The year ended December 31, 2002 included restructuring charges of $1.2 million and no restructuring charges for the year ended December 31, 2003. The reduction of the international sales and marketing work force in fiscal 2003 and the restructuring charges in fiscal 2002 were part of the plan during the second half of fiscal 2002 to streamline worldwide operations. The decrease in sales and marketing expenses for the year ended December 31, 2003 as compared to the year ended December 31, 2002 were partially offset by an increase in spending of $3.9 million related to incremental headcount in our North American sales force and $0.5 million in incremental media and advertisement costs for the year ended December 31, 2003 as compared to the year ended December 31, 2002. We expect sales and marketing expense to increase as we invest more on clinical education, direct-to-consumer mail advertising and related consumer spending.

General and administrative. General and administrative expenses for the year ended December 31, 2003 were $34.3 million compared to $39.3 million for the year ended December 31, 2002. General and administrative expenses included salaries for administrative personnel, outside consulting services, legal expenses and general corporate expenses. General and administrative expenses for the year ended December 31, 2003 and 2002 include stock-based compensation expenses of $7.1 million and $10.7 million, respectively. The decrease in general and administrative expenses for the year ended December 31, 2003 as compared to the year ended

December 31, 2002 resulted primarily from a decrease in stock-based compensation of $3.6 million. Salary expense decreased in fiscal 2003 by $2.5 million related to reductions in the North American and international administrative work forces and restructuring charges decreased by $2.9 million to $0.5 million for the year ended December 31, 2003 as compared to $3.4 million for the year ended December 31, 2002. Additionally, depreciation, amortization and overhead expenses also decreased by approximately $3.4 million in fiscal 2003. Partially offsetting the decreases in spending were increases of $1.7 million in outside consultant costs and $3.6 million in incremental legal expenses related our litigation matters. Also offsetting the overall decrease in spending was a litigation settlement charge of $2.1 million included in general and administrative expenses for the year ended December 31, 2003 related to the conclusion of the Discus arbitration proceedings.

Research and development. Research and development expenses for both the years ended December 31, 2003 and 2002 were $13.1 million. Research and development expenses included the costs associated with software engineering, the cost of designing, developing and testing our products and conducting clinical and post-marketing trials. We expense our research and development costs as they are incurred. Research and development expenses included $3.2 million of stock-based compensation for both the years ended December 31, 2003 and 2002, respectively. For the full year 2004, we expect to increase research and development spending for clinical research and product improvement initiatives.

Interest and other income (expense), net. Interest and other income (expense) was ($0.1) million for the year ended December 31, 2003 and $0.1 million for the year ended December 31, 2002. Interest and other expenses increased by $0.2 million for the year ended December 31, 2003 compared to the year ended December 31, 2002. Interest income decreased by $0.4 million for the year ended December 31, 2003 as compared to the year ended December 31, 2002, primarily due to lower interest rates paid on cash, cash equivalent and marketable securities balances. Included in other expense is foreign currency translation gain, which increased $0.4 million for the year ended December 31, 2003 compared to the year ended December 31, 2002.

Stock-based compensation. In connection with the grant of stock options to employees and non-employees prior to 2001, we recorded deferred stock-based compensation as a component of stockholders' equity. Deferred stock-based compensation for options granted to employees is the difference between the fair value of our common stock on the date such options were granted and their exercise price. For stock options granted to non-employees, the fair value of the options, estimated using the Black-Scholes valuation model, is initially recorded on the date of grant. As the non-employee options vest, we revalue the remaining unvested options, with the change in fair value from period to period represented as a change in deferred compensation. This stock-based compensation is amortized as charges to operations over the vesting periods of the options. For the year ended December 31, 2003 and 2002, we recorded amortization of deferred compensation of $12.8 million and $16.0 million, respectively. Additionally, we recorded expenses of $1.3 million and $2.0 million for the years ended December 31, 2003 and 2002, respectively, related to options granted to non-employees.

We have accelerated the vesting of options to several employees in connection with severance packages. This acceleration was accounted for as a charge to the consolidated statements of operations. We recorded charges of $1.0 million and $2.2 million for the years ended December 31, 2003 and 2002, respectively. Each respective charge is equal to the intrinsic value difference between the exercise price of the accelerated options and the fair value of the common stock on the date of acceleration.

Comparison of Years Ended December 31, 2002 and 2001:

Revenues. Revenues for the year ended December 31, 2002 increased 56% to $69.7 million compared to $44.8 million for the year ended December 31, 2001. Revenues of $63.7 million were derived from the sale of Invisalign compared to revenues of $43.4 million for the years ended December 31, 2002 and 2001, respectively. The increase in Invisalign revenues was primarily due to an increase in the domestic orthodontic channel of $6.2 million, the domestic general practitioner channel of $9.5 million and the international channel of $4.6 million for the year ended December 31, 2002 over the year ended December 31, 2001. The balance of our revenues

represented sales of ancillary products and other services of $6.0 million for the year ended December 31, 2002 and $1.4 million for the year ended December 31, 2001, with the increase primarily attributable to training.

Cost of revenues. Cost of revenues for the year ended December 31, 2002 was $45.0 million compared to $46.8 million for the year ended December 31, 2001. Cost of revenues include the salaries for staff involved in production, the cost of materials and packaging, shipping costs, depreciation on the capital equipment used in the production process, under/over absorbed manufacturing capacity, training costs and the cost of facilities. Also included in cost of revenues are stock based compensation expenses of $3.4 million and $4.6 million in 2002 and 2001, respectively, and $0.6 million of restructuring charges incurred as part of our July 2002 plan to streamline worldwide operations. Gross margin for the year ended December 31, 2002 was $24.7 million or 35% of revenue, compared with a negative gross margin of $2.0 million for the year ended December 31, 2001. We achieved positive gross margins in 2002 and the second half of 2001 mainly due to efficiencies in manufacturing as well as increased production volumes. Our gross margin is affected by changes in manufacturing volume, manufacturing capacity and changes in our average selling price.

Sales and marketing. Sales and marketing expenses for the year ended December 31, 2002 were $45.3 million compared to $51.9 million for the year ended December 31, 2001. Sales and marketing expenses include sales force compensation together with expenses for professional marketing, conducting training workshops and market surveys, advertising and attending dental professional trade shows. The decrease in sales and marketing expenses for the year ended December 31, 2002 resulted primarily from reduced spending in North America for media and advertising by approximately $13.2 million and reduced spending of direct mail advertising by approximately $1.6 million, partially offset by an increase in spending of $1.6 million related to incremental headcount in our North American sales force. Also offsetting spending reductions was an increase in spending at our international locations by approximately $5.7 million primarily in the first two quarters of fiscal 2002. Also included in sales and marketing expenses are stock based compensation expenses of $2.9 million and $3.9 million in 2002 and 2001, respectively, and $1.2 million of restructuring charges related to severance incurred as part of our July 2002 plan to streamline worldwide operations.

General and administrative. General and administrative expenses for the year ended December 31, 2002 were $39.3 million compared to $31.2 million for the year ended December 31, 2001. General and administrative expenses include salaries for administrative personnel, outside consulting services, facilities, legal expenses and general corporate expenses. The increase in general and administrative expenses for the year ended December 31, 2002 resulted primarily from expanding support infrastructure, at our international locations, primarily during the first two quarters of fiscal 2002. Included in general and administrative expenses in 2002 were $3.4 million of restructuring charges due to severance charges of $0.5 million, facility closure charges of $0.9 million, a loss on disposal of fixed assets of $1.1 million and an impairment charge of $0.9 million related to the land in Pakistan, incurred as part of our July 2002 plan to streamline worldwide operations.

Research and development. Research and development expenses for the year ended December 31, 2002 were $13.1 million compared to $15.6 million for the year ended December 31, 2001. Research and development expenses include the costs associated with software engineering, designing, developing and testing our products and conducting clinical and post-marketing trials. We expense our research and development costs as they are incurred. The decrease in research and development expenses for the year ended December 31, 2002 was primarily due to a decrease in outside consulting services of approximately $1.2 million and a decrease in headcount expense related to product development activities of approximately $1.5 million. Research and development expenses for 2002 also included $0.1 million of restructuring charges incurred as part of our July 2002 plan to streamline worldwide operations, and $3.2 million and $4.1 million of stock based compensation expense for 2002 and 2001, respectively.

Interest and other income (expense), net. Interest and other income was $0.1 million for the year ended December 31, 2002 compared to $1.7 million for the year ended December 31, 2001. Interest income decreased in fiscal 2002 by $3.3 million primarily due to the decrease in our cash, cash equivalent and marketable securities

balances. Interest income for the year ended December 31, 2001 was primarily generated from our cash and cash equivalents balance and investments in short-term marketable securities. Other expenses increased by $0.1 million for the year ended December 31, 2002 as compared to the year ended December 31, 2001. Offsetting the overall decreases in interest and other income (expense) was a charge of $1.8 million in the first quarter of 2001 for non-cash interest expense, related to the beneficial conversion feature embedded in convertible subordinated notes.

Dividend related to beneficial conversion feature of preferred stock. In 2000 we issued 9,535,052 shares of Series D preferred stock which were subject to an antidilution conversion price adjustment feature. We triggered this antidilution conversion price adjustment feature when we granted options to purchase our common stock beyond the number of options that were authorized under our 1997 Plan at the time we commenced our Series D preferred stock offering in May 2000. The conversion feature provided that if, during the period between May 12, 2000 (the commitment date for our Series D preferred stock offering) and the earlier of the closing of an initial public offering or January 31, 2001, we had granted more than an aggregate of 3,331,978 options to purchase our common stock, then the conversion price of our Series D preferred stock would be adjusted downward from its original conversion price of $10.625 per share. As of the end of January 2001, we had granted an aggregate of 3,591,458 options to purchase shares of our common stock in excess of the 3,331,978 options permitted. As a result we were required to issue an additional 790,342 shares of common stock upon the conversion of the Series D preferred stock. These shares were in addition to the 419,700 additional shares of common stock that we were required to issue upon conversion of the Series D preferred stock as of December 31, 2000. As a result, we recorded a deemed dividend for the year ended December 31, 2001 based on the fair value of the common stock. We also recorded at the commitment date of the Series D preferred stock offering $11.2 million related to the preferred stock sold and a charge to interest expense of $1.8 million for the beneficial conversion feature embedded in convertible subordinated notes that were previously converted. In 2002, we had no issued and outstanding preferred stock, and in 2002 we did not record any deemed dividends related to preferred stock.

Stock-based compensation. In connection with the grant of stock options to employees and non-employees, we recorded deferred stock-based compensation as a component of stockholders' equity. Deferred stock-based compensation for options granted to employees is the difference between the fair value of our common stock on the date such options were granted and their exercise price. For stock options granted to non-employees, the fair value of the options, estimated using the Black-Scholes valuation model, is initially recorded on the date of grant. As the non-employee options become exercisable, we revalue the remaining unvested options, with the change in fair value from period to period represented as a change in the deferred compensation charge. This stock-based compensation is amortized as charges to operations over the vesting periods of the options. For the years ended December 31, 2002 and 2001, we recorded amortization of deferred compensation of $16.0 million and $22.2 million, respectively. Additionally, we recorded expenses of $2.0 million for the year ended December 31, 2002, related to options granted to non-employees.

We accelerated the vesting of options to several employees in connection with severance packages. This acceleration was accounted for as a charge to the consolidated statements of operations. The charge for the years ended December 31, 2002 and 2001 were recorded as $2.2 million and $0.2 million, respectively. The charge is equal to the intrinsic value difference between the exercise price of the accelerated options and the fair value of the common stock on the date of acceleration.

Income Taxes

We have incurred immaterial amounts of income tax expense to date since we have not been profitable on an annual basis in either our domestic or international operations. As of December 31, 2003, we have aggregate federal and state net operating loss carryforwards of $238.9 million. As of December 31, 2003 we have recorded a full valuation allowance for our existing net deferred tax assets due to uncertainties regarding their realization. We have aggregate federal and state research tax credit carryforwards of $4.1 million as of December 31, 2003.

The federal research credit carryforwards expire beginning in the year 2017, if not utilized. The state research credit carryforward does not expire. The federal and state net operating loss carryforwards expire beginning in the year 2017 for federal and 2005 for state purposes, if not utilized. Utilization of the federal net operating losses and credit carryforwards may be limited by the change of ownership provisions contained in Section 382 of the Internal Revenue Code.

Liquidity and Capital Resources

Historically, we have funded our operations with the proceeds from the sale of our common and preferred stock, an equipment-based term loan and bridge loans. As of December 31, 2003, we had $44.9 million of cash and cash equivalents, $0.4 million of restricted cash and $2.3 million of short-term marketable securities. We had an accumulated deficit of $300.6 million as of December 31, 2003.

Net cash provided by (used in) operating activities totaled $12.1 million and ($40.4) million for the years ended December 31, 2003 and 2002, respectively. Net cash provided by operating activities for the year ended December 31, 2003 resulted primarily from cash collections from customers, increases in accrued liabilities and deferred revenue. For the year ended December 31, 2002, net cash used in operating activities resulted primarily from operating losses and increases in accounts receivable balances in fiscal 2002 over fiscal 2001.

Net cash used in investing activities totaled $4.3 million for the year ended December 31, 2003 and net cash provided by investing activities totaled $1.5 million for the year ended December 31, 2002. For the year ended December 31, 2003, net cash used in investing activities resulted primarily from the purchase of property and equipment for capacity expansion in Costa Rica. For the year ended December 31, 2002, net cash provided by investing activities resulted primarily from the maturities of marketable securities, partially offset by the purchases of property and equipment.

Net cash provided by financing activities were $1.6 million and $23.9 million for the years ended December 31, 2003 and 2002, respectively. For both the years ended December 31, 2003 and 2002, net cash provided by financing activities consisted of proceeds from the issuance of common stock, partially offset by payments on debt obligations. In November 2002, we completed a private placement of 9,578,944 shares common stock to a group of investors led by existing shareholders, raising $18.1 million, net of issuance costs. In December 2002, we accessed a $5.0 million equipment-based term loan, and the balance of the loan as of December 31, 2003 was $3.3 million.

Contractual Obligations

The impact that our contractual obligations as of December 31, 2003 are expected to have on our liquidity and cash flow in future periods is as follows:

		Payments Due by Period			
	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
		(in thousands)			
Equipment-based term loan, including current portion (1)	$ 3,334	$1,667	$ 1,667	$ —	$—
Capital lease obligation, including current portion (1)	504	322	182	—	—
Operating lease obligations	9,294	4,073	3,875	1,346	—
Computer support services	6,726	2,242	4,484	—	—
Manufacturing services	1,000	1,000	—	—	—
Total	$20,858	$9,304	$10,208	$1,346	$—

(1) Amounts represent the expected cash payments of our long-term debt and do not include any fair value adjustments.

We expect that our operating expenses will increase commensurate with an overall increase in the level of our business activity, including increased sales and the related costs of products sold, our consumer advertising campaign and dental professional marketing efforts, continuing efforts to automate our manufacturing processes, increases in the size of our sales force and dental professional training staff, continued international sales and marketing efforts, and development and improvements to our product. In addition, we may use cash to fund acquisitions of complementary businesses or technologies. Our capital requirements depend on market acceptance of our products and our ability to market, sell and support our products on a worldwide basis. We believe that our current cash and cash equivalents will be sufficient to fund our operations for at least the next 12 months. If we are unable to generate adequate operating cash flows, we may need to seek additional sources of capital through equity or debt financing, collaborative or other arrangements with other companies, bank financing and other sources in order to realize our objectives and to continue our operations. There can be no assurance that we will be able to obtain additional debt or equity financing on terms acceptable to us, or at all. If adequate funds are not available, we could be required to delay establishing a national brand, building manufacturing infrastructure and developing our product and process technology, or to reduce our expenditures in general. Accordingly, the failure to obtain sufficient funds on acceptable terms when needed could have a material adverse effect on our business, results of operations and financial condition.

Critical Accounting Policies

Management's discussion and analysis of our financial condition and results of operations is based upon our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of financial statements requires our management to make estimates and judgments that affect the reported amounts of assets and liabilities, revenue and expenses and disclosures at the date of the financial statements. We evaluate our estimates on an on-going basis, including those related to revenue recognition, accounts receivable, legal contingencies and income taxes. We use authoritative pronouncements, historical experience and other assumptions as the basis for making estimates. Actual results could differ from those estimates.

We believe the following critical accounting policies affect our more significant judgments and estimates used in the preparation of our consolidated financial statements.

Revenue Recognition

We recognize revenue in accordance with SEC Staff Accounting Bulletin, or SAB, No. 104, Revenue Recognition, and EITF 00-21. SAB No. 104 requires that four basic criteria must be met before revenue can be recognized: persuasive evidence of an arrangement exists; delivery has occurred or services have been rendered; the fee is fixed and determinable; and collectibility is reasonably assured. Determination of whether persuasive evidence of an arrangement exists and whether delivery has occurred or services have been rendered are based on management's judgments based on whether the fee is fixed or determinable based on the payment terms associated with the transaction and whether the sales price is subject to refund or adjustment. EITF 00-21 addresses the issue of accounting for arrangements that involve the delivery of multiple products or services. Should changes in conditions cause management to determine these criteria are not met for certain future transactions, revenue recognized for any reporting period could be adversely affected.

Revenue from the sale of Invisalign and ancillary products is recognized upon product shipment, provided that no significant obligations remain, transfer of title has occurred and collection of the receivable is deemed probable. The costs of producing the ClinCheck™ treatment plan, which are incurred prior to the production of Aligners, are deferred and recognized as related revenues are earned, i.e. upon shipment of the Aligners.

In cases where the dental professional elects to finish the treatment plan using Invisalign, the dental professional orders case refinement. From June 2001 through April 2003, we offered our dental professionals the opportunity to purchase case refinement in advance at a discount. The advance purchase price was non-

refundable. Revenue, in the amount of the stand-alone sales price of the undelivered element, is deferred until the earlier of shipment of the case refinement or case expiration. In cases where the dental professional did not purchase case refinement in advance, case refinement revenues are recognized when the new Aligners are shipped.

In May 2003, we updated our domestic pricing policy to include the future delivery of one case refinement in the price of each case and to offer additional case refinements at a price of $125 each, which we believe represents its fair value based on competitive product offerings. Revenue deferrals associated with future case refinement after May 1, 2003 are $125 per case. This revenue deferral amount represents the fair value of a case refinement as determined in accordance with EITF 00-21, which addresses the issue of accounting for arrangements that involve the delivery of multiple products or services. These revenue deferrals will be recognized when the case refinement has been utilized or upon case expiration, which ever is earliest.

Service revenues earned for training of dental professionals and staff for Invisalign are recorded as the services are performed. Service revenues earned under agreements with third parties are based on negotiated rates, which are intended to approximate a mark-up on our anticipated costs.

We estimate and record a provision for amounts of estimated losses on sales, if any, in the period such sales occur. Provisions for discounts and rebates to customers are provided for in the same period that the related product sales are recorded based upon historical discounts and rebates.

Warranty Expense

The Company generally warrants its products for a specific period of time against material defects. The Company provides for the estimated future costs of warranty obligations in costs of goods sold when the related revenue is recognized. The accrued warranty costs represents the best estimate at the time of sale of the total costs that the Company expects to incur to repair or replace product which fails while still under warranty. The amount of accrued estimated warranty costs are primarily based on historical experience as to product failures as well as current information on repair costs. On a quarterly basis, the Company reviews the accrued balances and updates the historical warranty cost trends. Actual warranty costs incurred have not materially differed from those accrued.

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 for the additional expense. The Invisalign product warranty does not provide any assurances regarding the outcome of treatment using Invisalign.

We accrue for estimated warranty costs upon shipment of products. Actual warranty costs incurred have not materially differed from those accrued. Our warranty policy is effective for shipped products which are considered defective or fail to meet the product specifications.

The amount of accrued estimated warranty costs is primarily based on our historical experience with product failures as well as current information on replacement costs. Actual warranty costs could differ from the estimate amounts. On a quarterly basis, we review the accrued balances and update the historical warranty cost trends. If we were required to accrue additional warranty cost in the future, it would negatively affect operating results.

Allowance for Doubtful Accounts

We maintain allowances for doubtful accounts for estimated losses resulting from the inability of our customers to make payments. We periodically review these estimated allowances, including an analysis of the customers' payment history and information regarding the customers' creditworthiness. If the financial condition of any of our customers were to deteriorate, resulting in their inability to make payments, an additional allowance may be required and would negatively impact our operating results.

Accounting for long-lived assets

We assess the impairment of long-lived assets periodically in accordance with the provisions of SFAS No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets." An impairment review is performed whenever events or changes in circumstances indicate that the carrying value may not be recoverable. Factors that could trigger an impairment review include, but are not limited to, significant underperformance relative to expected historical or projected future operating results, significant changes in the manner of use of the acquired assets or the strategy for the overall business, significant negative industry or economic trends, a significant decline in the stock price for a sustained period and the market capitalization relative to net book value. If these factors or their related assumptions change in the future, we may be required to record impairment charges which would negatively impact operating results.

Legal contingencies

We are currently involved in certain legal proceedings as discussed in Note 5 to our consolidated financial statements. Because of uncertainties related to both the potential amount and range of loss from pending litigation, management is unable to make a reasonable estimate of the liability that could result if there is an unfavorable outcome in these legal proceedings. As additional information becomes available, we will assess the potential liability related to this pending litigation and revise our estimates accordingly. Revisions of our estimates of such potential liability could materially impact our results of operations and financial condition.

Deferred Tax Valuation Allowance

We have established a full valuation allowance to reduce our deferred tax assets to the amount that is more likely than not to be realized. Deferred tax assets and liabilities are determined based on the difference between the financial statement and tax bases of assets and liabilities using the enacted tax rates in effect for the year in which the differences are expected to affect taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to the amounts expected to be realized.

While we have considered potential future taxable income and ongoing prudent and feasible tax planning strategies in assessing the need for the full valuation allowance, in the event that we were to determine that we would be able to realize our deferred tax assets in the future, an adjustment to the deferred tax asset would increase net income in the period such determination was made.

Recent Accounting Pronouncements

In May 2003, the FASB issued SFAS No. 149, "Amendment of Statement 133 on Derivative Instruments and Hedging Activities." SFAS No. 149 amends and clarifies accounting for derivative instruments, including certain derivative instruments embedded in other contracts, and for hedging activities under SFAS No. 133. SFAS No. 149 is effective for contracts entered into or modified after June 30, 2003 and for hedging relationships designated after June 30, 2003. The adoption of FAS 149 did not have a material impact on our consolidated financial statements.

In May 2003, the FASB issued SFAS No. 150, "Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity." SFAS No. 150 establishes standards for how companies classify and measures certain financial instruments with characteristics of both liabilities and equity. It requires companies to classify a financial instrument that is within its scope as a liability (or an asset in some circumstances). SFAS No. 150 is effective beginning second quarter of fiscal 2004. We do not expect the adoption of SFAS No. 150 to have a material impact on our consolidated financial statements.

RISK FACTORS

The statements contained below and elsewhere in this report on Form 10-K that are not purely historical are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 and Section 21E of the Securities Exchange Act of 1934, including, without limitation, statements regarding our expectations, hopes, beliefs, anticipations, commitments, intentions and strategies regarding the future. Actual results could differ from those projected in any forward-looking statements for the reasons, among others, detailed below. The fact that some of the risk factors may be the same or similar to our past filings means only that the risks are present in multiple periods. We believe that many of the risks detailed here are part of doing business in the industry in which we compete and will likely be present in all periods reported. The fact that certain risks are characteristic to the industry does not lessen the significance of the risk. The forward-looking statements are made as of the date of this Annual Report on Form 10-K, and we assume no obligation to update the forward-looking statements or to update the reasons why actual results could differ from those projected in the forward-looking statements.

The operating losses and negative cash flows we have experienced in the past may continue throughout fiscal 2004 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 operations. Since inception, we have incurred significant operating losses and we have only achieved profitability during the fourth quarter of fiscal 2003. 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 clinical education support 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.

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 fiscal 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, and even if we do achieve profitability in future periods, 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 which may cause volatility in our stock price.

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

- changes in the timing of product orders;

- unanticipated delays in production caused by insufficient capacity, any disruptions in the manufacturing process or 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 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

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 December 31, 2003, we had 41 issued U.S. patents, 73 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

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 our 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. We amended our counterclaim to add Allesee Orthodontic Appliances, Inc. ("AOA"), a wholly-owned subsidiary of Ormco, as a counterdefendant in regard to our counterclaim of infringement of U.S. Patent No. 6,398,548. The Court then permitted Ormco to amend its Complaint and permitted us to amend our counterclaim to add an additional patent each. Ormco filed a first amended complaint for infringement of U.S. Patent No. 6,616,444 on October 15, 2003. On October 27, 2003, we filed an answer to Ormco's first amended complaint and a counterclaim for invalidity and non-infringement of U.S. Patent No. 6,616,444 and for infringement of U.S. Patent No. 6,554,611.

At a Scheduling Conference held on November 24, 2003, the Court set a June 10, 2004 discovery cutoff and an October 2004 trial date.

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 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 Nos. 6,244,861 and 6,616,444 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 Nos. 6,398,548 and 6,554,611 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 our 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 might not be available on commercially reasonable terms or at all. In that event, we could be subject to damages or an injunction, which could materially adversely affect our business.

From time to time, we have received and may 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.

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 741 employees as of December 31, 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, technology development 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 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 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 achieved profitability for the first time in the fourth quarter of fiscal 2003. As of December 31, 2003, we had an accumulated deficit of approximately $300.6 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 in December 2003 negotiated more favorable terms and increased the line of credit up to $15 million. In December 2002, we also secured an equipment-based term loan of $5.0 million, which was fully drawn down in December 2002. As of December 31, 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.

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;
- 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 products in Europe, Canada, 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 2003, the market price for our common stock 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.

The factors include:

- quarterly variations in our results of operations and liquidity;
- 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.

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 and it was declared effective by the SEC on November 20, 2003. 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 December 31, 2003, our executive officers, directors and principal stockholders beneficially owned an aggregate of approximately 50.7% of our outstanding common stock. These stockholders, if acting together, would be able to influence significantly all matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. This could have the effect of delaying or preventing a change of control of us, which in turn could reduce the market price of our stock.

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

Quantitative Disclosures

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

Interest Rate Risk. We are subject to interest rate risks on cash and cash equivalents, available-for-sale marketable securities, existing long-term debts and any future financing requirements. Interest rate risks related to marketable securities are managed by monitoring maturities in our marketable securities portfolio. Our long-term debt at December 31, 2003 consists of outstanding balances on capital lease obligations of $0.5 million and a $3.3 million equipment-based term loan.

The fair value of our investment portfolio or related income would not be significantly impacted by changes in interest rates since the marketable securities maturities do not exceed fiscal year 2004 and the interest rates are primarily fixed. Our capital lease obligations of $0.5 million at December 31, 2003 carry fixed interest rates of 6.53% and 11.15% per annum, with principal payments due in 60 and 48 monthly installments, respectively, which began in 2000.

In December 2002, we obtained a $5.0 million equipment-based term loan which accrues interest at a rate of 2.25% above prime. In December 2002 we had drawn down $5.0 million from the equipment-based term loan. Principal payments are due in 36 monthly installments which began in January 2003.

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

	Expected Maturity Date (as of December 31, 2003)						
	2004	2005	2006	2007	2008	Total	Fair Value
	(in thousands)						
ASSETS:							
Cash and cash equivalents	$45,378	$ —	$ —	$ —	$ —	$45,378	$45,378
Short-term marketable securities	2,292	—	—	—	—	2,292	2,292
Weighted average interest rate	1.16%	—	—	—	—	—	—
LIABILITIES:							
Equipment-based term loan	$ 1,667	$1,667	$ —	$ —	$ —	$ 3,334	$ 3,334
Fixed rate debt lease obligation	322	182	—	—	—	504	504
Weighted average interest rate	6.5%	6.5%	—	—	—	—	—

Qualitative Disclosures

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

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

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

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

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

- Our decentralized or outsourced operations, whereby approximately $15.4 million of our annual expenses are related to operations outside the United States, denominated in currencies other than the U.S. dollar.

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

ITEM 8. CONSOLIDATED FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

Quarterly Results of Operations

	Three Months Ended							
	2003				2002			
	Dec. 31	Sep. 30	June 30	March 31	Dec. 31	Sep. 30	June 30	March 31
	(in thousands, except per share data) (unaudited)							
Revenues	$36,502	$34,038	$29,225	$ 22,960	$ 20,751	$ 17,375	$ 15,714	$ 15,858
Gross profit	23,576	20,592	15,956	11,036	9,112	6,777	4,984	3,834
Operating profit (loss)	470	(1,748)	(8,186)	(10,473)	(15,194)	(17,789)	(20,242)	(19,710)
Net profit (loss)	452	(2,144)	(7,759)	(10,671)	(15,396)	(17,806)	(20,313)	(19,304)
Net profit (loss) available to common stockholders	$ 452	$ (2,144)	$ (7,759)	$(10,671)	$(15,396)	$(17,806)	$(20,313)	$(19,304)
Net profit (loss) per share available to common stockholders, basic	$ 0.01	$ (0.04)	$ (0.13)	$ (0.19)	$ (0.30)	$ (0.38)	$ (0.44)	$ (0.42)
Shares used in computing per share amounts, basic	58,398	57,948	57,489	57,189	51,796	46,934	46,576	46,152
Net profit (loss) per share available to common stockholders, diluted	$ 0.01	$ (0.04)	$ (0.13)	$ (0.19)	$ (0.30)	$ (0.38)	$ (0.44)	$ (0.42)
Shares used in computing per share amounts, diluted	63,704	57,948	57,489	57,189	51,796	46,934	46,576	46,152

ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT AUDITORS

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

In our opinion, the consolidated financial statements listed in the accompanying index present fairly, in all material respects, the financial position of Align Technology, Inc. and its subsidiaries at December 31, 2003 and 2002, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2003 in conformity with accounting principles generally accepted in the United States of America. In addition, in our opinion, the financial statement schedule listed in the index appearing under item 15(a)2 presents fairly, in all material respects, the information set forth therein when read in conjunction with the related consolidated financial statements. These financial statements and financial statement schedule are the responsibility of the Company's management; our responsibility is to express an opinion on these financial statements and financial statement schedule based on our audits. We conducted our audits of these statements in accordance with auditing standards generally accepted in the United States of America, which require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

/s/ PRICEWATERHOUSECOOPERS LLP

San Jose, California
February 27, 2004

ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
(in thousands, except per share data)

	December 31, 2003	December 31, 2002
ASSETS		
Current assets:		
Cash and cash equivalents	$ 44,939	$ 35,552
Restricted cash	439	3,261
Marketable securities, short-term	2,292	2,693
Accounts receivable, net of allowance for doubtful accounts of $1,259 and $2,111 at December 31, 2003 and 2002, respectively	21,265	16,766
Inventories, net	1,395	1,533
Deferred costs	939	1,139
Prepaid expenses	4,097	2,352
Other current assets	1,748	2,536
Total current assets	77,114	65,832
Property and equipment, net	23,121	25,078
Other assets	1,967	1,946
Total assets	$ 102,202	$ 92,856
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 3,095	$ 3,403
Accrued liabilities	19,180	9,683
Deferred revenue	13,113	9,403
Current portion of equipment-based term loan	1,667	1,667
Current portion of capital lease obligations	322	516
Total current liabilities	37,377	24,672
Equipment-based term loan, net of current portion	1,667	3,333
Capital lease obligations, net of current portion	182	504
Total liabilities	39,226	28,509
Commitments and contingencies (Note 5)		
Stockholders' equity:		
Preferred stock, $0.0001 par value; Authorized: 5,000 shares at December 2003 and 2002; Issued and Outstanding: no shares at December 31, 2003 and 2002	—	—
Common stock, $0.0001 par value, Authorized: 200,000 shares at December 31, 2003 and 2002; Issued: 58,793 and 57,740 shares at December 31, 2003 and 2002, respectively; Outstanding: 58,753 and 57,700 shares at December 31, 2003 and 2002, respectively	6	6
Additional paid-in capital	368,796	364,691
Deferred stock-based compensation	(5,219)	(19,005)
Notes receivable from stockholders	(17)	(892)
Accumulated other comprehensive income	2	17
Accumulated deficit	(300,592)	(280,470)
Total stockholders' equity	62,976	64,347
Total liabilities and stockholders' equity	$ 102,202	$ 92,856

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

ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES

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

	Year Ended December 31,		
	2003	2002	2001
Revenues:			
Invisalign	$115,278	$ 63,690	$ 43,379
Ancillary products and other services	7,447	6,008	1,429
Total revenues	122,725	69,698	44,808
Cost of revenues:			
Invisalign	43,990	37,089	45,039
Ancillary products and other services	7,575	7,902	1,791
Total cost of revenues	51,565	44,991	46,830
Gross profit (loss)	71,160	24,707	(2,022)
Operating expenses:			
Sales and marketing	43,689	45,313	51,929
General and administrative	34,296	39,265	31,174
Research and development	13,112	13,064	15,644
Total operating expenses	91,097	97,642	98,747
Loss from operations	(19,937)	(72,935)	(100,769)
Interest income	531	979	4,261
Interest expense	(364)	(162)	(1,999)
Other expense	(268)	(701)	(532)
Net loss before provision for income taxes	(20,038)	(72,819)	(99,039)
Provision for income taxes	84	—	10
Net loss	(20,122)	(72,819)	(99,049)
Dividend related to beneficial conversion feature of preferred stock	—	—	(11,191)
Net loss available to common stockholders	$ (20,122)	$(72,819)	$(110,240)
Net loss per share available to common stockholders, basic and diluted	$ (0.35)	$ (1.52)	$ (2.61)
Shares used in computing net loss per share available to common stockholders, basic and diluted	57,758	47,878	42,247

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

ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)

For the years ended December 31, 2003, 2002 and 2001

(in thousands)

	Common Stock		Additional Paid-In Capital	Deferred Stock-Based Compensation	Notes Receivable from Stockholders	Accumulated Other Comprehensive Income	Accumulated Deficit	Total
	Shares	Amount						
Balances at December 31, 2000	9,622	$ 1	$105,828	$(80,160)	$(1,814)	$ 73	$(108,602)	$(84,674)
Net loss	—	—	—	—	—	—	(99,049)	(99,049)
Net change in unrealized gain from available-for-sale securities	—	—	—	—	—	153	—	153
Comprehensive loss								(98,896)
Issuance of common stock to preferred stockholders upon conversion	26,998	3	128,870	—	—	—	—	128,873
Sale of common stock upon the completion of initial public offering, net of issuance costs of $12,200	10,629	1	125,976	—	—	—	—	125,977
Issuance of common stock upon exercise of stock options	260	—	184	—	—	—	—	184
Issuance of common stock relating to employee stock purchase plan	39	—	245	—	—	—	—	245
Issuance of common stock upon the conversion and the exercise of warrants	529	—	1,818	—	—	—	—	1,818
Repurchase of common stock	(306)	—	(266)	—	213	—	—	(53)
Cancellations, net of deferred stock compensation	—	—	(9,627)	9,627	—	—	—	—
Charge for accelerated vesting of common stock options	—	—	224	—	—	—	—	224
Payments on stockholders notes receivable	—	—	—	—	287	—	—	287
Interest accrued on stockholders notes receivable	—	—	—	—	(170)	—	—	(170)
Amortization of deferred stock compensation	—	—	—	22,209	—	—	—	22,209
Beneficial conversion feature embedded in convertible subordinated notes	—	—	1,803	—	—	—	—	1,803
Beneficial conversion feature embedded in preferred stock sold	—	—	11,191	—	—	—	—	11,191
Deemed dividend on preferred stock	—	—	(11,191)	—	—	—	—	(11,191)
Balances at December 31, 2001	47,771	5	355,055	(48,324)	(1,484)	226	(207,651)	97,827
Net loss	—	—	—	—	—	—	(72,819)	(72,819)
Net change in unrealized gain from available-for-sale securities	—	—	—	—	—	(209)	—	(209)
Comprehensive loss,								(73,028)
Sale of common stock upon the completion of private stock offering, net of issuance costs of $54	9,579	1	18,145	—	—	—	—	18,146
Issuance of common stock relating to employee stock purchase plan	163	—	480	—	—	—	—	480
Issuance of common stock upon exercise of stock options	670	—	625	—	(3)	—	—	622
Repurchase of common stock contributed to the treasury	(40)	—	(170)	—	—	—	—	(170)
Repurchase of common stock	(443)	—	(410)	—	263	—	—	(147)
Payments on stockholder notes receivable	—	—	—	—	401	—	—	401
Interest accrued on stockholder notes receivable	—	—	—	—	(69)	—	—	(69)
Cancellations, net of deferred stock compensation	—	—	(13,289)	12,735	—	—	—	(554)
Amortization of deferred stock compensation	—	—	—	16,584	—	—	—	16,584
Charge for compensation expense on non-employee stock options	—	—	2,010	—	—	—	—	2,010
Charge for accelerated vesting of employee stock options	—	—	2,245	—	—	—	—	2,245
Balances at December 31, 2002	57,700	6	364,691	(19,005)	(892)	17	(280,470)	64,347
Net loss	—	—	—	—	—	—	(20,122)	(20,122)
Net change in unrealized gain from available-for-sale securities	—	—	—	—	—	(15)	—	(15)
Comprehensive loss								(20,137)
Issuance of common stock relating to employee stock purchase plan	194	—	434	—	—	—	—	434
Issuance of common stock upon exercise of stock options	879	—	2,446	—	—	—	—	2,446
Repurchase of common stock	(20)	—	(20)	—	—	—	—	(20)
Payments on stockholder notes receivable	—	—	—	—	921	—	—	921
Interest accrued on stockholder notes receivable	—	—	—	—	(46)	—	—	(46)
Cancellations, net of deferred stock compensation	—	—	(990)	990	—	—	—	—
Amortization of deferred stock compensation	—	—	—	12,796	—	—	—	12,796
Charge for compensation expense on non-employee stock options	—	—	1,276	—	—	—	—	1,276
Charge for accelerated vesting of employee stock options	—	—	959	—	—	—	—	959
Balances at December 31, 2003	58,753	$ 6	$368,796	$ (5,219)	$ (17)	$ 2	$(300,592)	$ 62,976

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

ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Year Ended December 31,		
	2003	2002	2001
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net loss	$(20,122)	$(72,819)	$ (99,049)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:			
Depreciation and amortization	9,119	13,051	7,592
Amortization of deferred stock-based compensation	12,796	16,030	22,209
Compensation expense for accelerated vesting of stock options	959	2,245	224
Stock-based compensation	1,276	2,010	—
Loss on retirement, disposal and impairment of fixed assets	279	2,052	35
Provision for doubtful accounts	(86)	229	1,388
Non-cash interest income on notes receivable from stockholders	(46)	(69)	(170)
Non-cash interest expense on convertible subordinated notes	—	—	1,803
Non-cash accretion on marketable securities	1	98	(1,174)
Provision for excess and obsolete inventory	(216)	(86)	555
Changes in operating assets and liabilities:			
Accounts receivable	(4,413)	(5,439)	(8,479)
Deferred costs	200	(425)	1,717
Inventories	354	102	(80)
Prepaid expenses and other current assets	(940)	(891)	(1,886)
Accounts payable	(246)	(2,450)	(450)
Accrued liabilities	9,497	(313)	(2,867)
Deferred revenue	3,710	6,276	777
Net cash provided by (used in) operating activities	12,122	(40,399)	(77,855)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchase of property and equipment	(7,585)	(8,112)	(19,175)
Proceeds from sale of property and equipment	65	—	—
Restricted cash	2,822	(2,538)	15,263
Purchase of marketable securities	(7,684)	(1,972)	(72,219)
Maturities of marketable securities	8,069	14,093	54,412
Proceeds from sale of marketable securities	—	—	19,898
Other assets	(21)	41	(139)
Net cash (used in) provided by investing activities	(4,334)	1,512	(1,960)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from issuance of common stock	2,880	19,248	138,606
Proceeds from payment on stockholders' notes receivable	921	401	287
Repurchase of common stock	(20)	(317)	(53)
Payments for incurred IPO costs	—	—	(10,853)
Proceeds from draw down of line of credit	—	5,000	—
Payments on line of credit	(1,666)	—	—
Payments on capital lease obligations	(516)	(443)	(450)
Net cash provided by financing activities	1,599	23,889	127,537
Net increase (decrease) in cash and cash equivalents	9,387	(14,998)	47,722
Cash and cash equivalents, beginning of year	35,552	50,550	2,828
Cash and cash equivalents, end of year	$ 44,939	$ 35,552	$ 50,550

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

Note 1 Organization

Formation and business of the Company

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

Note 2 Summary of Significant Accounting Policies

Basis of consolidation

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

Use of estimates

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

Fair value of financial instruments

The carrying amounts of the Company's cash and cash equivalents, accounts receivable, accounts payable and other current liabilities approximate the fair value. The carrying value of marketable securities approximates their fair value as determined by market quotes. Based on borrowing rates currently available to the Company for debt with similar terms, the carrying value of its debt obligations approximates fair value.

Cash and cash equivalents

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

Restricted cash

The Company's restricted cash as of December 31, 2003 of $439,000 was primarily comprised of security against leasing arrangements in Europe. The Company's restricted cash as of December 31, 2002 was primarily comprised of $3,000,000, which represented the minimum deposit requirement in connection with the Company's revolving line of credit and equipment loan facility with Comerica Bank (see note 7). The minimum deposit requirement for the Comerica loan facility was removed from the loan agreement in December 2003.

Short- and long-term marketable securities

Marketable securities are classified as available-for-sale and are carried at fair value. Marketable securities classified as current assets have scheduled maturities of less than one year, while marketable securities classified

as non-current assets have scheduled maturities of more than one year. Unrealized holding gains or losses on such securities are included in accumulated other comprehensive income in stockholders' equity. Realized gains and losses on sales of all such securities are reported in earnings and computed using the specific identification cost method. Realized gains or losses and charges for other-than-temporary declines in value, if any, on available-for-sale securities are reported in other income or expense as incurred. The Company periodically evaluates these investments for other-than-temporary impairment.

Certain risks and uncertainties

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

Financial instruments which potentially expose the Company to concentrations of credit risk consist primarily of cash equivalents and accounts receivable. The Company invests excess cash primarily in money market funds of major financial institutions, commercial paper and notes. The Company provides credit to customers in the normal course of business. Collateral is not required for accounts receivable, but ongoing evaluations of customers' credit worthiness are performed. The Company maintains reserves for potential credit losses and such losses have been within management's expectations. No individual customer accounted for 10% or more of the Company's accounts receivable at December 31, 2003 and 2002, or net revenues in fiscal 2003, 2002 and 2001.

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

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

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

Inventories

Inventories are stated at the lower of cost or market. Cost is computed on a first-in, first-out basis. The Company records provisions to write down its inventory and related purchase commitments for estimated obsolescence or unmarketable inventory equal to the difference between the cost of the inventory and the estimated market value based upon assumptions about the future demand and market conditions. If actual future demand or market conditions are less favorable than the Company estimates, additional inventory provisions may be required.

Property and equipment

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

Development costs for internal use software and web-site development

Website development and related costs consist of external and internal costs incurred to purchase and implement the website software and significant enhancements used in the Company's business. Costs incurred in the development of application and infrastructure of the website are capitalized and amortized over the estimated useful life of the website. During fiscal 2002, the Company re-engineered its website, and previously capitalized costs of $392,000 were written off. Website development costs of $103,000 had been capitalized as of December 31, 2003 and 2002. Amortization of website development costs commenced upon launch of the website. Accumulated amortization as of December 31, 2003 and 2002 amounted to $74,000 and $40,000, respectively.

Internal and external costs of designing, creating and maintaining website content, graphics and user interface on the web site are expensed as incurred.

There was other software developed for internal use and capitalized as of December 31, 2003 and 2002 in the amount of $1,099,000 and $1,124,000, respectively. Accumulated amortization as of December 31, 2003 and 2002 amounted to $369,000 and $192,000 respectively.

Impairment of long-lived assets

The Company identifies and records impairment losses on long-lived assets used in operations when events and circumstances indicate that the assets may not be recoverable. Recoverability is measured by comparison of the assets carrying amount to future net undiscounted cash flows the assets are expected to generate. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value, as measured by the discounted future cash flows.

Product Warranty

The Company generally warrants its products for a specific period of time against material defects. The Company provides for the estimated future costs of warranty obligations in costs of goods sold when the related revenue is recognized. The accrued warranty costs represents the best estimate at the time of sale of the total

costs that the Company expects to incur to repair or replace product which fails while still under warranty. The amount of accrued estimated warranty costs are primarily based on historical experience as to product failures as well as current information on repair costs. On a quarterly basis, the Company reviews the accrued balances and updates the historical warranty cost trends. Actual warranty costs incurred have not materially differed from those accrued.

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 in 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 for the additional expense. The Invisalign product warranty does not provide any assurances regarding the outcome of treatment using Invisalign.

The following table reflects the change in the Company's warranty accrual during the year ended December 31, 2003.

	(in thousands)
Warranty accrual, December 31, 2002	$ 514
Charged to costs and expenses	2,004
Actual warranty expenditures	(1,656)
Warranty accrual, December 31, 2003	$ 862

Revenue Recognition

Revenue from the sale of Invisalign and ancillary products is recognized upon product shipment, provided that no significant obligations remain, transfer of title has occurred and collection of the receivable is deemed probable. The costs of producing the ClinCheck™ treatment plan, which are incurred prior to the production of Aligners, are deferred and recognized as related revenues are earned, i.e. upon shipment of the Aligners.

In cases where the dental professional elects to finish the treatment plan using Invisalign, the dental professional orders case refinement. From June 2001 through April 2003, the Company offered its dental professionals the opportunity to purchase case refinement in advance at a discount. The advance purchase price was non-refundable. Revenue, in the amount of the stand-alone sales price of the undelivered element, is deferred until the earlier of shipment of the case refinement or case expiration. In cases where the dental professional did not purchase case refinement in advance, case refinement revenues are recognized when the new Aligners are shipped.

In May 2003, the Company updated its domestic pricing policy to include the future delivery of one case refinement in the price of each case and to offer additional case refinements at a price of $125 each, which the Company believes represents its fair value based on competitive product offerings. Revenue deferrals associated with case refinement after May 1, 2003 are $125 per case. This revenue deferral represents the fair value of a case refinement as determined in accordance with EITF 00-21, which addresses the issue of accounting for arrangements that involve the delivery of multiple products or services. These revenue deferrals will be recognized when the case refinement has been utilized or upon case expiration, which ever is earliest.

Service revenues earned under agreements with third parties for training of dental professionals and staff for Invisalign are recorded as the services are performed. Charges to third parties are based on negotiated rates which are intended to approximate a mark-up on anticipated costs.

The Company estimates and records a provision for amounts of estimated losses on sales, if any, in the period such sales occur.

Research and development

Research and development costs are expensed as incurred.

Advertising costs

The cost of advertising and media is expensed as incurred. For the years ended December 31, 2003, 2002 and 2001 advertising costs totaled $5,003,000, $5,993,000 and $17,466,000, respectively.

Foreign currency

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

Income taxes

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

Stock-based compensation

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

Under APB 25, compensation expense for grants to employees is based on the difference, if any, on the date of the grant, between the fair value of the Company's stock and the option's exercise price. SFAS 123 defines a "fair value" based method of accounting for an employee stock option or similar equity investment.

The Company accounts for stock-based employee compensation using the intrinsic value method under Accounting Principles Board Opinion No. 25 and related interpretations and complies with the disclosure requirements of SFAS 148, "Accounting for Stock-Based Compensation Transition and Disclosure an amendment of FASB Statement No. 123." The following table illustrates the effect on net loss and net loss per common share if the Company had applied the fair value recognition provisions of SFAS 123 to stock-based employee compensation:

	Year Ended December 31,		
	2003	2002	2001
	(in thousands, except per share amounts)		
Net loss available to common stockholders, as reported	$(20,122)	$(72,819)	$(110,240)
Add: Total stock-based employee compensation expense included in reported net earnings	13,378	18,784	22,571
Deduct: Total stock-based employee compensation determined under fair value based method for all awards	(26,742)	(29,350)	(28,271)
Pro forma net loss available to common stockholders	$(33,486)	$(83,385)	$(115.940)
Basic and diluted net loss per common share available to common stockholders:			
As reported	$ (0.35)	$ (1.52)	$ (2.61)
Pro forma	$ (0.58)	$ (1.74)	$ (2.74)

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

The value of options granted to employees is estimated on the date of grant using the minimum value method for shares issued prior to January 25, 2001, the date of the IPO, and using the Black-Scholes option valuation model subsequent to the IPO with the following weighted assumptions:

	Year Ended December 31,		
	2003	2002	2001
Risk-free interest rate	3.02%	3.03%	4.36%
Expected life	5 years	5 years	5 years
Volatility	101.8%	119.8%	117%

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

Segments

The Company reports segment data based on the management approach which designates the internal reporting that is used by management for making operating decisions and assessing performance as the source of the Company's reportable operating segments. During all periods presented, the Company operated in a single business segment. No single country, other than the United States of America, accounted for 10% or more of assets or 10% or more of revenues in fiscal 2003, 2002 and 2001.

Comprehensive Income

Comprehensive income, as defined, includes all changes in equity (net assets) during a period from non-owner sources. Net loss and other comprehensive loss, including unrealized gains and losses on investments, are reported, net of their related tax effect, to arrive at comprehensive loss.

Net loss per share

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

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

	Year Ended December 31,		
	2003	2002	2001
Net loss available to common stockholders	$(20,122)	$(72,819)	$(110,240)
Basic and diluted:			
Weight-average common shares outstanding	58,166	49,112	45,189
Less: Weighted-average shares subject to repurchase	408	1,234	2,942
Weighted-average shares used in basic and diluted net loss per share	57,758	47,878	42,247
Net loss per share available to common stockholders	$ (0.35)	$ (1.52)	$ (2.61)

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

	Year Ended December 31,		
	2003	2002	2001
Options to purchase common stock	8,767	7,670	5,489
Common stock subject to repurchase	200	637	1,969
	8,967	8,307	7,458

Recent Accounting Pronouncements

In May 2003, the FASB issued SFAS No. 149, “Amendment of Statement 133 on Derivative Instruments and Hedging Activities.” SFAS No. 149 amends and clarifies accounting for derivative instruments, including certain derivative instruments embedded in other contracts, and for hedging activities under SFAS No. 133. SFAS No. 149 is effective for contracts entered into or modified after June 30, 2003 and for hedging relationships designated after June 30, 2003. The adoption of FAS 149 did not have a material impact on the Company’s consolidated financial statements.

In May 2003, the FASB issued SFAS No. 150, "Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity." SFAS No. 150 establishes standards for how companies classify and measures certain financial instruments with characteristics of both liabilities and equity. It requires companies to classify a financial instrument that is within its scope as a liability (or an asset in some circumstances). SFAS No. 150 is effective beginning second quarter of fiscal 2004. The Company does not expect the adoption of SFAS No. 150 to have a material impact on its consolidated financial statements.

Note 3 Short- and long-term marketable securities

The amortized cost and fair value of available-for-sale securities at December 31, 2003 are as follows (in thousands):

	Amortized Cost	Unrealized Gain	Fair Value	Maturity Date
Short-term marketable securities				
Corporate notes	$2,290	$2	$2,292	February 2004

Note 4 Balance Sheet Components

Inventories consist of the following (in thousands):

	December 31,	
	2003	2002
Raw materials	$ 859	$ 931
Work in progress	201	285
Finished goods	335	317
	$1,395	$1,533

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

	December 31,	
	2003	2002
Clinical and manufacturing equipment	$ 26,558	$ 24,662
Computer hardware	7,471	7,130
Computer software	3,413	3,350
Furniture and fixtures	3,961	3,813
Leasehold improvements	5,522	5,321
Construction in progress	2,133	191
	49,058	44,467
Less: Accumulated depreciation and amortization	(25,937)	(19,389)
	$ 23,121	$ 25,078

During fiscal 2002, the Company recorded an impairment charge for the land in Pakistan of $0.9 million (See note 6).

Property and equipment includes approximately $2,223,000 of assets under capital leases at December 31, 2003 and 2002. Accumulated amortization of assets under capital leases totaled approximately $1,771,000 and $1,264,000 at December 31, 2003 and 2002, respectively.

Depreciation expense and amortization was $9,119,000, $13,051,000 and $7,592,000 for the years ended December 31, 2003, 2002 and 2001, respectively.

Accrued liabilities consist of the following (in thousands):

	December 31,	
	2003	2002
Accrued marketing expenses	$ 2,391	$1,828
Accrued payroll and benefits	7,348	4,231
Sales and franchise taxes	2,041	1,055
Warranty	862	514
Litigation settlement	2,094	—
Other	4,444	2,055
	$19,180	$9,683

Note 5 Commitments and Contingencies

Operating leases

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

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

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

In February 2003, the Company entered into an agreement to lease an operating facility in San Jose, Costa Rica. The lease term began on November 1, 2003 and expires on November 30, 2008.

Total rent expense was $3,504,000, $4,355,000 and $3,349,000 for the years ended December 31, 2003, 2002 and 2001, respectively. The terms of the facility lease provide for rental payments on a graduated scale. The Company recognizes rent expense on a straight-line basis over the lease period, and has accrued for rent expense incurred but not paid.

The future minimum lease payments under operating leases as of December 31, 2003 are $4,073,000, $2,739,000, $1,136,000, $746,000, $600,000 and $0 for the years ended December 31, 2004, 2005, 2006, 2007, 2008 and thereafter, respectively.

Capitalized lease obligations

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

In May and August 2000, the Company leased two stereolithography machines from 3D Capital Corporation ("3D") under a Master Lease Agreement entered into in March 2000 for a total value of $1,479,000 at a borrowing rate of 6.533% per annum for a period of 60 months. In July 2001 this lease was assigned to DeLage Landen.

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

Year Ended December 31,	
2004	$ 348
2005	187
2006	—
2007	—
Minimum lease payments	535
Less: Amount representing interest	(31)
Present value of minimum lease payments	504
Amount due within one year	(322)
Amount due after one year	$ 182

Contingencies

In October 2003, the Company entered into a Loan Agreement with General Orthodontics, LLC, whereby the Company agrees to make loan advances to General Orthodontics, LLC of amounts not to exceed an aggregate principle balance of $200,000. The commitment by the Company to make loans to General Orthodontics, LLC shall expire upon General Orthodontics, LLC obtaining alternative financing. Interest on the loans will accrue on the unpaid principal amount of the outstanding loans at an annual rate of 5%. All loan advances and accrued interest are due and payable no later than October 2006.

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 our 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. We amended our counterclaim to add Allesee Orthodontic Appliances, Inc. ("AOA"), a wholly-owned subsidiary of Ormco, as a counterdefendant in regard to our counterclaim of infringement of U.S. Patent No. 6,398,548. The Court then permitted Ormco to amend its Complaint and permitted us to amend our counterclaim to add an additional patent each. Ormco filed a first amended complaint for infringement of U.S. Patent No. 6,616,444 on

October 15, 2003. On October 27, 2003, we filed an answer to Ormco's first amended complaint and a counterclaim for invalidity and non-infringement of U.S. Patent No. 6,616,444 and for infringement of U.S. Patent No. 6,554,611.

At a Scheduling Conference held on November 24, 2003, the Court set a June 10, 2004 discovery cutoff and an October 2004 trial date.

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 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 Nos. 6,244,861 and 6,616,444 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 Nos. 6,398,548 and 6,554,611 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 our 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 might not be available on commercially reasonable terms or at all. In that event, we could be subject to damages or an injunction, which could materially adversely affect our business.

From time to time, we have received and may 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.

On April 9, 2002, the Company exercised its 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, the Company received a demand for arbitration submitted by 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 the Company from selling Invisalign to dentists in the U.S. and Canada. Based on a review of the factual and legal issues, the Company denied all claims made by Discus Dental in its demand and contended that such claims were entirely without merit. In addition, on or about June 13, 2002, the Company submitted a counter-claim against Discus in the arbitration seeking damages of approximately $40 million arising out of the Company's claims for misrepresentation, breach of confidentiality provisions, and unfair competition, among others. Three arbitrators were selected (the "Panel"), 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 closing argument was heard on October 29, 2003. At the closing argument before the Panel, Discus sought lost profit damages of $46.5 million and loss of good will/out of pocket damages of $13.5 million. The Company previously and voluntarily dismissed its damage counter-claims but maintained its counter-claim for declaratory relief, seeking a judicial declaration that the Company properly terminated the Agreement with Discus.

On February 9, 2004, the Panel issued its final arbitration award which concluded the arbitration proceedings initiated by Discus. Under the final arbitration award, Discus is entitled to a judgment in the amount of $1.00 in damages and reasonable attorney fees and costs in the amount of $2.1 million. In reaching their decision, the arbitrators found that Align's termination of its marketing agreement with Discus in April of 2002 was wrongful. The Company included the $2.1 million charge relating to the final arbitration award in general and administrative expenses for the year ended December 31, 2003.

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

Note 6 Restructuring, Land and Impairment

In July 2002, the Company announced a plan to streamline worldwide operations. The plan included closing the Company's facilities in Pakistan and the U.A.E. The Company transitioned operations performed at these facilities to the United States and Costa Rica. For the period ending December 31, 2002, the Company recorded severance charges of $2.3 million, facility closure charges of $0.9 million, a loss on disposal of fixed assets of $1.1 million and an impairment charge of $0.9 million related to the land in Pakistan. The land was written down to a zero value to reflect its fair value as estimated by management. Approximately $0.1 million of accrued charges related to professional fees were included in accrued liabilities as of December 31, 2002. The Company discontinued operations at its facilities in Pakistan and the U.A.E. in October and December 2002, respectively. The Company concluded the remainder of its indirect operational activities related to the Costa Rica transition in January 2003. The Company will cease non-operational closing activities in Pakistan when the land is disposed of and in the U.A.E. when the necessary statutory filings have been completed.

Note 7 Credit Facilities

In December 2002 the Company obtained up to a $10.0 million revolving line of credit based on domestic accounts receivable. In December 2003, the Company negotiated more favorable terms and increased the line of

credit up to $15.0 million which accrues interest at a rate of 0.5% above prime. In December 2002, the Company also obtained and accessed a $5.0 million equipment-based term loan which accrues interest at a rate of 2.25% above prime. As of December 31, 2003 the Company had not drawn down the revolving line of credit and had not drawn down on any new funds in fiscal 2003 from the $5.0 million equipment-based term loan. As of December 31, 2003, the equipment-based term loan had an outstanding balance of $3.3 million. Accessing the accounts receivable based revolving line of credit is restricted based on qualifying accounts receivable and compliance with certain loan covenants. Principal payments are due in 36 monthly installments beginning in January 2003. Annual principal payments of $1.7 million are due for each of the years 2004 and 2005.

Note 8 Stockholders Equity

Preferred Stock

As of December 31, 2003, the Company has authorized 5,000,000 shares of preferred stock, $0.0001 par value, none of which was issued and outstanding. The Company's Board of Directors is authorized to determine the designation, powers, preferences and rights of preferred stock.

Common Stock

The holders of common stock are entitled to receive dividends whenever funds are legally available and when declared by the Board of Directors, subject to the prior rights of holders of all classes of stock having priority rights as to dividends. The Company has not declared or paid and dividends as of December 31, 2003.

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

In November 2002, the Company completed a private placement of 9,578,944 shares of common stock to a group of institutional investors led by existing shareholders, at $1.90 per share. Net proceeds to the Company were approximately $18,146,000.

Restricted stock purchase agreement

The Company has sold shares of its common stock to founders of the Company under agreements which provide for repurchase of the stock by the Company at the stock's original purchase price upon termination of employment. The Company's right to repurchase lapses at any time prior to the earlier of: (i) three years from date of agreement; (ii) the closing of an "Asset Transfer" or an "Acquisition"; or (iii) the voluntary liquidation, dissolution, or winding up of the Company. The Company has also sold shares of its common stock to employees, directors and consultants under the terms of the 1997 Equity Incentive Plan that includes an early exercise feature. The Company's right to repurchase under those terms lapses over the vesting period of the underlying option exercised. At December 31, 2003 and 2002, 200,298 and 636,809 shares of common stock, respectively, were subject to repurchase.

1997 Equity Incentive Plan

In April 1997, the Company adopted the 1997 Equity Incentive Plan (the "1997 Plan") under which the Board of Directors may issue incentive and non-qualified stock options to employees, directors and consultants. The Company has reserved 9,709,092 shares of common stock for issuance under the Plan. The Board of Directors has the authority to determine to whom options will be granted, the number of shares, the term and exercise price. Options are to be granted at an exercise price not less than fair market value for incentive stock options or 85% of fair market value for non-qualified stock options. For individuals holding more than 10% of the voting rights of all classes of stock, the exercise price of incentive stock options will not be less than 110% of fair market value. Options become exercisable and vest on a cumulative basis at the discretion of the Board of

Directors but at a rate not less than 20% per year over five years from the date of grant and generally vest at a rate of 25% on the first anniversary and 1/48th each month thereafter. The term of the options is no longer than five years for incentive stock options for which the grantee owns greater than 10% of the voting power of all classes of stock and no longer than ten years for all other options.

Executive Grants

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

2001 Stock Incentive Plan

On January 4, 2001, the Board of Directors adopted the 2001 Plan, which will terminate no later than 2011, provides for the granting of incentive stock options, non statutory stock options and restricted stock purchase frights and stock bonuses to employees, and consultants. As of December 31, 2003, a total of 13,273,369 shares of common stock have been authorized for issuance under the 2001 Plan. The 2001 Plan was approved by the Stockholders prior to the IPO.

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

	Options Outstanding			
	Shares Available for Grant	Shares	Weighted Average Exercise Price	Aggregate Price
Balances at December 31, 2000	1,324	2,862	$ 0.82	$ 2,345
Increase in pool	10,000	—	—	—
Options granted	(3,423)	3,423	11.11	38,038
Options exercised	—	(260)	0.71	(184)
Stock repurchased	306	—	0.87	—
Options cancelled	536	(536)	1.88	(1,006)
Balances at December 31, 2001	8,743	5,489	$ 7.14	$(39,193)
Increase in pool	2,388	—	—	—
Options granted	(4,150)	4,150	4.22	17,513
Options exercised	—	(670)	0.93	(622)
Stock repurchased	443	—	0.96	—
Options cancelled	1,299	(1,299)	4.54	(5,902)
Balances at December 31, 2002	8,723	7,670	$ 6.54	$ 50,182
Increase in pool	2,885	—	—	—
Options granted	(2,720)	2,720	8.48	23,062
Options exercised	—	(879)	2.78	(2,446)
Stock repurchased	20	—	1.02	—
Options cancelled	244	(244)	6.88	(1,677)
Options expired	—	(500)	15.00	(7,500)
Balances at December 31, 2003	9,152	8,767	$ 7.03	$ 61,621

The options outstanding and currently exercisable by exercise price at December 31, 2003 are as follows (in thousands, except per share data):

	Options Outstanding			Vested	
Range of Exercise Prices	Number of Outstanding and Exercisable	Weighted-Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Number of Shares	Weighted Average Exercise Price
$ 0.01 – 1.86	1,097	6.7	$ 0.87	966	$ 0.75
1.87 – 3.72	914	8.7	2.66	214	2.39
3.73 – 5.58	2,638	8.2	4.79	1,236	4.77
5.59 – 7.44	1,618	9.1	6.17	191	6.28
7.45 – 9.31	137	8.7	8.02	24	8.13
9.32 – 11.17	109	8.3	10.06	40	9.88
11.18 – 13.03	246	9.6	12.39	32	12.30
13.04 – 14.89	245	9.7	13.97	92	14.25
14.90 – 16.75	1,658	7.3	15.14	1,229	15.00
$16.76 – 18.61	105	9.9	$17.47	—	$ —
	8,767			4,024	

The weighted average per share fair values of options granted during the years ended December 31, 2003, 2002 and 2001 were $6.03, $3.50 and, $9.25, respectively.

Employee Stock Purchase Plan

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

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

Under the Employee Stock Purchase Plan, the Company sold approximately 194,000 and 163,000 shares of common stock during the years ended December 31, 2003 and 2002, respectively. The fair value of the employees' purchase rights was estimated using the Black-Scholes option pricing model with the following assumptions:

	Year Ended December 31,	
	2003	2002
Risk free interest rate	1.73%	3.03%
Expected life	2 years	2 years
Expected volatility	117.%	119.8%

Stock-based compensation

The Company records deferred stock-based compensation for the excess of the deemed fair market value over the exercise price at the date of grant related to options granted to employees. The Company did not record stock-based compensation for the fiscal years 2003 and 2002 related to options issued to employees. In fiscal 2001 the Company has recorded deferred stock-based compensation of $3,530,000 related to options issued to employees to purchase common stock. During fiscal 2003, 2002, and 2001, the Company reversed $1,355,000, $12,419,000 and $12,673,000, respectively, of unrecognized deferred compensation relating to employees that have terminated employment with the Company. The compensation expense is being recognized over the option vesting period of four years using the straight-line method. For the years ended December 31, 2003, 2002, and 2001, the Company recorded amortization of stock-based compensation of $12,419,000, $16,539,000 and $22,347,000, respectively, in connection with options granted to employees.

For options granted to consultants, the Company determines the fair value of the options using the Black-Scholes pricing model. The Company has recorded additional (reversals of) deferred stock-based compensation of $365,000, $(316,000) and $(484,000) for the years ended December 31, 2003, 2002 and 2001, respectively, for options issued to non-employees in fiscal 2001 and 2000. The compensation expense is being recognized over the option vesting period of four years, using the method presented by FIN 28. For the years ended December 31, 2003, 2002 and 2001, the Company recorded amortization of stock-based compensation expense/(reversals of expense) of $377,000, $45,000 and $(138,000), respectively, in connection with options granted to consultants.

The Company recorded stock-based compensation expense of $1,276,000 and $2,010,000 related to stock options granted to non-employees in fiscal 2003 and fiscal 2002, respectively.

The Company accelerated the vesting of options to several employees in connection with related severance packages. The acceleration was accounted for in accordance with FIN 44 as a one-time charge to the statement of operations. The charges for December 31, 2003, 2002 and 2001 were $959,000, $2,245,000 and $224,000, respectively. The charge was equal to the intrinsic value difference between the exercise price of the accelerated options and the fair value of the common stock on the date of acceleration.

Stock based compensation has been recorded as follows (in thousands):

	Year Ended December 31,		
	2003	2002	2001
Cost of revenues	$ 2,560	$ 3,399	$ 4,602
Sales and marketing	2,202	3,002	3,920
General and administrative	7,107	10,663	9,763
Research and development	3,162	3,221	4,148
	$15,031	$20,285	$22,433

Note 9 Income Taxes

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

	Year Ended December 31,	
	2003	2002
Deferred tax assets (liabilities):		
Start-up costs	$ —	$ (129)
Net operating loss carryforwards	63,986	74,290
Research and development credit	4,022	4,642
Deferred revenue	4,597	3,668
Accruals, allowances & other	2,323	2,511
Deferred tax assets	74,928	84,982
Less: Valuation allowance	(74,928)	(84,982)
Net deferred tax asset	$ —	$ —

Based on the available objective evidence, management believes it is more likely than not that the net deferred tax assets will not be fully realizable. Accordingly, the Company has provided a full valuation allowance against its net deferred tax assets at December 31, 2003.

Reconciliation of the statutory federal income tax to the Company's effective tax:

	Year Ended December 31,	
	2003	2002
Tax at federal statutory rate	(34.00)%	(34.00)%
State, net of federal benefit	(6.00)	(6.00)
Deferred tax benefit not recognized	5.64	20.00
Amortization of stock-based compensation	30.00	11.15
Other	4.78	8.85
	0.42%	0.00%

As of December 31, 2003, the Company had a net operating loss carryforward of approximately $171.2 million for federal purposes and $67.7 million for state tax purposes. If not utilized, these carryforwards will begin to expire beginning in 2017 for federal purposes and 2005 for state purposes.

The Company has research credit carryforwards of approximately $2.8 million and $1.3 million for federal and California state income tax purposes. If not utilized, the federal carryforward will expire in various amounts beginning in 2017. The California state credit can be carried forward indefinitely.

The Tax Reform Act of 1986 limits the use of net operating loss and tax credit carryforwards in certain situations where changes occur in the stock ownership of a company. In the event the Company has had a change in ownership, utilization of the carryforwards could be restricted.

The components of the provision for income taxes are as follows (in thousands):

	Year Ended December 31,		
	2003	2002	2001
Current:			
Federal	$ 17	$ —	$ —
State	67	—	10
Total provision for income taxes	$ 84	$ —	$ 10

Note 10 Supplemental Cash Flow Information

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

	Year Ended December 31,		
	2003	2002	2001
Taxes paid	$ 222	$ 231	$ 100
Interest paid	$ 364	$ 143	$ 150
Non-cash investing and financing activities:			
Repurchase of note receivable for common stock	$ —	$ (260)	$ (213)
Fixed assets acquired under capital lease	$ —	$ —	$ 13
Fixed assets acquired with accounts payable or accrued liabilities	$ —	$ 48	$ 640
Accrual for IPO costs	$ —	$ —	$ 20
Conversion of warrants in conjunction with line of credit financings	$ —	$ —	$ (1,818)
Deferred stock-based compensation	$ 549	$13,289	$ 9,627
Conversion of convertible subordinated notes into convertible preferred stock	$ —	$ —	$128,873

Note 11 Employee Benefit Plan

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

Note 12 Related Party Transactions

Loan to Officer

In April 2002, the Company issued a loan in the amount of $200,000 at a note of 9.5% per annum to a former officer of the Company, who at the time the loan was made was the Company's Chairman of the Board. The note was secured by common stock of the Company. The loan was paid in full in fiscal 2003.

Employee Notes Receivable

In connection with the exercise of certain stock options granted under the Company's stock option plan, the Company has received promissory notes equal to the total exercise price of these stock options. These notes are full recourse promissory notes, which bear interest at 9.5% per annum, and accrued interest is payable annually on the anniversary of the issuance date of the note. During 2002, the original due date of the notes were extended by 18 months. The notes are collateralized by the shares of common stock held by employees. Promissory notes for the exercise of certain stock options totaling $17,000 and $892,000 were outstanding as of December 31, 2003 and 2002, respectively. These notes are classified as a reduction of stockholders' equity.

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

Not applicable.

ITEM 9A. CONTROLS AND PROCEDURES.

(a) *Evaluation of disclosure controls and procedures.*

Within the 90 days prior to the filing of this Annual Report on Form 10-K (the "Evaluation Date"), we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-14(c) and 15d-14(c) under the Exchange Act). Based upon that evaluation, our Chief Executive Officer and our Chief Financial Officer concluded that our disclosure controls and procedures are effective to ensure that material information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission rules and forms.

(b) *Changes in internal controls.*

Subsequent to the Evaluation Date, there have been no significant changes in our internal controls or in other factors that could significantly affect these controls subsequent to the date of their last evaluation.

PART III

Certain information required by Part III is omitted from this Form 10-K because we intend to file a definitive Proxy Statement for our 2004 Annual Meeting of Stockholders (the "Proxy Statement") not later than 120 days after the end of the fiscal year covered by this Form 10-K, and certain information to be included therein is incorporated herein by reference.

ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT.

The information required by this Item concerning our directors is incorporated by reference to the Proxy Statement under the section captioned "Election of Directors." The information required by this item concerning our executive officers is set forth in Part I, Item 1—"Business" of this Report on Form 10-K. The information required by this item concerning compliance with Section 16(a) of the Exchange Act is incorporated by reference to the section entitled "Section 16(a) Beneficial Ownership Reporting Compliance" contained in the Proxy Statement.

Audit Committee Financial Expert

Under Item 401(h) of Regulation S-K, Mr. Greg J. Santora is the designated audit committee financial expert. Mr. Santora is considered "independent" as the term is used in Item 7(d)(3)(iv) of Schedule 14A under the Exchange Act.

Code of Ethics

We have a code of ethics that applies to all of our employees, including our principal executive officer, principal financial officer and principal accounting officer. This code of ethics is posted on our Internet website. The Internet address for our website is http://www.aligntech.com, and the code of ethics may be found on the "Corporate Governance" section of our Investor Relations webpage.

We intend to satisfy the disclosure requirement under Item 10 of Form 8-K regarding an amendment to, or waiver from, a provision of this code of ethics by posting such information on our website, at the address and location specified above, or as otherwise required by The NASDAQ Stock Market.

ITEM 11. EXECUTIVE COMPENSATION.

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

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS.

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

Equity Compensation Plan Information

The following table provides information as of December 31, 2003 about our common stock that may be issued upon the exercise of options and rights granted to employees, consultants or members of our Board of Directors under all existing equity compensation plans including the 1997 Equity Incentive Plan, the Employee Stock Purchase Plan, the 2001 Stock Incentive Plan, each as amended, and certain individual arrangements.

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
Equity compensation plans approved by security holders	8,767,000(1)(2)	$7.03	13,190,000(3)
Equity compensation plans not approved by security holders	—	—	—
Total	8,767,000	$7.03	13,190,000

(1) This number reflects the number of securities to be issued upon exercise of outstanding options under the 2001 Stock Incentive Plan and arrangements outside of this Plan between Align Technology, Inc. and two former employees. In January 2001, all outstanding options under the 1997 Equity Incentive Plan were subsumed under the 2001 Stock Incentive Plan. Currently there are no options outstanding under the 1997 Equity Incentive Plan.

(2) We are unable to ascertain with specificity the number of securities to be issued upon exercise of outstanding rights under the Employee Stock Purchase Plan or the weighted average exercise price of outstanding rights under the Employee Stock Purchase Plan.

(3) This number reflects securities available for future issuance under the 2001 Stock Incentive Plan and the Employee Stock Purchase Plan. In January 2001, all of the options available for issuance under the 1997 Equity Incentive Plan were subsumed under the 2001 Stock Incentive Plan. Currently there are no options available for issuance under the 1997 Equity Incentive Plan. Additionally, no options are available for issuance under any arrangement between Align Technology, Inc. and any individual. The 2001 Stock Incentive Plan provides that the number of shares of our Common Stock reserved for issuance thereunder will automatically increase on the first trading day of January in each calendar year by an amount equal to five percent (5%) of the total number of shares of Common Stock outstanding on the last trading day in

December of the immediately preceding calendar year, with this annual increase not to exceed 3,000,000 shares. The Employee Stock Purchase Plan provides that the number of shares of our Common Stock reserved for issuance thereunder will automatically increase on the first trading day of January in each calendar year by an amount equal to three percent (3%) of the total number of shares of Common Stock outstanding on the last trading day in December of the immediately preceding calendar year, with this annual increase not to exceed 1,500,000 shares. As of December 31, 2003, the total number of our Common Stock reserved for issuance under the Employee Stock Purchase Plan is 4,038,000 shares. As of December 31, 2003, the number of options available for future issuance under the 2001 Stock Incentive Plan is 9,152,000.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS.

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

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this item is included under the captions "Ratification of Appointment of Independent Accountants" in our Proxy Statement and is incorporated herein by reference.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES AND REPORTS ON FORM 8-K.

(a)

1. Consolidated Financial Statements

The following documents are filed as part of this Annual Report on Form 10-K:

2. The following financial statement schedule is filed as part of this Annual Report on Form 10-K:

Schedule II—Valuation and Qualifying Accounts and Reserves

All other schedules have been omitted as they are not required, not applicable, or the required information is otherwise included.

SCHEDULE II: VALUATION AND QUALIFYING ACCOUNTS AND RESERVES

	Balance at Beginning of Period	Additions (reductions) to Costs and Expenses	Write-offs	Reclasses from Other Accounts	Balance at End of Period
			(in thousands)		
Allowance for doubtful accounts:					
Year ended December 31, 2001	494	1,399	(24)	13	1,882
Year ended December 31, 2002	1,882	1,068	(821)	(18)	2,111
Year ended December 31, 2003	2,111	(86)	(753)	(13)	1,259
Allowance for deferred taxes:					
Year ended December 31, 2001	32,523	30,617	—	—	63,140
Year ended December 31, 2002	63,140	21,842	—	—	84,982
Year ended December 31, 2003	84,982	(10,054)	—	—	74,928
Allowance for excess and obsolete inventory and abandoned product:					
Year ended December 31, 2001	—	555	—	—	555
Year ended December 31, 2002	555	51	(107)	(30)	469
Year ended December 31, 2003	469	18	(234)	—	253

3. Exhibits

Exhibit Number	Description
3.1*	Amended and Restated Certificate of Incorporation of registrant.
3.2*	Amended and Restated Bylaws of registrant.
4.1*	Form of Specimen Common Stock Certificate.
4.2(1)	Stock Purchase Agreement, dated November 26, 2002, by and between certain investors and registrant.
10.1*	Amended and Restated Investors' Rights Agreement, among registrant and certain of its stockholders, dated September 16, 2000.
10.2	Reserved.
10.3	Reserved.
10.4*	Lease Agreement by and between James Lindsey and registrant, dated June 20, 2000, for office space located at 881 Martin Avenue, Santa Clara, CA.
10.5	Reserved.
10.6	Reserved.
10.7*	Shelter Services Agreement between registrant and ELAMEX, S.A. DE C.V. dated February 16, 2000.
10.7.1(2)	Amendment dated June 3, 2002 to Shelter Services Agreement by ELAMEX, S.A. DE C.V. and registrant.
10.7.2(8)	Assignment of Interest and Obligations dated July 4, 2003 by and between ELAMEX, S.A. DE C.V. and International Manufacturing Solutions Operaciones, S.R.L.
10.8	Reserved.
10.9	Reserved.
10.10	Reserved.
10.11	Reserved.
10.12	Reserved.
10.13*†	Registrant's 2001 Stock Incentive Plan.
10.14*†	Registrant's Employee Stock Purchase Plan.
10.15*	Form of Indemnification Agreement by and between registrant and its Board of Directors.
10.17	Reserved.
10.18(3)	Agreement to confirm consulting and board duties, dated February 26, 2002, between Kelsey Wirth and registrant.
10.19(3)	Transition, Consulting and Separation Agreement, dated March 27, 2002, between Muhammad Ziaulluh Chishti and registrant.
10.20†(3)	Employment Agreement dated March 27, 2002 between Thomas M. Prescott and registrant.
10.22(4)	Employment Offer Letter dated July 10, 2002 for Roger E. George, Vice-President of Legal Affairs and General Counsel.
10.23(5)	Employment Offer Letter dated July 15, 2002 for David S. Thrower, Vice-President of Global Marketing.
10.24(6)	Employment Offer Letter dated August 22, 2002 for Eldon M. Bullington, Chief Financial Officer and Vice-President, Finance.

Exhibit Number	Description
10.25†[2]	Form of Employment Agreement entered into by and between registrant and each of Amir Abolfathi, Eldon M. Bullington, Jon Field, Roger E. George, Len M. Hedge and David S. Thrower.
10.26†[2]	Stock Option Agreement dated January 4, 2001 by and between Kelsey Wirth and registrant.
10.27†[2]	Stock Option Agreement dated January 4, 2001 by and between Zia Chishti and registrant.
10.28[2]	Lease Agreement dated August 30, 2001 by and between James S. Lindsey and registrant for office space located at 821 Martin Avenue, Santa Clara, CA.
10.29[2]	Amendment to Master Professional Services Agreement dated May 20, 2002 by and between Invisible IT Inc. and registrant.
10.30[2]	Settlement Agreement and Mutual Release dated February 6, 2003 by and among GW Com, Inc., now known as Byair, Inc., Intelecady, Inc., James S. Lindsey and registrant.
10.31[2]	Consulting Agreement dated June 17, 2002 by and between Peter Riepenhausen and registrant.
10.32	Reserved
10.33[2]	Director Offer Letter dated March 6, 2003 for David E. Collins.
10.34	Reserved
10.35[2]	Loan and Security Agreement dated December 20, 2002 by and between Comerica Bank-California and registrant.
10.35.1[9]	Amendment No. 1 to Loan and Security Agreement with Limited Waiver dated as of August 4, 2003 by and between the registrant and Comerica Bank.
10.35.2	Amendment No. 3 to Loan and Security Agreement dated as of December 17, 2003 by and between registrant and Comerica Bank.
10.36[7]	Lease Agreement dated February 26, 2003 between KPMG FIDES (COSTA RICA) S.A., PARQUE GLOBAL S.A. and registrant.
10.37[10]	Director Offer Letter dated July 18, 2003 for Greg J. Santora.
10.38	Employment Agreement dated as of December 15, 2003 by and between registrant and Patricia Wadors.
21.1*	Subsidiaries of the registrant.
23.1	Consent of PricewaterhouseCoopers LLP, Independent Accountants.
24.1	Power of Attorney.
31.1	Certification of Chief Executive Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Chief Financial Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32	Certifications of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

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

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

(1) Incorporated by reference to Exhibit 4.1 filed with the registrant's Report on Form 8-K, filed with the Securities and Exchange Commission on November 21, 2002.

(2) Incorporated by reference to the exhibit bearing the same number filed with registrant's Annual Report on Form 10-K for the year ended December 31, 2002.

(3) Incorporated by reference to the exhibit bearing the same number filed with registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2002.

(4) Incorporated by reference to Exhibit 10.18 filed with registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2002.

(5) Incorporated by reference to Exhibit 10.19 filed with registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2002.

(6) Incorporated by reference to Exhibit 10.20 filed with registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2002.

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(8) Incorporated by reference to Exhibit 10.7.1 filed with the registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2003.

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(10) Incorporated by reference to the exhibit bearing the same number filed with the registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2003.

(b) *Reports on Form 8-K*

On October 23, 2003 we furnished a current Report on Form 8-K reporting under Item 12 that on October 23, 2003, we were issuing a press release and holding a conference call regarding our financial results for the third quarter of fiscal 2003, ended September 30, 2003.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this amendment to be signed on its behalf by the undersigned, thereunto duly authorized, on March 9, 2004.

ALIGN TECHNOLOGY, INC.

By: /s/ THOMAS M. PRESCOTT

Thomas M. Prescott
President and Chief Executive Officer

KNOW ALL MEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Thomas M. Prescott, his or her attorney-in-fact, with the power of substitution, for him or her in any and all capacities, to sign any amendments to this Report on Form 10-K and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that each of said attorneys-in-fact, or his or her substitute or substitutes, may do or cause to be done by virtue hereof.

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

Signature	Title	Date
/s/ THOMAS M. PRESCOTT **Thomas M. Prescott**	President and Chief Executive Officer (Principal Executive Officer)	March 9, 2004
/s/ ELDON M. BULLINGTON **Eldon M. Bullington**	Chief Financial Officer and Vice President, Finance (Principal Financial Officer and Principal Accounting Officer)	March 9, 2004
/s/ KELSEY WIRTH **Kelsey Wirth**	Director	March 9, 2004
/s/ BRIAN DOVEY **Brian Dovey**	Director	March 9, 2004
/s/ JOSEPH LACOB **Joseph Lacob**	Director	March 9, 2004
/s/ H. KENT BOWEN **H. Kent Bowen**	Director	March 9, 2004
/s/ DAVID E. COLLINS **David E. Collins**	Director	March 9, 2004
/s/ GREG J. SANTORA **Greg J. Santora**	Director	March 9, 2004

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Exhibit 10.35.2

AMENDMENT NO. 3
TO
LOAN AND SECURITY AGREEMENT

THIS AMENDMENT NO. 3 TO LOAN AND SECURITY AGREEMENT dated as of December 17, 2003 (the ***"Amendment"),*** is entered into by and between **ALIGN TECHNOLOGY, INC.,** a Delaware corporation (the ***"Borrower"),*** and **COMERICA BANK** (the ***"Bank").***

RECITAL

A. Borrower and Bank have entered into that certain Loan and Security Agreement dated as of December 20, 2002, as amended by that certain Amendment No. 1 dated as of August 4, 2003, and that certain Second Amendment dated as of September 29, 2003 (as the same may be amended, modified, supplemented or restated hereafter from time to time, the ***"Loan Agreement"),*** pursuant to which the Bank has agreed to extend and make available to the Borrower certain advances of money upon the terms and conditions set forth in the Loan Agreement and the other Loan Documents.

B. Borrower and Bank desire to amend certain provisions of the Loan Agreement, as more fully set forth herein.

C. Subject to the representations and warranties of Borrower and upon the terms and conditions set forth in this Amendment, Bank is willing to so amend the Loan Agreement.

AGREEMENT

NOW, THEREFORE, in consideration of the foregoing recitals, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, and intending to be legally bound, Borrower and Bank hereby agree as follows:

SECTION 1. DEFINITIONS. Capitalized terms used herein without definitions shall have the meanings given to them in the Loan Agreement.

SECTION 2. AMENDMENTS TO LOAN AGREEMENT. The Loan Agreement is hereby amended as follows:

2.1 Section 2.1(b) – Letter of Credit Usage. Section 2.1(b) of the Loan Agreement is hereby amended by replacing the reference to "One Million Dollars ($1,000,000)" in line thirteen thereof with "Three Million Dollars ($3,000,000)."

2.2 Section 2.4(a)(i) – Interest Rates on Revolving Advances. Section 2.4(a)(i) of the Loan Agreement is hereby amended by replacing the rate of "One and Three Quarters of One Percent (1.75%)" therein with "One-half of One Percent (0.50%)."

2.3 Section 2.6 – Fees. The amount of the Revolving Facility Fee in Section 2.6(b) is hereby increased from "Twenty Five Thousand Dollars ($25,000)" to "Thirty Seven Thousand Five Hundred Dollars ($37,500)".

2.4 Section 6.2(c) – Financial Statements, Reports, Certificates. Section 6.2(c)(i) of the Loan Agreement is hereby amended and restated to read in its entirety as follows: "audit Borrower's Accounts one time per calendar year in the absence of an Event of Default."

2.5 Section 6.6 – Primary Depositary. Section 6.6 of the Loan and Security Agreement is hereby amended to delete the second sentence thereof (requiring Borrower to maintain unrestricted cash with Bank) in its entirety.

2.6 Section 6.7(c) – EBITDA Covenant. The minimum EBITDA covenant is hereby modified to delete the minimum EBITDA amounts shown for the following fiscal quarter ends and replace them with the amounts shown in this Amendment:

12/31/03	$1,000,000
3/31/04	$2,500,000
6/30/04	$3,000,000
9/30/04	$4,000,000
12/31/04 and thereafter	$5,000,000

2.7 Exhibit A – Definitions. The following definitions contained in exhibit A to the Loan Agreement are hereby amended as follows:

(a) "Committed Revolving Line" is hereby amended by replacing the amount "Ten Million Dollars ($10,000,000)" with the amount "Fifteen Million Dollars ($15,000,000)."

(b) "Eligible Accounts" is hereby amended by replacing "fifty percent (50%)" in item (b) with "twenty-five percent (25%)." A corresponding change is hereby made in item 5 of Exhibit D – Borrowing Base Certificate.

(c) "Revolving Maturity Date" is amended by replacing the date "June 20, 2004" with "December 9, 2005."

SECTION 3. REFERENCE TO AND EFFECT ON THE LOAN AGREEMENT AND OTHER LOAN DOCUMENTS. Upon the effectiveness of this Amendment, on or after the date hereof, each reference in the Loan Agreement to "this Agreement," "hereunder," "hereof," "herein" or words of like import shall mean and be a reference to the Loan Agreement as amended by this Amendment, and each reference in any other document in which the Loan Agreement is referenced shall also mean and be a reference to the Loan Agreement, as amended by this Amendment.

SECTION 4. LIMITATION OF AMENDMENT. Each of the amendments set forth in **Section 2** above shall be limited precisely as written and shall not be deemed to (i) be a modification or amendment to any other term or condition of the Loan Agreement or any other Loan Document, (ii) prejudice any right or remedy which Bank may now have or may have in the future under or in connection with the Loan Agreement or any other Loan Document, or (iii) be a consent to any

future amendment, waiver or modification of any other term or condition of the Loan Agreement or any other Loan Document.

SECTION 5. REPRESENTATIONS AND WARRANTIES. In order to induce Bank to enter into this Amendment, Borrower represents and warrants to Bank as follows:

5.1 Immediately after giving effect to this Amendment (a) the representations and warranties contained in the Loan Agreement (other than those which expressly speak as of a particular prior date) are true and accurate in all material respects as of the date hereof and (b) no Event of Default has occurred and is continuing;

5.2 Borrower has the power and authority to execute and deliver this Amendment and to perform its obligations under the Loan Agreement, as amended by this Amendment, and each of the other Loan Documents to which it is a party;

5.3 The execution and delivery by Borrower of this Amendment and the performance by Borrower of its obligations under the Loan Agreement, as amended by this Amendment, and each of the other Loan Documents to which it is a party have been duly authorized by all necessary action on the part of Borrower; and

5.4 This Amendment has been duly executed and delivered by Borrower and is the binding obligation of Borrower, enforceable against it in accordance with its terms, except as such enforceability may be limited by bankruptcy, insolvency, reorganization, liquidation, moratorium or other similar laws of general application relating to or affecting creditors' rights, and by equitable principles (regardless of whether endorsement is sought in equity or at law).

SECTION 6. EXPENSES. Borrower agrees to pay to Bank upon demand, the amount of any and all out-of-pocket expenses, including the reasonable fees and expenses of its counsel, which Bank may incur in connection with the preparation, documentation, and negotiation of this Amendment and all related documents.

SECTION 7. FULL FORCE AND EFFECT; REAFFIRMATION. Except to the extent expressly provided in this Amendment, the terms and conditions of the Loan Agreement shall remain in full force and effect. Borrower hereby reaffirms its obligations under each of the Loan Documents to which it is a party.

SECTION 8. CONDITIONS PRECEDENT. This Amendment shall be deemed effective upon the satisfaction of all of the following conditions precedent:

8.1 Amendment. Bank shall have received this Amendment duly executed and delivered by Borrower.

8.2 Payment of Costs. Borrower shall have paid to Bank all costs incurred by Bank in connection with the preparation of this Amendment, including, without limitation, reasonable attorneys' fees.

SECTION 9. GOVERNING LAW. This Amendment shall be governed by and shall be construed and enforced in accordance with the laws of the state of California.

SECTION 10. COUNTERPARTS. This Amendment may be executed in any number of counterparts, each of which when so delivered shall be deemed an original, but all such counterparts taken together shall constitute but one and the same instrument.

IN WITNESS WHEREOF, the parties hereto have caused this Amendment to be executed as of the date first written above.

BORROWER:

ALIGN TECHNOLOGY, INC.,
a Delaware corporation

By: /s/ Eldon M. Bullington

Printed Name: Eldon M. Bullington
Its: Chief Financial Officer and Vice President, Finance

BANK:

COMERICA BANK

By: /s/ Kathy Conte

Printed Name: Kathy Conte
Its: Senior Vice President

Exhibit 10.38

EMPLOYMENT AGREEMENT

This AGREEMENT is entered into as of December 15, 2003, by and between Patricia Wadors (the "Executive") and Align Technology, Inc., a Delaware corporation (the "Company").

1. Duties and Scope of Employment.

(a) Position. For the term of her employment under this Agreement ("Employment"), the Company agrees to employ the Executive in the position of Vice President of Human Resources. The Executive shall report to the Chief Executive Officer. The Executive accepts such employment and agrees to discharge all of the duties normally associated with said position, and to faithfully and to the best of her abilities perform such other services consistent with her position as Vice President of Human Resources as may from time to time be assigned to her by the Chief Executive Officer (the "CEO").

(b) Obligations to the Company. During the term of her Employment, the Executive shall devote her full business efforts and time to the Company. The Executive agrees not to actively engage in any other employment, occupation or consulting activity for any direct or indirect remuneration without the prior approval of the CEO, provided, however, that the Executive may, without the approval of the CEO, serve in any capacity with any civic, educational or charitable organization. The Executive may own, as a passive investor, no more than one percent (1%) of any class of the outstanding securities of any publicly traded corporation.

(c) No Conflicting Obligations. The Executive represents and warrants to the Company that she is under no obligations or commitments, whether contractual or otherwise, that are inconsistent with her obligations under this Agreement. The Executive represents and warrants that she will not use or disclose, in connection with her employment by the Company, any trade secrets or other proprietary information or intellectual property in which the Executive or any other person has any right, title or interest and that her employment by the Company as contemplated by this Agreement will not infringe or violate the rights of any other person or entity. The Executive represents and warrants to the Company that she has returned all property and confidential information belonging to any prior employers.

(d) Commencement Date. The Executive commenced full-time Employment on December 15, 2003.

2. Cash and Incentive Compensation.

(a) Salary. The Company shall pay the Executive as compensation for her services a base salary at a gross annual rate of $200,000.00, payable in accordance with the Company's standard payroll schedule. The compensation specified in this Subsection (a),

together with any adjustments by the Company from time to time, is referred to in this Agreement as "Base Salary."

(b) Target Bonus. The Executive shall be eligible to participate in an annual bonus program that will provide her with an opportunity to earn a potential annual bonus equal to 30.0% of the Executive's Base Salary; provided, however, that Executive shall receive a bonus of 30.0% of her base 2004 salary, payable in accordance with the Company's annual review process in 2005. The amount of the bonus shall be based upon the performance of the Executive, as set by the individual performance objectives described in this Subsection, and the Company in each calendar year, and shall be paid by no later than January 31 of the following year, contingent on the Executive remaining employed by the Company as of such date. The Executive's individual performance objectives and those of the Company's shall be set by the CEO after consultation with the Executive by no later than March 31, of each calendar year. For calendar year 2002, the Executive's bonus shall be prorated based on the number of days of such year that the Executive was employed by the Company. Any bonus awarded or paid to the Executive will be subject to the discretion of the Board.

(c) Stock Options. The Executive shall be eligible for an annual incentive stock option grant subject to the approval of the Board. The per share exercise price of the option will be equal to the per share fair market value of the common stock on the date of grant, as determined by the Board of Directors. The term of such option shall be ten (10) years, subject to earlier expiration in the event of the termination of the Executive's Employment. Such option shall be immediately exercisable, but the purchased shares shall be subject to repurchase by the Company at the exercise price in the event that the Executive's Employment terminates before he vests in the shares. The Executive shall vest in 25% of the option shares after the first twelve (12) months of continuous service and shall vest in the remaining option shares in equal monthly installments over the next three (3) years of continuous service. The grant of each such option shall be subject to the other terms and conditions set forth in the Company's 2001 Stock Incentive Plan and in the Company's standard form of stock option agreement.

3. Vacation and Executive Benefits. During the term of her Employment, the Executive shall be eligible for 17 days vacation per year, in accordance with the Company's standard policy for senior management, as it may be amended from time to time. During the term of her Employment, the Executive shall be eligible to participate in any employee benefit plans maintained by the Company for senior management, subject in each case to the generally applicable terms and conditions of the plan in question and to the determinations of any person or committee administering such plan.

4. Business Expenses. During the term of her Employment, the Executive shall be authorized to incur necessary and reasonable travel, entertainment and other business expenses in connection with her duties hereunder. The Company shall reimburse the Executive for such expenses upon presentation of an itemized account and appropriate supporting documentation, all in accordance with the Company's generally applicable policies.

5. Term of Employment.

(a) Basic Rule. The Company agrees to continue the Executive's Employment, and the Executive agrees to remain in Employment with the Company, from the commencement date set forth in Section 1(d) until the date when the Executive's Employment terminates pursuant to Subsection (b) below. The Executive's Employment with the Company shall be "at will," and either the Executive or the Company may terminate the Executive's Employment at any time, for any reason, with or without Cause. Any contrary representations, which may have been made to the Executive shall be superseded by this Agreement. This Agreement shall constitute the full and complete agreement between the Executive and the Company on the "at will" nature of the Executive's Employment, which may only be changed in an express written agreement signed by the Executive and a duly authorized officer of the Company.

(b) Termination. The Company may terminate the Executive's Employment at any time and for any reason (or no reason), and with or without Cause, by giving the Executive notice in writing. The Executive may terminate her Employment by giving the Company fourteen (14) days advance notice in writing. The Executive's Employment shall terminate automatically in the event of her death or Permanent Disability. For purposes of this Agreement, "Permanent Disability" shall mean that the Executive has become so physically or mentally disabled as to be incapable of satisfactorily performing the duties under this Agreement for a period of one hundred eighty (180) consecutive calendar days.

(c) Rights Upon Termination. Except as expressly provided in Section 6, upon the termination of the Executive's Employment pursuant to this Section 5, the Executive shall only be entitled to the compensation, benefits and reimbursements described in Sections 2, 3 and 4 for the period preceding the effective date of the termination. The payments under this Agreement shall fully discharge all responsibilities of the Company to the Executive.

(d) Termination of Agreement. The termination of this Agreement shall not limit or otherwise affect any of the Executive's obligations under Section 7.

6. Termination Benefits.

(a) General Release. Any other provision of this Agreement notwithstanding, Subsections (b), (c) or (d) below shall not apply unless the Executive (i) has executed a general release in a form prescribed by the Company of all known and unknown claims that he may then have against the Company or persons affiliated with the Company, and (ii) has agreed not to prosecute any legal action or other proceeding based upon any of such claims.

(b) Termination without Cause. If, during the term of this Agreement, the Company terminates the Executive's Employment for any reason other than Cause or Permanent Disability, and not in connection with a Change of Control as addressed by Subsection (c) below, then the Company shall pay the Executive, an amount equal to: (i) the then current year's Target Bonus prorated for the number of days of Executive is employed in said year, payable in a lump sum within 30 days of the date of termination of Employment; (ii) one year's Base Salary, payable in equal installments in accordance with the Company's standard payroll schedule; and (iii) the greater of the then current year's Target Bonus or the

actual prior year's bonus, payable in a lump sum on the one year anniversary of termination of Employment. The Executive's Base Salary shall be paid at the rate in effect at the time of the termination of Employment.

(c) Upon a Change of Control. In the event of the occurrence of a Change in Control while the Executive is employed by the Company:

(i) the Executive shall immediately vest in an additional number of shares under all outstanding options as if he had performed twelve (12) additional months of service; and

(ii) if within twelve (12) months following the occurrence of the Change of Control, one of the following events occurs:

(A) the Executive's employment is terminated by the Company without Cause; or

(B) the Executive resigns for Good Reason

then the Executive shall immediately vest as to all shares under all outstanding options and the Company shall pay the Executive, in a lump sum, an amount equal to: (i) the then current year's Target Bonus prorated for the number of days of Executive is employed in said year; (ii) one year's Base Salary; and (iii) the greater of the then current year's Target Bonus or the actual prior year's bonus. The Executive's Base Salary shall be paid at the rate in effect at the time of the termination of Employment.

(d) Health Insurance. If Subsection (b) or (c) above applies, and if the Executive elects to continue her health insurance coverage under the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended ("COBRA") following the termination of her Employment, then the Company shall pay the Executive's monthly premium under COBRA until the earliest of (i) 12 months following the termination of the Executive's Employment, or (ii) the date upon which The Executive commences employment with an entity other than the Company.

(e) Definition of "Cause." For all purposes under this Agreement, "Cause" shall mean any of the following:

(i) Unauthorized use or disclosure of the confidential information or trade secrets of the Company;

(ii) Any breach of this Agreement or the Employee Proprietary Information and Inventions Agreement between the Executive and the Company;

(iii) Conviction of, or a plea of "guilty" or "no contest" to, a felony under the laws of the United States or any state thereof;

(iv) Misappropriation of the assets of the Company or any act of fraud or embezzlement by Executive, or any act of dishonesty by Executive in connection with the performance of her duties for the Company that adversely affects the business or affairs of the Company; or

(v) Intentional misconduct or the Executive's failure to satisfactorily perform her/her duties after having received written notice of such failure and at least thirty (30) days to cure such failure.

The foregoing shall not be deemed an exclusive list of all acts or omissions that the Company may consider as grounds for the termination of the Executive's Employment.

(f) Definition of "Good Reason." For all purposes under this Agreement, the Executive's resignation for "Good Reason" shall mean the Executive's resignation within ninety (90) days the occurrence of any one or more of the following events:

(i) The Executive's position, authority or responsibilities being significantly reduced;

(ii) The Executive being asked to relocate her principal place of employment such that her commuting distance from her residence prior to the Change of Control is increased by over thirty-five (35) miles;

(iii) The Executive's annual Base Salary or bonus being reduced; or

(iv) The Executive's benefits being materially reduced.

(g) Definition of "Change of Control." For all purposes under this Agreement, "Change of Control" shall mean any of the following:

(i) a sale of all or substantially all of the assets of the Company;

(ii) the acquisition of more than fifty percent (50%) of the common stock of the Company (with all classes or series thereof treated as a single class) by any person or group of persons;

(iii) a reorganization of the Company wherein the holders of common stock of the Company receive stock in another company (other than a subsidiary of the Company), a merger of the Company with another company wherein there is a fifty percent (50%) or greater change in the ownership of the common stock of the Company as a result of such merger, or any other transaction in which the Company (other than as the parent corporation) is consolidated for federal income tax purposes or is eligible to be consolidated for federal income tax purposes with another corporation; or

(iv) in the event that the common stock is traded on an established securities market, a public announcement that any person has acquired or has

the right to acquire beneficial ownership of more than fifty percent (50%) of the then-outstanding common stock and for this purpose the terms "person" and "beneficial ownership" shall have the meanings provided in Section 13(d) of the Securities and Exchange Act of 1934 or related rules promulgated by the Securities and Exchange Commission, or the commencement of or public announcement of an intention to make a tender offer or exchange offer for more than fifty percent (50%) of the then outstanding Common Stock.

7. Non-Solicitation and Non-Disclosure.

(a) Non-Solicitation. During the period commencing on the date of this Agreement and continuing until the first anniversary of the date when the Executive's Employment terminated for any reason, the Executive shall not directly or indirectly, personally or through others, solicit or attempt to solicit (on the Executive's own behalf or on behalf of any other person or entity) the employment of any employee of the Company or any of the Company's affiliates.

(b) Proprietary Information. As a condition of employment, the Executive has entered into a Proprietary Information and Inventions Agreement with the Company, attached to this Agreement as Exhibit A, which is incorporated herein by reference.

8. Successors.

(a) Company's Successors. This Agreement shall be binding upon any successor (whether direct or indirect and whether by purchase, lease, merger, consolidation, liquidation or otherwise) to all or substantially all of the Company's business and/or assets. For all purposes under this Agreement, the term "Company" shall include any successor to the Company's business and/or assets which becomes bound by this Agreement.

(b) Executive's Successors. This Agreement and all rights of the Executive hereunder shall inure to the benefit of, and be enforceable by, the Executive's personal or legal representatives, executors, administrators, successors, heirs, distributees, devisees and legatees.

9. Miscellaneous Provisions.

(a) Notice. Notices and all other communications contemplated by this Agreement shall be in writing and shall be deemed to have been duly given when personally delivered or when mailed by overnight courier, U.S. registered or certified mail, return receipt requested and postage prepaid. In the case of the Executive, mailed notices shall be addressed to him at the home address which he most recently communicated to the Company in writing. In the case of the Company, mailed notices shall be addressed to its corporate headquarters, and all notices shall be directed to the attention of its Secretary.

(b) Modifications and Waivers. No provision of this Agreement shall be modified, waived or discharged unless the modification, waiver or discharge is agreed to in writing and signed by the Executive and by an authorized officer of the Company (other than the Executive). No waiver by either party of any breach of, or of compliance with, any condition or

provision of this Agreement by the other party shall be considered a waiver of any other condition or provision or of the same condition or provision at another time.

(c) Whole Agreement. No other agreements, representations or understandings (whether oral or written) which are not expressly set forth in this Agreement have been made or entered into by either party with respect to the subject matter of this Agreement. This Agreement and the Proprietary Information and Inventions Agreement contain the entire understanding of the parties with respect to the subject matter hereof.

(d) Withholding Taxes. All payments made under this Agreement shall be subject to reduction to reflect taxes or other charges required to be withheld by law.

(e) Choice of Law. The validity, interpretation, construction and performance of this Agreement shall be governed by the laws of the State of California (except provisions governing the choice of law).

(f) Severability. The invalidity or unenforceability of any provision or provisions of this Agreement shall not affect the validity or enforceability of any other provision hereof, which shall remain in full force and effect.

(g) Arbitration. Each party agrees that any and all disputes which arise out of or relate to the Executive's employment, the termination of the Executive's employment, or the terms of this Agreement shall be resolved through final and binding arbitration. Such arbitration shall be in lieu of any trial before a judge and/or jury, and the Executive and Company expressly waive all rights to have such disputes resolved via trial before a judge and/or jury. Such disputes shall include, without limitation, claims for breach of contract or of the covenant of good faith and fair dealing, claims of discrimination, claims under any federal, state or local law or regulation now in existence or hereinafter enacted and as amended from time to time concerning in any way the subject of the Executive's employment with the Company or its termination. The only claims not covered by this Agreement to arbitrate disputes are: (i) claims for benefits under the unemployment insurance benefits; (ii) claims for workers' compensation benefits under any of the Company's workers' compensation insurance policy or fund; (iii) claims arising from or relating to the non-competition provisions of this Agreement; and (iv) claims concerning the validity, infringement, ownership, or enforceability of any trade secret, patent right, copyright, trademark or any other intellectual property right, and any claim pursuant to or under any existing confidential/proprietary/trade secrets information and inventions agreement(s) such as, but not limited to, the Proprietary Information and Inventions Agreement. With respect to such disputes, they shall not be subject to arbitration; rather, they will be resolved pursuant to applicable law.

Arbitration shall be conducted in accordance with the National Rules for the Resolution of Employment Disputes of the American Arbitration Association ("AAA Rules"), provided, however, that the arbitrator shall allow the discovery authorized by *California Code of Civil Procedure* section 1282, *et seq*., or any other discovery required by applicable law in arbitration proceedings, including, but not limited to, discovery available under the applicable state and/or federal arbitration statutes. Also, to the extent that any of the AAA Rules or

anything in this arbitration section conflicts with any arbitration procedures required by applicable law, the arbitration procedures required by applicable law shall govern.

Arbitration will be conducted in Santa Clara County, California or, if the Executive does not reside within 100 miles of Santa Clara County at the time the dispute arises, then the arbitration may take place in the largest metropolitan area within 50 miles of the Executive's place of residence when the dispute arises.

During the course of the arbitration, the Executive and the Company will each bear equally the arbitrator's fee and any other type of expense or cost of arbitration, unless applicable law requires otherwise, and each shall bear their own respective attorneys' fees incurred in connection with the arbitration. The arbitrator will not have authority to award attorneys' fees unless a statute or contract at issue in the dispute authorizes the award of attorneys' fees to the prevailing party. In such case, the arbitrator shall have the authority to make an award of attorneys' fees as required or permitted by the applicable statute or contract. If there is a dispute as to whether the Executive or the Company is the prevailing party in the arbitration, the arbitrator will decide this issue.

The arbitrator shall issue a written award that sets forth the essential findings of fact and conclusions of law on which the award is based. The arbitrator shall have the authority to award any relief authorized by law in connection with the asserted claims or disputes. The arbitrator's award shall be subject to correction, confirmation, or vacation, as provided by applicable law setting forth the standard of judicial review of arbitration awards. Judgment upon the arbitrator's award may be entered in any court having jurisdiction thereof.

(h) No Assignment. This Agreement and all rights and obligations of the Executive hereunder are personal to the Executive and may not be transferred or assigned by the Executive at any time. The Company may assign its rights under this Agreement to any entity that assumes the Company's obligations hereunder in connection with any sale or transfer of all or a substantial portion of the Company's assets to such entity.

(i) Counterparts. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

[*The remainder of this page intentionally left blank.*]

IN WITNESS WHEREOF, each of the parties has executed this Agreement, in the case of the Company by its duly authorized officer, as of the day and year first above written.

Patricia Wadors

/s/ Patricia Wadors

Align Technology, Inc.

/s/ Thomas Prescott

By: Thomas Prescott
Title: President and CEO

EXHIBIT A

PROPRIETARY INFORMATION AND INVENTIONS AGREEMENT

EXHIBIT 23.1

CONSENT OF INDEPENDENT ACCOUNTANTS

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (No. 333-109800) and Form S-8 (No. 333-55020 and No. 333-82874) of Align Technology, Inc. of our report dated February 27, 2004 relating to the consolidated financial statements and financial statement schedule, which appears in this Annual Report on Form 10-K.

/s/ PricewaterhouseCoopers LLP

San Jose, California
March 8, 2004

Exhibit 31.1

CERTIFICATIONS

I, Thomas M. Prescott, certify that:

1. I have reviewed this annual report on Form 10-K of Align Technology, Inc.;
2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and have:
   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;
   (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
   (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 9, 2004

/s/ THOMAS M. PRESCOTT

Thomas M. Prescott
President and Chief Executive Officer

Exhibit 31.2

I, Eldon M. Bullington, certify that:

1. I have reviewed this annual report on Form 10-K of Align Technology, Inc.;
2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and have:
    a) Designed such disclosure controls and procedures or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;
    (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
    (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
    (c) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 9, 2004

/s/ ELDON M. BULLINGTON

Eldon M. Bullington
Chief Financial Officer and
Vice President, Finance

Exhibit 32

CERTIFICATION OF CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER
PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, Thomas M. Prescott, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Annual Report of Align Technology, Inc. on Form 10-K for the fiscal year ended December 31, 2003 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in this Form 10-K fairly presents in all material respects the financial condition and results of operations of Align Technology, Inc.

Date: March 9, 2004

By: /s/ THOMAS M. PRESCOTT
Name: **Thomas M. Prescott**
Title: **President and Chief Executive Officer**

I, Eldon M. Bullington, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Annual Report of Align Technology, Inc. on Form 10-K for the fiscal year ended December 31, 2003 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in this Form 10-K fairly presents in all material respects the financial condition and results of operations of Align Technology, Inc.

Date: March 9, 2004

By: /s/ ELDON M. BULLINGTON
Name: **Eldon M. Bullington**
Title: **Chief Financial Officer and Vice President, Finance**

SHAREHOLDER INFORMATION

Corporate Headquarters
Align Technology, Inc.
881 Martin Ave.
Santa Clara, CA 95050
408.470.1000

Web Sites
www.aligntech.com
www.invisalign.com

Investor Relations
For additional information about Align, additional copies of this Annual Report and Align's Annual Report on Form 10-K as filed with the Securities and Exchange Commission, or other financial information, contact:

Investor Relations
Align Technology, Inc.
881 Martin Ave.
Santa Clara, CA 95050
Email: investorinfo@aligntech.com
408.470.1000

Transfer Agent
EquiServe Trust Company, N.A.
P.O. Box 219045
Kansas City, MO 64121-9045
Shareholder Inquiries 816.843.4299
Website: www.EquiServe.com

Independent Auditors
PricewaterhouseCoopers LLP
Ten Almaden Blvd., Suite 1600
San Jose, CA 95113

General Counsel
Wilson Sonsini Goodrich & Rosati
650 Page Mill Road
Palo Alto, CA 94304

Annual Meeting
May 19, 2004, 9:30 a.m. PDT
Align Technology, Inc.
881 Martin Avenue
Santa Clara, CA 95050

Safe Harbor Statement
Align's 2003 Annual Report contains forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995 that are based on management's current expectations and assumptions. These forward-looking statements, including the statements in the Letter to Shareholders, the section entitled "Q&A with Tom Prescott, CEO, and Eldon Bullington, CFO," the section entitled "Our Business Model Is Working," the section entitled "We're Creating Opportunities for Orthodontists and Dentists" and the section entitled "Invisalign Applications Continue to Expand" are subject to certain risks and uncertainties that could cause actual results to differ materially from the potential results discussed in the forward-looking statements. Please refer to the information set forth under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations – Risk Factors," in Item Seven and elsewhere in our fiscal 2003 Form 10-K Annual Report, for factors that could impact our future results.

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ALIGN

ALIGN TECHNOLOGY, INC.

ALN-AR-04

Align Technology, Inc. | 881 Martin Ave. | Santa Clara, CA 95050 | 408.470.1000 | www.aligntech.com | www.invisalign.com