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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2004

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

881 Martin Avenue
Santa Clara, California 95050
(Address of principal executive offices) (Zip Code))

(408) 470-1000
(Registrant's telephone number, including area code)

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

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

The number of shares outstanding of the registrant's Common Stock, $0.0001 par value, as of October 31, 2004 was 60,628,658.

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PART I—FINANCIAL INFORMATION

ITEM 1 FINANCIAL STATEMENTS
ALIGN TECHNOLOGY, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands)
(unaudited)

	September 30, 2004	December 31, 2003
ASSETS		
Current assets:		
Cash and cash equivalents	$ 63,215	$ 44,939
Restricted cash	281	439
Marketable securities, short-term	519	2,292
Accounts receivable, net of allowance	27,663	21,265
Inventories	2,150	2,334
Prepaid expenses and other current assets	5,855	5,845
Total current assets	99,683	77,114
Property and equipment, net	23,304	23,121
Other assets	2,197	1,967
Total assets	$ 125,184	$ 102,202
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 3,899	$ 3,095
Accrued liabilities	21,733	19,180
Deferred revenues	13,798	13,113
Debt	1,932	1,989
Total current liabilities	41,362	37,377
Debt, net of current portion	428	1,849
Total liabilities	41,790	39,226
Commitments and contingencies (Note 5)		
Stockholders' equity:		
Preferred stock: $0.0001 par value; Authorized: 5,000 shares; Issued and outstanding: none at September 30, 2004 and December 31, 2003	—	—
Common stock: $0.0001 par value; Authorized: 200,000; Issued: 60,661 and 58,793 at September 30, 2004 and December 31, 2003, respectively; Outstanding: 60,621 and 58,753 shares at September 30, 2004 and December 31, 2003, respectively	6	6
Additional paid-in capital	376,528	368,796
Deferred compensation	(191)	(5,219)
Notes receivable from stockholders	—	(17)
Accumulated other comprehensive income	(4)	2
Accumulated deficit	(292,945)	(300,592)
Total stockholders' equity	83,394	62,976
Total liabilities and stockholders' equity	$ 125,184	$ 102,202

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

ALIGN TECHNOLOGY, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except per share data)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2004	2003	2004	2003
Revenues	$45,766	$34,038	$129,175	$ 86,223
Cost of revenues	14,922	13,446	42,565	38,639
Gross profit	30,844	20,592	86,610	47,584
Operating expenses:				
Sales and marketing	13,884	10,505	40,555	32,551
General and administrative	8,263	8,722	25,196	25,630
Research and development	4,846	3,113	11,750	9,810
Total operating expenses	26,993	22,340	77,501	67,991
Profit (loss) from operations	3,851	(1,748)	9,109	(20,407)
Interest and other income (expense), net	(217)	(359)	(619)	(129)
Net profit (loss) before income tax provision	3,634	(2,107)	8,490	(20,536)
Income tax provision	(316)	(37)	(843)	(38)
Net profit (loss)	$ 3,318	$ (2,144)	$ 7,647	$(20,574)
Net profit (loss) per share, basic	$ 0.06	$ (0.04)	$ 0.13	$ (0.36)
Shares used in computing net profit (loss) per share, basic	60,319	57,948	59,703	57,543
Net profit (loss) per share, diluted	$ 0.05	$ (0.04)	$ 0.12	$ (0.36)
Shares used in computing net profit (loss) per share, diluted	64,055	57,948	64,298	57,543

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

ALIGN TECHNOLOGY, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)
(unaudited)

	Nine Months Ended September 30,	
	2004	**2003**
Cash Flows from Operating Activities:		
Net profit (loss)	$ 7,647	$ (20,574)
Adjustments to reconcile net profit (loss) to net cash provided by operating activities:		
Depreciation and amortization	6,628	6,925
Stock-based compensation expense	5,665	11,990
Loss on retirement and disposal of fixed assets	63	195
Provision for doubtful accounts	266	229
Non-cash interest income on notes receivable from stockholders	—	(43)
Changes in operating assets and liabilities:		
Accounts receivable	(6,664)	(4,257)
Inventories	184	326
Other current assets	(10)	(846)
Accounts payable	663	(157)
Accrued liabilities	2,362	7,207
Deferred revenue	685	3,898
Net cash provided by operating activities	17,489	4,893
Cash Flows from Investing Activities:		
Purchase of property and equipment	(7,399)	(4,496)
Proceeds from sale of property and equipment	851	42
Decrease (increase) in restricted cash	158	(159)
Purchases of marketable securities	(519)	(5,390)
Maturities of marketable securities	2,292	6,069
Other assets	(230)	(14)
Net cash used in investing activities	(4,847)	(3,948)
Cash Flows from Financing Activities:		
Proceeds from issuance of common stock	7,095	1,799
Proceeds from payment on stockholders’ notes receivable	17	591
Repurchase of common stock	—	(6)
Payments on debt obligations	(1,478)	(1,631)
Net cash provided by financing activities	5,634	753
Net increase in cash and cash equivalents	18,276	1,698
Cash and cash equivalents at beginning of period	44,939	35,552
Cash and cash equivalents at end of period	$63,215	$ 37,250

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

ALIGN TECHNOLOGY, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(unaudited)

1. Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared by Align Technology, Inc. (the “Company” or “Align”) in accordance with the rules and regulations of the Securities and Exchange Commission. Certain information and footnote disclosures normally included in consolidated financial statements prepared in accordance with accounting principles generally accepted in the United States of America have been condensed or omitted in accordance with such rules and regulations. In the opinion of management, the accompanying unaudited condensed consolidated financial statements reflect all adjustments, consisting only of normal recurring adjustments, necessary to present fairly the financial position of the Company as of September 30, 2004 and December 31, 2003, and its results of operations and cash flows for the three and nine months ended September 30, 2004 and 2003. These unaudited condensed consolidated financial statements should be read in conjunction with the annual audited consolidated financial statements and notes as of and for the year ended December 31, 2003 included in the Company’s Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 9, 2004.

The results of operations for the three and nine months ended September 30, 2004 are not necessarily indicative of the results that may be expected for the year ending December 31, 2004 or any other interim period, and the Company makes no representations related thereto.

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

Certain prior period amounts have been reclassified to conform with current period presentation.

Certain risks and uncertainties

The Company’s operating results depend on, to a significant extent, 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 Company’s inability 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 commercial paper. 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 September 30, 2004 or at December 31, 2003, or net revenues for the three and nine months ended September 30, 2004 or 2003.

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 were to be denied approval or clearance or such approval were to be 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 a third party manufacturer 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 the manufacturing process, 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.

2. Inventories

Inventories comprise (in thousands):

	September 30, 2004	December 31, 2003
Raw materials	$ 1,077	$ 859
Work in process	811	1,140
Finished goods	262	335
	$ 2,150	$ 2,334

Work in process includes costs to produce the Invisalign product, including deferred costs. Finished goods primarily represent ancillary products that support the Invisalign system.

3. Net Profit (Loss) Per Share

Basic net profit (loss) per share is computed using the weighted average number of shares of common stock during the year less unvested common shares subject to repurchase. Diluted net profit per share is computed using the weighted average number of shares of common stock, adjusted for the dilutive effect of potential common stock. Potential common stock, computed using the treasury stock method, includes options and unvested shares subject to repurchase.

The following table sets forth the computation of basic and diluted net profit (loss) per share attributable to common stock (in thousands, except per share amounts):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2004	2003	2004	2003
Numerator:				
Net profit (loss)	$ 3,318	$ (2,144)	$ 7,647	$ (20,574)
Denominator:				
Weighted-average common shares outstanding	60,348	58,300	59,797	58,001
Less: Unvested common shares subject to repurchase	(29)	(352)	(94)	(458)
Total shares, basic	60,319	57,948	59,703	57,543
Effect of dilutive securities:				
Add: Dilutive common stock equivalents	3,707	—	4,501	—
Unvested shares subject to repurchase	29	—	94	—
Total shares, diluted	64,055	57,948	64,298	57,543
Basic net profit (loss) per share	$ 0.06	$ (0.04)	$ 0.13	$ (0.36)
Diluted net profit (loss) per share	$ 0.05	$ (0.04)	$ 0.12	$ (0.36)

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2004	2003	2004	2003
Options to purchase common stock	2,310	5,980	1,150	5,042
Common stock subject to repurchase	—	352	—	458
	2,310	6,332	1,150	5,500

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4. Stock-based Compensation

The Company accounts for stock-based employee compensation using the intrinsic value method under Accounting Principles Board Opinion No. 25, “Accounting for Stock Issued to Employees” (“APB 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 (“SFAS 148”). The following table illustrates the effect on net profit (loss) and net profit (loss) per common share if the Company had applied the fair value recognition provisions of SFAS 123 to stock-based employee compensation (in thousands, except per share data):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2004	2003	2004	2003
Net profit (loss), as reported	$ 3,318	$ (2,144)	$ 7,647	$ (20,574)
Add: Stock-based employee compensation expense included in reported net profit (loss), net of related tax effects	1,754	3,051	5,383	10,736
Deduct: Total stock-based employee compensation determined under fair value based method for all awards, net of related tax effects	(4,271)	(6,967)	(14,173)	(18,981)
Pro forma net profit (loss)	$ 801	$ (6,060)	$ (1,143)	$ (28,819)
Basic net profit (loss) per common share:				
As reported	$ 0.06	$ (0.04)	$ 0.13	$ (0.36)
Pro forma	$ 0.01	$ (0.10)	$ (0.02)	$ (0.50)
Diluted net profit (loss) per common share:				
As reported	$ 0.05	$ (0.04)	$ 0.12	$ (0.36)
Pro forma	$ 0.01	$ (0.10)	$ (0.02)	$ (0.50)

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 fair value of each option grant is estimated on the date of grant using the Black-Scholes option pricing model. The following are the weighted average assumptions:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2004	2003	2004	2003
Risk free interest rate	4.32%	2.72%	3.36%	2.93%
Expected life	5 years	5 years	5 years	5 years
Expected volatility	51%	110%	56%	112%

5. Commitments and Contingencies

Short-term and Long-term Obligations

As of September 30, 2004, future minimum payments under lease obligations and financing agreements are as follows (in thousands):

	2004	2005	2006	2007	2008	Thereafter	Total
Operating leases	$1,032	$2,676	$1,209	$961	$811	$ —	$6,689
Capital lease obligations	89	187	—	—	—	—	276
Equipment-based term loan	417	1,667	—	—	—	—	2,084
Total	$1,538	$4,530	$1,209	$961	$811	$ —	$9,049

Product Warranty

The Company generally warrants its products for a specific period of time against material defects in materials and workmanship. The Company provides for the estimated future costs of warranty obligations in costs of goods sold when the related product is shipped. Accrued estimated warranty costs are primarily based on historical experience as to product failures as well as current information on replacement costs. Management periodically 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, and is contingent upon proper use of the Aligners. The Invisalign product warranty is in force until the case is completed. In the event the Aligners fall within the scope of the Invisalign product warranty, the Company will replace the Aligners at its expense. 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 nine months ended September 30, 2004 (in thousands):

Warranty accrual, December 31, 2003	$ 862
Charged to cost and expenses	1,996
Actual warranty expenses	(1,480)
Warranty accrual, September 30, 2004	$ 1,378

Contingencies

In October 2003, the Company entered into a Loan Agreement with General Orthodontics, LLC ("GO"), whereby the Company agrees to make loan advances to GO of amounts not to exceed an aggregate principle balance of $200,000. The commitment by the Company to make advances to GO shall expire upon GO 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. No advances were made by the Company to GO as of September 30, 2004.

Legal Proceedings

On January 6, 2003, Ormco Corporation ("Ormco") filed suit against the Company 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, the Company answered the complaint and asserted counterclaims seeking a declaration by the Court of invalidity and non-infringement of the asserted patents. In addition, the Company counterclaimed for infringement of U.S. Patent No. 6,398,548, seeking unspecified monetary damages and injunctive relief. Ormco filed a reply to the Company's counterclaims on March 10, 2003 and asserted counterclaims against the Company seeking a declaration by the Court of invalidity and non-infringement of U.S. Patent No. 6,398,548. The Company responded to Ormco's counterclaims on April 2, 2003. The Company amended its counterclaim to add Allesee Orthodontic Appliances, Inc. ("AOA"), a wholly-owned subsidiary of Ormco, as a counterdefendant in regard to the Company's counterclaim of infringement of U.S. Patent No. 6,398,548. The Court then permitted Ormco to amend its Complaint and permitted the Company to amend its 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, the Company 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.

In connection with these claims, the Court granted three motions for summary judgment that we filed. First, on May 14, 2004, the Court granted the Company's motion for summary judgment of non-infringement, finding that the Company's Invisalign system does not infringe any of the asserted Ormco patents (5,477,432, 5,683,243, 6,244,861 and 6,616,644). Second, on July 2, 2004, the Court granted in part the Company's motion for summary judgment of infringement, finding that Ormco and AOA infringe certain, but not all, claims of the Company's patents Nos. 6,398,548 and 6,554,611 through the manufacture and sale of Red, White & Blue appliances. Third, on August 26, 2004, the Court granted the Company's motion for summary judgment of invalidity of Ormco's asserted patents claims (5,477,432, 5,683,243, 6,244,861 and 6,616,644). As noted above, the Court earlier found that the Company does not infringe these patents. In addition, the Court also denied Ormco's motion for summary judgment seeking a finding of invalidity of the Company's asserted patent claims (6,398,548 and 6,554,611).

The Court initially scheduled trial for October 29, 2004. At a pretrial conference held on September 10, 2004, however, the Court decided to allow the parties to file further dispositive motions. Subsequently, the Court took the trial date off calendar to permit briefing of these motions. The Company then filed a motion for summary judgment that its asserted patent claims are not invalid. The Company also filed a motion for summary judgment that its patents are not unenforceable based on Ormco's allegations of inequitable conduct. Ormco filed a motion for summary judgment that it did not willfully infringe the Company's patents. Ormco also moved to dismiss the case for alleged lack of subject matter jurisdiction. Ormco's motion to dismiss has been denied. Each of the remaining motions, as well as various other motions filed by the parties, was heard by the Court on October 29, 2004. The Company expects the trial to be scheduled after the Court rules on such motions.

From time to time, the Company has received and may in the future receive letters from third parties drawing its attention to their patent rights. While the Company does not believe that it infringes upon any valid and enforceable rights that have been brought to its attention, there may be other more pertinent rights of which the Company is presently unaware. The defense and prosecution of intellectual property suits, interference proceedings and related legal and administrative proceedings could result in substantial expense to the Company and significant diversion of effort by its technical and management personnel. In the event the court's decision in the Ormco litigation discussed above is overturned on appeal, or if the Company is subject to an adverse determination in a patent suit by Ormco or in any other litigation or interference proceeding to which the Company may become a party, the Company could be subject to significant liabilities. An adverse determination of this nature could also put the Company's patents at risk of being invalidated or interpreted narrowly or require the Company to seek licenses from third parties. Licenses may not be available on commercially reasonable terms or at all, in which event, the Company's business would be materially adversely affected.

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.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

In addition to historical information, this Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. These statements include, among other things, statements concerning our expectations regarding the anticipated benefit of increased collaboration between orthodontists and general practitioner dentists on our revenue growth, our expectation that the percentage of revenue generated by general practitioner dentists may, in the future, represent a larger percentage of our revenue than revenue generated by orthodontists, our expectations regarding further expansion into North American and international markets, the number of new doctors we anticipate certifying in 2004, our anticipated revenue growth for fiscal 2004, our expectation that sales and marketing expense as well as our research and development spending will increase as well as other statements regarding our future operations, financial condition and prospects and business strategies. These statements may contain words such as "expects," "anticipates," "intends," "plans," "believes," "estimates," or other words indicating future results. These forward-looking statements are subject to certain risks and uncertainties that could cause actual results to differ materially from those reflected in the forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the following discussion, and in particular, the risks discussed below under the subheading "Risk Factors" and in other documents we file with the Securities and Exchange Commission. 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 our condensed consolidated financial statements and related notes included elsewhere in this Quarterly Report on Form 10-Q.

Overview

Align Technology, founded in March 1997, designs, manufactures and markets Invisalign, a proprietary method for treating malocclusion, or the misalignment of teeth. Invisalign corrects malocclusion using a series of clear, nearly invisible, removable appliances that gently move teeth to a desired final position. Because it does not rely on the use of metal or ceramic brackets and wires, Invisalign significantly reduces the aesthetic and other limitations associated with braces. Invisalign is appropriate for treating adults and teens with mature dentition. Align Technology received FDA clearance to market Invisalign in 1998.

The Invisalign product is manufactured in phases. The initial step in our manufacturing process is the creation of electronic treatment plans using ClinCheck™, an internally developed computer-modeling program. These treatment plans are developed in our operations facility in Costa Rica and are transmitted electronically back to the U.S. ClinCheck™ allows dental professionals to simulate treatment in three dimensions by modeling two-week stages of tooth movement. The electronic files which form the basis for ClinCheck™, are used in conjunction with stereolithography technology to manufacture Aligner molds. These molds are then used by a third party manufacturer in Mexico to fabricate Aligners. 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™. After the Aligners are produced, the third party manufacturer ships the finished products to our customers.

Align has two customer channels: the orthodontist and the general practitioner, or GP dentist. We have historically generated a majority of our revenues from orthodontists, and we expect to continue to do so for the foreseeable future. There exists, however, a significantly greater number of GPs in North America than orthodontists. As the primary care dental provider, GPs have access to a greater number of patients than orthodontists, and possess a unique opportunity to educate these patients and introduce them to Invisalign. GPs also have the ability to refer appropriate cases to orthodontists and, in certain instances, may choose to treat less complex cases themselves. We are committed to improving the collaboration and referral relationships between orthodontists and GPs. We believe that improved collaboration is beneficial to the orthodontist and the GP and will accelerate growth in Invisalign cases and consequently increase our revenues. In addition, although we expect that orthodontists will continue to treat the majority of complex cases and continue to drive research for expanding Invisalign applications, we expect that the percentage of revenue generated by GPs will increase, largely due to the fact that there are significantly more GPs than orthodontists, and may, in the future, represent a larger percentage of our revenue than revenue generated by orthodontists. We believe this expected increase in the number of cases treated by GPs will result in an increase in the overall market for Invisalign as patients that would not have otherwise sought orthodontic treatment are introduced to Invisalign by GPs.

Our domestic orthodontist and GP dentist customers represented over 90% of our total product revenue during fiscal 2004. We expect to continue to increase our market penetration into the North American market. We will also focus our efforts towards the expansion of our international markets. We currently have patients in treatment in over 30 countries. For the remainder of fiscal 2004, we expect to increase our infrastructure and support in key countries in Europe and initiate strategic moves in Asia, more specifically in Japan, in order to take advantage of this emerging opportunity.

Clinical education and ongoing training are critical to our customers' success with Invisalign. We certify several thousand new doctors to use Invisalign annually, and we expect to certify approximately 4,000 newly trained doctors during fiscal 2004. Additionally, we share product enhancements, treatment tips and techniques, and clinical research data with our customers on an ongoing basis through continuing education in the form of hundreds of provider workshops, study clubs and third-party online educational centers. This information ensures that our customers understand Invisalign's expanding applications and best uses, and that they feel confident about treating more of their patients with Invisalign.

Net revenue for the third quarter of fiscal 2004 was $45.8 million, an increase of 35% as compared to $34.0 million for the third quarter of fiscal 2003. The increase was driven primarily from increases in the number of cases submitted for both the domestic orthodontic and general practitioner channels. Net profit was $3.3 million, or $0.06 net profit per share, basic and $0.05 net profit per share, diluted, compared to a net loss of $2.1 million, or $0.04 net loss per share, basic and diluted, for the third quarter of fiscal 2003.

Results of Operations

Revenues. Invisalign product revenues by channel and other revenue, which represented training and sales of ancillary products, for the three and nine-months periods ended September 30, 2004 and 2003 are as follows:

	Three Months Ended				Nine Months Ended			
(Amounts in $ million)	September 30, 2004	September 30, 2003	Increase*	Percentage Increase	September 30, 2004	September 30, 2003	Increase*	Percentage Increase
Domestic:								
Orthodontic	$ 22.2	$ 19.6	$ 2.6	13%	$ 66.4	$ 51.6	$ 14.8	29%
GP	$ 17.4	$ 9.4	$ 8.0	85%	$ 45.0	$ 20.8	$ 24.2	116%
International	$ 4.1	$ 3.0	$ 1.1	37%	$ 11.8	$ 8.5	$ 3.3	39%
Total Product	$ 43.7	$ 32.0	$ 11.7	37%	$ 123.2	$ 80.9	$ 42.3	52%
Other revenue	$ 2.1	$ 2.0	$ 0.1	5%	$ 6.0	$ 5.3	$ 0.7	13%
Total Revenue	$ 45.8	$ 34.0	$ 11.8	35%	$ 129.2	$ 86.2	$ 43.0	50%

* **Primary reasons for increase**: For the quarter and nine-months ended September 30, 2004, growth in the domestic orthodontic and general practitioner channels over the same periods in fiscal 2003 resulted primarily from higher case volumes driven by an increase in the number of participating clinicians and utilization within their practices. Higher product sales during the three and nine-month periods ended September 30, 2004 as compared to the same periods in fiscal 2003 also benefited from increased promotional advertising campaigns and sales initiatives in effect during fiscal 2004.

Cost of revenues. Cost of revenues for the quarter ended September 30, 2004 was $14.9 million compared to $13.4 million for the quarter ended September 30, 2003. Cost of revenues for the nine-month period ended September 30, 2004 was $42.6 million compared to $38.6 million for the nine-month period ended September 30, 2003. 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, training costs and the cost of facilities. Also included in cost of revenues are stock-based compensation expenses of $0.1 million and $0.6 million for the third quarters of fiscal 2004 and 2003, respectively, and stock-based compensation expenses of $0.9 million and $2.0 million for the nine-month periods ended September 30, 2004 and 2003, respectively. Gross profit for the quarter ended September 30, 2004 was $30.8 million or 67% of revenue, compared to a gross profit of $20.6 million or 61% of revenue for the quarter ended September 30, 2003. Gross profit for the nine-month period ended September 30, 2004 was $86.6 million or 67% of revenue, compared to a gross profit of $47.6 million or 55% of revenue for the nine-month period ended September 30, 2003. The higher gross profit in the third quarter and nine-month period ended September 30, 2004 as compared to the quarter and nine-month period ended September 30, 2003 is primarily attributable to improved fixed cost absorption related to increasing case volumes and continued manufacturing process efficiencies.

Sales and marketing. Sales and marketing expenses for the quarter ended September 30, 2004 were $13.9 million compared to $10.5 million for the quarter ended September 30, 2003. Sales and marketing expenses for the nine-month period ended September 30, 2004 were $40.6 million compared to $32.6 million for the nine-month period ended September 30, 2003. Sales and marketing expenses include sales force compensation (combined with travel related costs and expenses for professional marketing programs), conducting workshops and market surveys, advertising and dental professional trade show attendance. Sales and marketing expenses include stock-based compensation expenses of $0.1 million and $0.5 million in the third quarters of fiscal 2004 and 2003, respectively, and stock-based compensation expenses of $0.6 million and $1.8 million for the nine-month periods ended September

30, 2004 and 2003, respectively. The increase in sales and marketing expense of $3.4 million for the third quarter of fiscal 2004 as compared to the third quarter of fiscal 2003 resulted primarily from an increase in spending of $1.6 million related to incremental headcount in our North American sales and marketing work force, $0.8 million related to our international sales and marketing workforce and consulting services, and $1.4 million related to increases in media, advertising costs and marketing promotions. The increase in spending was partially offset by the decrease of $0.4 million in stock-based compensation expense. The increase in sales and marketing expense of $8.0 million for the nine-month period ended September 30, 2004 as compared to the nine-month period ended September 30, 2003 resulted primarily from an increase in spending of $3.4 million related to incremental headcount in our North American sales and marketing work force, $0.8 million related to North America sales force training, $2.6 million related to our international workforce and consulting services, and $2.3 million related to increases in media, advertising costs and marketing promotions. The increase in spending was partially offset by the decrease of $1.1 million in stock-based compensation expense. The increases during fiscal 2004 have been consistent with our marketing and sales initiatives and we expect these initiatives to continue in the remainder of fiscal 2004. Accordingly, we expect sales and marketing expense to increase during the fourth quarter of fiscal 2004 as we continue to invest in sales force staffing, clinical education, direct-to-consumer advertising and related consumer programs.

General and administrative. General and administrative expenses for the quarter ended September 30, 2004 were $8.3 million compared to $8.7 million for the quarter ended September 30, 2003. General and administrative expenses for the nine-month period ended September 30, 2004 were $25.2 million compared to $25.6 million for the nine-month period ended September 30, 2003. General and administrative expenses included salaries for administrative personnel, outside consulting services, legal expenses and general corporate expenses. General and administrative expenses include stock-based compensation expenses of $0.5 million and $1.6 million for the third quarters of fiscal 2004 and 2003, respectively, and stock-based compensation expenses of $2.6 million and $5.7 million for the nine-month periods ended September 30, 2004 and 2003, respectively. The decrease in general and administrative expense of $0.4 million for the quarter ended September 30, 2004 as compared to the quarter ended September 30, 2003 was primarily due to decreases in stock-based compensation expense of $1.1 million and general corporate expenses of $0.5 million. Partially offsetting the decreases were $1.2 million in incremental payroll expenses from additional headcount expense for the third quarter of fiscal 2004 as compared the third quarter of fiscal 2003. The $0.4 million decrease in general and administrative expenses for the nine-month period ended September 30, 2004 as compared to the nine-month period ended September 30, 2003 was primarily due to the decrease in stock-based compensation expense of $3.1 million and the sales tax charge of $1.4 million incurred during the second quarter of fiscal 2003. The decreased expenses in the nine-month period ended September 30, 2004 as compared to the nine-month period ended September 30, 2003 was partially offset by increases of $2.8 million in payroll expenses and $1.3 million in general corporate expenses.

Research and development. Research and development expenses for the quarter ended September 30, 2004 were $4.8 million and $3.1 million for the quarter ended September 30, 2003. Research and development expenses for the nine-month period ended September 30, 2004 were $11.8 million and $9.8 million for the nine-month period ended September 30, 2003. Research and development expenses include 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 $0.9 million and $0.6 million of stock-based compensation for the third quarters of fiscal 2004 and 2003, receptively, and $1.6 million and $2.5 million of stock-based compensation for the nine-month periods ended September 30, 2004 and 2003, respectively. The increase in research and development expense of $1.7 million for the quarter ended September 30, 2004 as compared to the quarter ended September 30, 2003 resulted primarily from a $1.1 million severance charge related to the departure of Align's vice president of engineering and increased spending of $0.6 million for product improvement initiatives. For the nine-month period ended September 30, 2004 as compared to September 30, 2003, the increase of $2.0 million resulted from the $1.1 million severance charge and increased spending of $1.8 million for product improvement initiatives, partially offset by a $0.9 million decrease in stock-based compensation expense. For the remainder of fiscal 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 expense was ($0.2) million for the quarter ended September 30, 2004 as compared to ($0.4) million for the quarter ended September 30, 2003. Interest and other expense was ($0.6) million for the nine-month period ended September 30, 2004 as compared to ($0.1) million for the nine-month period ended September 30, 2003. Interest and other income (expense), net, includes interest income earned on cash balances, interest expense on debt, foreign currency translation gains and losses for the dollar against other currencies related to international businesses and other miscellaneous charges. For the quarter ended September 30, 2004 as compared to the quarter ended September 30, 2003, other expenses increased by $0.2 million for the quarter ended September 30, 2004 as compared to the quarter ended September 30, 2003. For the nine-month period ended September 30, 2004 as compared to the nine-month period ended September 30, 2003, other expenses decreased by $0.2 million, and foreign currency translation loss was reduced by $0.3 million for the nine-month period ended September 30, 2004 compared to the nine-month period ended September 30, 2003.

Income tax provision. Income tax provision was $0.3 million and $0.8 million for the quarter and nine-month periods ended September 30, 2004, respectively, and was as a result of taxable income during fiscal 2004. Income tax provision for the quarter and nine-month periods ended September 30, 2003 was $38,000 primarily related to the net loss during fiscal 2003. We expect tax expense for fiscal year 2004 to be at an effective tax rate of approximately 10%.

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 remeasure 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 quarters ended September 30, 2004 and 2003, we recorded amortization of deferred compensation of $1.0 million and $3.1 million, respectively. For the nine-month periods ended September 30, 2004 and 2003, we recorded amortization of deferred compensation of $4.7 million and $10.2 million, respectively.

We recorded expenses of $0.1 million and $0.3 million for the quarters ended September 30, 2004 and 2003, respectively, related to options granted to non-employees after 2001. We recorded expenses of $0.4 million and $0.9 million for the nine-month periods ended September 30, 2004 and 2003, respectively, related to options granted to non-employees after 2001.

Historically, 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 condensed consolidated statements of operations. We recorded $0.7 million for the quarter and nine-months ended September 30, 2004 related to the departure of Align's vice president of engineering. We recorded no such charge for the quarter ended September 30, 2003 and $0.8 million for the nine-months ended September 30, 2003 related to severance packages for several employees. This charge is equal to the intrinsic value of the options which was calculated as the difference between the exercise price of the accelerated options and the fair value of the common stock on the date of acceleration.

Liquidity and Capital Resources

We have funded our operations with the proceeds from the sale of our common and preferred stock, an equipment-based term loan, bridge loans and cash provided from operations. We have incurred operating losses from inception through the third quarter of 2003.

As of September 30, 2004, we had $63.2 million of cash and cash equivalents, $0.3 million of restricted cash and $0.5 million of marketable securities. We had an accumulated deficit of $292.9 million as of September 30, 2004.

Net cash provided by operating activities totaled $17.5 million and $4.9 million for the nine-month periods ended September 30, 2004 and 2003, respectively. Net cash provided by operating activities for the nine-month period ended September 30, 2004 resulted primarily from operating profit and increases in current liabilities. For the nine-month period ended September 30, 2003, net cash provided by operating activities resulted primarily from increases in accrued liabilities and deferred revenue, partially offset by operating losses.

Net cash used in investing activities totaled $4.8 million for the nine-month period ended September 30, 2004 and $3.9 million for the nine-month period ended September 30, 2003. For the nine-month period ended September 30, 2004, net cash used in investing activities resulted primarily from the purchase of property and equipment for capacity expansion and manufacturing improvements, partially offset by proceeds from the sale of equipment and maturities of marketable securities. For the nine-month period ended September 30, 2003, net cash used in investing activities resulted primarily from the purchase of property and equipment for capacity expansion and manufacturing improvements and purchases of marketable securities, partially offset by maturities of marketable securities.

Net cash provided by financing activities was $5.6 million and $0.8 million for the nine-month periods ended September 30, 2004 and 2003, respectively. For the nine-month period ended September 30, 2004, net cash provided by financing activities consisted of proceeds from the issuance of common stock, primarily from exercises of employee stock options, partially offset by payments on debt obligations related to the equipment-based term loan and capital lease obligations. For the nine-month periods ended September 30, 2003, net cash provided by financing activities consisted of proceeds from the issuance of common stock, primarily from exercises of employee stock options, and proceeds from payment on stockholders' notes receivable, partially offset by payments on debt obligations related to the equipment-based term loan and capital lease obligations.

Contractual Obligations. There have been no material changes to our contractual obligations outside the ordinary course of business from those disclosed in our annual report on Form 10-K for the fiscal year ended December 31, 2003.

In December 2003, we increased our accounts receivable-based revolving line of credit from $10.0 million to $15.0 million, and negotiated more favorable terms. Accessing the revolving line of credit is restricted based on qualifying accounts receivable and compliance with certain loan covenants. As of September 30, 2004, we had not utilized the revolving line of credit. In December 2002, we secured an equipment-based term loan of $5.0 million, which was fully drawn down in December 2002. As of September 30, 2004, the equipment-based term loan had an outstanding balance of $2.1 million.

We expect that the increase in our operating expenses will be 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 condensed 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 condensed 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; shipments have occurred; 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 involve 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 certain instances, adjustments to a patient's teeth are made in the final stages of orthodontic treatment. To make these final adjustments and move a patient's teeth to the final desired position, dental professionals may elect to use Invisalign as a finishing treatment tool and order newly manufactured Aligners. These newly manufactured Aligners, or "case refinement", are not provided with the Aligners produced as part of the initial treatment plan and are manufactured only upon the request of the dental professional if final adjustments are desired.

From June 2001 through April 2003, we offered our dental professionals the opportunity, at the time of the creation of the initial treatment plan, to purchase at a discount a one-time, non-refundable case refinement. 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, if case refinement is never requested, the point in time when the case is deemed completed, or "case expiration". In cases where the dental professional did not purchase case refinement in advance, case refinement revenues, if any, are recognized when the new Aligners are shipped.

We updated our domestic and international pricing policies in May 2003 and January 2004, respectively, 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 and at a comparable price internationally, 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 and a comparable price internationally after January 2004. 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 shipped or upon case expiration, whichever 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

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 Company generally warrants its products for a specific period of time against material defects. We accrue for estimated warranty costs upon shipment of products. 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 represent 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. Actual warranty costs could differ from the estimate amounts. The Company regularly reviews the accrued balances and updates the historical warranty cost trends. Actual warranty costs incurred have not materially differed from those accrued. If we were to experience higher rates of warranty events, we would be required to accrue additional warranty costs, which would negatively affect our 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 condensed 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

Pursuant to the guidance provided in the Statement of Financial Accounting Standards No. 109, Accounting for Income Taxes (SFAS No. 109), we anticipate that we will again provide a full valuation allowance against our net deferred income tax assets at the end of 2004. This conclusion is based upon the belief that it is more likely than not that these assets will not be realized.

The principal business condition necessary to realize the benefits of these assets is the generation of significant future profits. Although we anticipate that profits will result from our future operations, historical data is insufficient develop the trend data that is necessary to reasonably predict future profits.

RISK FACTORS

We have only recently experienced significant revenue growth and achieved profitability. If we fail to sustain or increase profitability or revenue growth in future periods, the market price of our common stock may decline.

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 incurred significant operating losses and we have only achieved profitability since 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 noted above, we have only recently achieved profitability, as a result, to sustain or increase profitability in future periods, we will need to continue to increase our revenue, while controlling our expenses. We generated positive operating cash flow for the first time during fiscal year 2003, 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. In addition, we have recently experienced significant revenue growth. Because our business is evolving it is difficult to predict our future operating results or levels of growth and we may not be able to sustain such growth levels in future periods. If we do not sustain or increase profitability or revenue growth or otherwise meet the expectations of securities analysts or investors, the market price of our common stock will likely decline.

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 it difficult to evaluate our future prospects and your investment in our stock. 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.

Our information technology systems are critical to our business. System integration and implementation issues and system security risks could disrupt our operations, which could have a material adverse impact on our operations, sales and operating results.

We rely on the efficient and uninterrupted operation of complex information technology systems. All information technology systems are vulnerable to damage or interruption from a variety of sources. For instance, as our business has grown in size and complexity, the growth has placed, and will continue to place, significant demands on our information technology systems. To effectively manage this growth, we will need to continually upgrade and enhance our information systems to more effectively manage our operations.

In October 2004, we implemented a new version of our enterprise resource planning system and new software for our manufacturing execution system. During the remainder of fiscal 2004 and throughout 2005 we will integrate additional functionality into our manufacturing execution system, which will more efficiently integrate this system with our other system applications, such as customer facing and manufacturing tools. System upgrades and enhancements require significant capital expenditures and allocation of valuable employee resources. Delays in integration or disruptions to our business from implementation of these new or upgraded systems could have a material adverse impact on our financial condition and operating results.

In addition, experienced computer programmers and hackers may be able to penetrate our network security and misappropriate our confidential information or that of third parties, create system disruptions or cause shutdowns. Furthermore, sophisticated hardware and operating system software and applications that we either internally produce or procure from third parties may contain defects in design and manufacture, including “bugs” and other problems that can unexpectedly interfere with the operation of the system. The costs to eliminate or alleviate security problems, viruses and bugs could be significant, and the efforts to address these problems could result in interruptions that may have a material adverse impact on our operations, sales and operating results.

If we fail to maintain the adequacy of our internal controls, our ability to provide accurate financial reports could be impaired, and any failure to maintain our internal controls and provide accurate financial reports would cause our market price to decrease substantially.

Effective internal controls are necessary for us to provide reliable financial reports and help prevent fraud. We are continuously evaluating and working to improve our internal controls. Our evaluation may conclude that enhancements, modifications or changes to our internal controls are necessary to satisfy the requirements of the Sarbanes-Oxley Act of 2002. We cannot be certain that the measures we implement will ensure that we maintain adequate controls over our financial processes and reporting in the future. Any failure to implement required new or improved controls, or difficulties encountered in their implementation, could harm our operating results or cause us to fail to meet our financial reporting obligations. Any failure to maintain the adequacy of our internal controls and provide accurate financial reports could subject us to costly litigation, could make it difficult to attract and retain quality management personnel and could have a negative effect on the market price of our stock.

We have limited product offerings, and if demand for Invisalign declines or fails to develop as we expect or if dental professionals or consumers do not adopt Invisalign in sufficient numbers or as rapidly as we anticipate, or if orthodontists and GP dentists do not collaborate 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 by both dental professionals and consumers is critical to our future success. 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, or if orthodontists and GP dentists do not collaborate as we expect, our operating results could be harmed. Factors that could cause Invisalign not achieve market acceptance at the rate at which we expect, or at all are described more fully below.

- *Dental professionals may not adopt Invisalign in sufficient numbers or as rapidly as we anticipate.*

  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.

- *Consumers may not adopt Invisalign in sufficient numbers or as rapidly as we anticipate.*

  Our success depends upon the acceptance of Invisalign by a substantially larger number of dental professionals as well as potential patients to whom we are now actively marketing. 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. 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.

- *The orthodontist and GP dentist may choose not to collaborate and referrals between orthodontists and GPs may not increase at the rate that we anticipate or at all.*

  Our success depends in part upon improving the collaboration and referral relationships between orthodontists and GP dentists. Although orthodontists have historically generated a majority of our revenues, there exists a significantly greater number of general practitioners in North America than orthodontists. As the primary care dental provider, GPs have access to a greater number of patients than orthodontists, possess a unique opportunity to educate these patients and introduce them to Invisalign, have the ability to refer appropriate cases to orthodontists and, in certain instances, may chose to treat less complex cases themselves. We are committed to improving the collaboration and referral relationships between orthodontists and GPs. We believe that improved collaboration is beneficial to the orthodontist and the GP and will accelerate growth in Invisalign cases and consequently increase our revenues. If, however, this improved collaboration and increase in referrals does not occur or occurs more slowly than we anticipate, our operating results could 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 September 30, 2004, we had 56 issued U.S. patents, 82 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 third party's patents in the past and, while these actions have been dismissed, we may be the subject of patent or other litigation in the future.

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 of any 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.

See Part II Item 1 of this Form 10-Q for a summary of our material pending legal proceedings.

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, there is no assurance that the court's decision in the Ormco litigation will not be overturned on appeal. In addition, 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.

See Part II Item 1 of this Form 10-Q for a summary of our material pending legal proceedings.

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. Any difficulties encountered by the third party manufacturer with respect to hiring personnel, 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 932 employees as of September 30, 2004. 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.

Complying with regulations enforced by the Food and Drug Administration (FDA) and other regulatory authorities 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.

Our failure to comply with applicable regulatory requirements could result in enforcement action by the FDA or state agencies, which may include any of the following sanctions:

- Warning letters, fines, injunctions, consent decrees and civil penalties;
- Repair, replacement, refunds, recall or seizure of our products;
- Operating restrictions or partial suspension or total shutdown of production;
- Refusing our requests for 510(k) clearance or premarket approval of new products, new intended uses, or modifications to existing products;
- Withdrawing clearance or premarket approvals that have already been granted; and
- Criminal prosecution.

If any of these events were to occur, they could harm our business.

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. We have not yet been subject to an FDA inspection, and we cannot assure you we will successfully pass such an inspection in the future. Our failure to take satisfactory corrective action in response to an adverse inspection or our failure to comply with applicable manufacturing regulations could result in enforcement action, and 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., or market a new use of or claim for an existing product we must obtain FDA clearance or approval, unless an exemption applies. Obtaining regulatory clearances or approvals can be a lengthy and time-consuming process. Even though the devices we market have obtained the necessary clearances from the FDA, we may be unable to maintain such clearances in the future. Furthermore, we may be unable to obtain the necessary clearances for new devices that we intend to 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, and 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 regarding the security of healthcare information, 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 healthcare regulations 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 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.

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), including regulations affecting the security and privacy of patient healthcare information held by healthcare providers and the business associates may require us to make significant and 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 and newly enacted regulations 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.

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. In addition, 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., if we fail to receive these approvals, we may be unable to market our products or enhancements in international markets in a timely manner, if at all.

Our business exposes us to 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 and during fiscal 2004, the market price for our common stock was volatile.

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;
- 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.

If we account for employee stock options using the fair value method, it could significantly reduce our net profit.

There has been ongoing public debate whether stock options granted to employees should be treated as a compensation expense and, if so, how to properly value such charges. On March 31, 2004, the Financial Accounting Standard Board (FASB) issued an Exposure Draft, Share-Based Payment: an amendment of FASB statements No. 123 and 95, which would require a company to recognize, as an expense, the fair value of stock options and other stock-based compensation to employees beginning in 2005 and subsequent reporting periods. If we elect or are required to record an expense for our stock-based compensation plans using the fair value method as described in the Exposure Draft, we could have significant and ongoing accounting charges, which could significantly reduce our net profit.

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

The interests of our management could conflict with those of our other stockholders. As of September 30, 2004, our executive officers, directors and principal stockholders beneficially owned an aggregate of approximately 29% 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.

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.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Quantitative Disclosures

For quantitative and qualitative disclosures about market risk affecting us, see Item 7A, "Quantitative and Qualitative Disclosures About Market Risk," of our Annual Report on Form 10-K for the fiscal year ended December 31, 2003, which is incorporated herein by reference. Our exposure to market risk has not changed materially since December 31, 2003.

ITEM 4. CONTROLS AND PROCEDURES

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

Our management evaluated, under the supervision and with the participation of our Chief Executive Officer and our Chief Financial Officer, the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of the end of the period covered by this Quarterly Report on Form 10-Q. Based upon that evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that our disclosure controls and procedures are effective as of September 30, 2004 to provide reasonable assurance that 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 over financial reporting.*

There was no change in our internal controls over financial reporting that occurred during the period covered by this Quarterly Report on Form 10-Q that has materially affected, or is reasonably likely to materially affect, our internal controls over financial reporting.

Since 2003 we have invested significant resources to comprehensively document and evaluate our system of internal controls. In the course of this ongoing evaluation, we have identified areas of our internal controls requiring improvement and we are in the process of designing processes and controls to enhance our controls in these areas. We plan to continue this initiative as we prepare for our first management report on internal control over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act of 2002 on December 31, 2004. As a result of this process, we expect to continue to make changes to our internal controls over financial reporting.

PART II—OTHER INFORMATION

ITEM 1. 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.

In connection with these claims, the Court granted three motions for summary judgment that we filed. First, on May 14, 2004, the Court granted our motion for summary judgment of non-infringement, finding that our Invisalign system does not infringe any of the asserted Ormco patents (5,477,432, 5,683,243, 6,244,861 and 6,616,644). Second, on July 2, 2004, the Court granted in part our motion for summary judgment of infringement, finding that Ormco and AOA infringe certain, but not all, claims of our patents Nos. 6,398,548 and 6,554,611 through the manufacture and sale of Red, White & Blue appliances. Third, on August 26, 2004, the Court granted our motion for summary judgment of invalidity of Ormco’s asserted patents claims (5,477,432, 5,683,243, 6,244,861 and 6,616,644). As noted above, the Court earlier found that Align does not infringe these patents. In addition, the Court also denied Ormco’s motion for summary judgment seeking a finding of invalidity of our asserted patent claims (6,398,548 and 6,554,611).

The Court initially scheduled trial for October 29, 2004. At a pretrial conference held on September 10, 2004, however, the Court decided to allow the parties to file further dispositive motions. Subsequently, the Court took the trial date off the calendar to permit briefing of these motions. We then filed a motion for summary judgment that our asserted patent claims are not invalid. We also filed a motion for summary judgment that our patents are not unenforceable based on Ormco’s allegations of inequitable conduct. Ormco filed a motion for summary judgment that it did not willfully infringe our patents. Ormco also moved to dismiss the case for alleged lack of subject matter jurisdiction. Ormco’s motion to dismiss has been denied. Each of the remaining motions, as well as various other motions filed by the parties, was heard by the Court on October 29, 2004. We expect the trial to be scheduled after the Court rules on such motions.

From time to time, we have received and may in the future receive letters from third parties drawing its 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. In the event the court’s decision in the Ormco litigation discussed above is overturned on appeal, or if we are subject to an adverse determination in a patent suit by Ormco or in any other litigation or interference proceeding to which we may become a party, we could be subject to significant liabilities. An adverse determination of this nature could also put our patents at risk of being invalidated or interpreted narrowly or require us to seek licenses from third parties. Licenses may not be available on commercially reasonable terms or at all, in which event, our business would be materially adversely affected.

We are 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 our financial condition, results of operations or cash flows.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

Not applicable.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

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

Not applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

(a) Exhibits:

Exhibit Number	Description
10.13.1†	Form of option agreement under Align's 2001 Stock Incentive Plan
10.44†	Employment Agreement between Robert D. Mitchell and Align dated July 12, 2004
10.45†	Employment Agreement between Cecilia Claudio and Align dated September 13, 2004
10.46†	Severance Agreement between Jon Fjeld and Align dated July 14, 2004
31.1	Certifications pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	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.

† Management contract or compensatory plan

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Date: November 5, 2004	ALIGN TECHNOLOGY, INC.	
	By:	/s/ THOMAS M. PRESCOTT
		Thomas M. Prescott *President and Chief Executive Officer*
	By:	/s/ ELDON M. BULLINGTON
		Eldon M. Bullington *Vice President of Finance and Chief Financial Officer*

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† Management contract or compensatory plan

Exhibit 10.13.1

ALIGN TECHNOLOGY, INC.

STOCK OPTION AGREEMENT

A. The Board has adopted the Plan for the purpose of retaining the services of selected Employees, non-employee members of the Board (or the board of directors of any Parent or Subsidiary) and consultants and other independent advisors who provide services to the Corporation (or any Parent or Subsidiary).

B. Optionee is to render valuable services to the Corporation (or a Parent or Subsidiary), and this Agreement is executed pursuant to, and is intended to carry out the purposes of, the Plan in connection with the Corporation's grant of an option to Optionee.

C. All capitalized terms in this Agreement shall have the meaning assigned to them in the attached Appendix.

NOW, THEREFORE, it is hereby agreed as follows:

1. **Grant of Option**. The Corporation hereby grants to Optionee, as of the Grant Date, an option to purchase up to the number of Option Shares specified in the Grant Notice. The Option Shares shall be purchasable from time to time during the option term specified in Paragraph 2 at the Exercise Price.

2. **Option Term**. This option shall have a maximum term of ten (10) years measured from the Grant Date and shall accordingly expire at the close of business on the Expiration Date, unless sooner terminated in accordance with Paragraph 5 or 6.

3. **Limited Transferability**.

(a) This option shall be neither transferable nor assignable by Optionee other than by will or the laws of inheritance following Optionee's death and may be exercised, during Optionee's lifetime, only by Optionee. However, Optionee may designate one or more persons as the beneficiary or beneficiaries of this option, and this option shall, in accordance with such designation, automatically be transferred to such beneficiary or beneficiaries upon the Optionee's death while holding this option. Such beneficiary or beneficiaries shall take the transferred option subject to all the terms and conditions of this Agreement, including (without limitation) the limited time period during which this option may, pursuant to Paragraph 5, be exercised following Optionee's death.

(b) If this option is designated a Non-Statutory Option in the Grant Notice, then this option may be assigned in whole or in part during Optionee's lifetime to one or more members of Optionee's family or to a trust established for the exclusive benefit of one or more such family members or to Optionee's former spouse, to the extent such assignment is in connection with the Optionee's estate plan or pursuant to a domestic relations order. The assigned portion shall be exercisable only by the person or persons who acquire a proprietary interest in the option pursuant to such assignment. The terms applicable to the assigned portion shall be the same as those in effect for this option immediately prior to such assignment.

4. **Dates of Exercise**. This option shall become exercisable for the Option Shares in one or more installments as specified in the Grant Notice. As the option becomes exercisable for such installments, those installments shall accumulate, and the option shall remain exercisable for the accumulated installments until the Expiration Date or sooner termination of the option term under Paragraph 5 or 6.

5. **Cessation of Service**. The option term specified in Paragraph 2 shall terminate (and this option shall cease to be outstanding) prior to the Expiration Date should any of the following provisions become applicable:

(a) Should Optionee cease to remain in Service for any reason (other than death, Permanent Disability or Misconduct) while holding this option, then Optionee shall have a period of three (3) months (commencing with the date of such cessation of Service) during which to exercise this option, but in no event shall this option be exercisable at any time after the Expiration Date.

(b) Should Optionee die while holding this option, then the personal representative of Optionee's estate or the person or persons to whom the option is transferred pursuant to Optionee's will or the laws of inheritance shall have the right to exercise this option. However, if Optionee has designated one or more beneficiaries of this option, then those persons shall have the exclusive right to exercise this option following Optionee's death. Any such right to exercise this option shall lapse, and this option shall cease to be outstanding, upon the earlier of (i) the expiration of the twelve (12)-month period measured from the date of Optionee's death or (ii) the Expiration Date.

(c) Should Optionee cease Service by reason of Permanent Disability while holding this option, then Optionee shall have a period of twelve (12) months (commencing with the date of such cessation of Service) during which to exercise this option. In no event shall this option be exercisable at any time after the Expiration Date.

(d) During the limited period of post-Service exercisability, this option may not be exercised in the aggregate for more than the number of Option Shares for which the option is exercisable at the time of Optionee's cessation of Service. Upon the expiration of such limited exercise period or (if earlier) upon the Expiration Date, this option shall terminate and cease to be outstanding for any exercisable Option Shares for which the option has not been exercised. However, this option shall, immediately upon Optionee's cessation of Service for any reason, terminate and cease to be outstanding with respect to any Option Shares for which this option is not otherwise at that time exercisable.

(e) Should Optionee's Service be terminated for Misconduct or should Optionee otherwise engage in any Misconduct while this option is outstanding, then this option shall terminate immediately and cease to remain outstanding.

6. **Special Acceleration of Option**.

(a) This option, to the extent outstanding at the time of a Corporate Transaction but not otherwise fully exercisable, shall automatically accelerate so that this option shall, immediately prior to the effective date of such Corporate Transaction, become exercisable for all of the Option Shares at the time subject to this option and may be exercised for any or all of those Option Shares as fully vested shares of Common Stock. However, this option shall **not** become exercisable on such an accelerated basis, if and to the extent: (i) this option is, in connection with the Corporate Transaction, to be assumed by the successor corporation (or parent thereof) or (ii) this option is to be replaced with a cash incentive program of the successor corporation which preserves the spread existing at the time of the Corporate Transaction on any Option Shares for which this option is not otherwise at that time exercisable (the excess of the Fair Market Value of those Option Shares over the aggregate Exercise Price payable for such shares) and provides for subsequent payout in accordance with the same option exercise/vesting schedule for those Option Shares set forth in the Grant Notice.

(b) Immediately following the Corporate Transaction, this option shall terminate and cease to be outstanding, except to the extent assumed by the successor corporation (or parent thereof) in connection with the Corporate Transaction.

(c) If this option is assumed in connection with a Corporate Transaction, then this option shall be appropriately adjusted, immediately after such Corporate Transaction, to apply to the number and class of securities which would have been issuable to Optionee in consummation of such Corporate Transaction had the option been exercised immediately prior to such Corporate Transaction, and appropriate adjustments shall also be made to the Exercise Price, provided the aggregate Exercise Price shall remain the same. To the extent the actual holders of the Corporation's outstanding Common Stock receive cash consideration for their Common Stock in consummation of the Corporate Transaction, the successor corporation may, in connection with the assumption of this option, substitute one or more shares of its own common stock with a fair market value equivalent to the cash consideration paid per share of Common Stock in such Corporate Transaction.

(d) This Agreement shall not in any way affect the right of the Corporation to adjust, reclassify, reorganize or otherwise change its capital or business structure or to merge, consolidate, dissolve, liquidate or sell or transfer all or any part of its business or assets.

7. **Adjustment in Option Shares**. Should any change be made to the Common Stock by reason of any stock split, stock dividend, recapitalization, combination of shares, exchange of shares or other change affecting the outstanding Common Stock as a class without the Corporation's receipt of consideration, appropriate adjustments shall be made to (i) the total number and/or class of securities subject to this option and (ii) the Exercise Price in order to reflect such change and thereby preclude a dilution or enlargement of benefits hereunder.

8. **Stockholder Rights**. The holder of this option shall not have any stockholder rights with respect to the Option Shares until such person shall have exercised the option, paid the Exercise Price and become a holder of record of the purchased shares.

9. **Manner of Exercising Option**.

(a) In order to exercise this option with respect to all or any part of the Option Shares for which this option is at the time exercisable, Optionee (or any other person or persons exercising the option) must take the following actions:

(i) Execute and deliver to the Corporation a Notice of Exercise for the Option Shares for which the option is exercised.

(ii) Pay the aggregate Exercise Price for the purchased shares in one or more of the following forms:

(A) cash or check made payable to the Corporation;

(B) a promissory note payable to the Corporation, but only to the extent authorized by the Plan Administrator in accordance with Paragraph 13;

(C) shares of Common Stock held by Optionee (or any other person or persons exercising the option) for the requisite period necessary to avoid a charge to the Corporation's earnings for financial reporting purposes and valued at Fair Market Value on the Exercise Date; or

(D) through a special sale and remittance procedure pursuant to which Optionee (or any other person or persons exercising the option) shall concurrently provide irrevocable instructions (i) to a Corporation-designated brokerage firm to effect the immediate sale of the purchased shares and remit to the Corporation, out of the sale proceeds available on the settlement date, sufficient funds to cover the aggregate Exercise Price payable for the purchased shares plus all applicable Federal, state and local income and employment taxes required to be withheld by the Corporation by reason of such exercise and (ii) to the Corporation to deliver the certificates for the purchased shares directly to such brokerage firm in order to complete the sale.

Except to the extent the sale and remittance procedure is utilized in connection with the option exercise, payment of the Exercise Price must accompany the Notice of Exercise delivered to the Corporation in connection with the option exercise.

(iii) Furnish to the Corporation appropriate documentation that the person or persons exercising the option (if other than Optionee) have the right to exercise this option.

(iv) Make appropriate arrangements with the Corporation (or Parent or Subsidiary employing or retaining Optionee) for the satisfaction of all Federal, state and local income and employment tax withholding requirements applicable to the option exercise.

(b) As soon as practical after the Exercise Date, the Corporation shall issue to or on behalf of Optionee (or any other person or persons exercising this option) a certificate for the purchased Option Shares, with the appropriate legends affixed thereto.

(c) In no event may this option be exercised for any fractional shares.

10. **Compliance with Laws and Regulations**.

(a) The exercise of this option and the issuance of the Option Shares upon such exercise shall be subject to compliance by the Corporation and Optionee with all applicable requirements of law relating thereto and with all applicable regulations of any stock exchange (or the Nasdaq National Market, if applicable) on which the Common Stock may be listed for trading at the time of such exercise and issuance.

(b) The inability of the Corporation to obtain approval from any regulatory body having authority deemed by the Corporation to be necessary to the lawful issuance and sale of any Common Stock pursuant to this option shall relieve the Corporation of any liability with respect to the non-issuance or sale of the Common Stock as to which such approval shall not have been obtained. The Corporation, however, shall use its best efforts to obtain all such approvals.

11. **Successors and Assigns**. Except to the extent otherwise provided in Paragraphs 3 and 6, the provisions of this Agreement shall inure to the benefit of, and be binding upon, the Corporation and its successors and assigns and Optionee, Optionee's assigns, the legal representatives, heirs and legatees of Optionee's estate and any beneficiaries of this option designated by Optionee.

12. **Notices**. Any notice required to be given or delivered to the Corporation under the terms of this Agreement shall be in writing and addressed to the Corporation at its principal corporate offices. Any notice required to be given or delivered to Optionee shall be in writing and addressed to Optionee at the address indicated below Optionee's signature line on the Grant Notice. All notices shall be deemed effective upon personal delivery or upon deposit in the U.S. mail, postage prepaid and properly addressed to the party to be notified.

13. **Financing**. The Plan Administrator may, in its absolute discretion and without any obligation to do so, permit Optionee to pay the Exercise Price for the purchased Option Shares (to the extent such Exercise Price is in excess of the par value of those shares) by delivering a full-recourse promissory note payable to the Corporation. The terms of any such promissory note (including the interest rate, the requirements for collateral and the terms of repayment) shall be established by the Plan Administrator in its sole discretion.

14. **Construction**. This Agreement and the option evidenced hereby are made and granted pursuant to the Plan and are in all respects limited by and subject to the terms of the Plan. All decisions of the Plan Administrator with respect to any question or issue arising under the Plan or this Agreement shall be conclusive and binding on all persons having an interest in this option.

15. **Governing Law**. The interpretation, performance and enforcement of this Agreement shall be governed by the laws of the State of California without resort to that State's conflict-of-laws rules.

16. **Excess Shares**. If the Option Shares covered by this Agreement exceed, as of the Grant Date, the number of shares of Common Stock which may without stockholder approval be issued under the Plan, then this option shall be void with respect to those excess shares, unless stockholder approval of an amendment sufficiently increasing the number of shares of Common Stock issuable under the Plan is obtained in accordance with the provisions of the Plan.

17. **Additional Terms Applicable to an Incentive Option**. In the event this option is designated an Incentive Option in the Grant Notice, the following terms and conditions shall also apply to the grant:

(a) This option shall cease to qualify for favorable tax treatment as an Incentive Option if (and to the extent) this option is exercised for one or more Option Shares: (A) more than three (3) months after the date Optionee ceases to be an Employee for any reason other than death or Permanent Disability or (B) more than twelve (12) months after the date Optionee ceases to be an Employee by reason of Permanent Disability.

(b) No installment under this option shall qualify for favorable tax treatment as an Incentive Option if (and to the extent) the aggregate Fair Market Value (determined at the Grant Date) of the Common Stock for which such installment first becomes exercisable hereunder would, when added to the aggregate value (determined as of the respective date or dates of grant) of the Common Stock or other securities for which this option or any other

Incentive Options granted to Optionee prior to the Grant Date (whether under the Plan or any other option plan of the Corporation or any Parent or Subsidiary) first become exercisable during the same calendar year, exceed One Hundred Thousand Dollars ($100,000) in the aggregate. Should such One Hundred Thousand Dollar ($100,000) limitation be exceeded in any calendar year, this option shall nevertheless become exercisable for the excess shares in such calendar year as a Non-Statutory Option.

(c) Should the exercisability of this option be accelerated upon a Corporate Transaction, then this option shall qualify for favorable tax treatment as an Incentive Option only to the extent the aggregate Fair Market Value (determined at the Grant Date) of the Common Stock for which this option first becomes exercisable in the calendar year in which the Corporate Transaction occurs does not, when added to the aggregate value (determined as of the respective date or dates of grant) of the Common Stock or other securities for which this option or one or more other Incentive Options granted to Optionee prior to the Grant Date (whether under the Plan or any other option plan of the Corporation or any Parent or Subsidiary) first become exercisable during the same calendar year, exceed One Hundred Thousand Dollars ($100,000) in the aggregate. Should the applicable One Hundred Thousand Dollar ($100,000) limitation be exceeded in the calendar year of such Corporate Transaction, the option may nevertheless be exercised for the excess shares in such calendar year as a Non-Statutory Option.

(d) Should Optionee hold, in addition to this option, one or more other options to purchase Common Stock which become exercisable for the first time in the same calendar year as this option, then the foregoing limitations on the exercisability of such options as Incentive Options shall be applied on the basis of the order in which such options are granted.

EXHIBIT I

NOTICE OF EXERCISE

I hereby notify Align Technology, Inc. (the "Corporation") that I elect to purchase __________ shares of the Corporation's Common Stock (the "Purchased Shares") at the option exercise price of $ __________ per share (the "Exercise Price") pursuant to that certain option (the "Option") granted to me under the Corporation's 2001 Stock Incentive Plan on __________, __.

Concurrently with the delivery of this Exercise Notice to the Corporation, I shall hereby pay to the Corporation the Exercise Price for the Purchased Shares in accordance with the provisions of my agreement with the Corporation (or other documents) evidencing the Option and shall deliver whatever additional documents may be required by such agreement as a condition for exercise. Alternatively, I may utilize the special broker-dealer sale and remittance procedure specified in my agreement to effect payment of the Exercise Price.

__________, ____
Date

____
Optionee

Address: ______________________________

____

Print name in exact manner it is to appear on the stock certificate: ______________________________

Address to which certificate is to be sent, if different from address above: ______________________________

____

____

Social Security Number: ______________________________

APPENDIX

The following definitions shall be in effect under the Agreement:

A. **Agreement** shall mean this Stock Option Agreement.

B. **Board** shall mean the Corporation's Board of Directors.

C. **Common Stock** shall mean shares of the Corporation's common stock.

D. **Code** shall mean the Internal Revenue Code of 1986, as amended.

E. **Corporate Transaction** shall mean either of the following stockholder-approved transactions to which the Corporation is a party:

(i) a merger, consolidation or other reorganization approved by the Corporation's stockholders, unless securities representing more than fifty percent (50%) of the total combined voting power of the voting securities of the successor corporation are immediately thereafter beneficially owned, directly or indirectly and in substantially the same proportion, by the persons who beneficially owned the Corporation's outstanding voting securities immediately prior to such transaction, or

(ii) the sale, transfer or other disposition of all or substantially all of the Corporation's assets in complete liquidation or dissolution of the Corporation.

F. **Corporation** shall mean Align Technology, Inc., a Delaware corporation, and any successor corporation to all or substantially all of the assets or voting stock of Align Technology, Inc. which shall by appropriate action adopt the Plan.

G. **Employee** shall mean an individual who is in the employ of the Corporation (or any Parent or Subsidiary), subject to the control and direction of the employer entity as to both the work to be performed and the manner and method of performance.

H. **Exercise Date** shall mean the date on which the option shall have been exercised in accordance with Paragraph 9 of the Agreement.

I. **Exercise Price** shall mean the exercise price per Option Share as specified in the Grant Notice.

J. **Expiration Date** shall mean the date on which the option expires as specified in the Grant Notice.

K. **Fair Market Value** per share of Common Stock on any relevant date shall be determined in accordance with the following provisions:

(i) If the Common Stock is at the time traded on the Nasdaq National Market, then the Fair Market Value shall be deemed equal to the closing selling price per share of Common Stock on the date in question, as the price is reported by the National Association of Securities Dealers on the Nasdaq National Market and published in The Wall Street Journal. If there is no closing selling price for the Common Stock on the date in question, then the Fair Market Value shall be the closing selling price on the last preceding date for which such quotation exists, or

(ii) If the Common Stock is at the time listed on any Stock Exchange, then the Fair Market Value shall be deemed equal to the closing selling price per share of Common Stock on the date in question on the Stock Exchange determined by the Plan Administrator to be the primary market for the Common Stock, as such price is officially quoted in the composite tape of transactions on such exchange and published in The Wall Street Journal. If there is no closing selling price for the Common Stock on the date in question, then the Fair Market Value shall be the closing selling price on the last preceding date for which such quotation exists.

L. **Grant Date** shall mean the date of grant of the option as specified in the Grant Notice.

M. **Grant Notice** shall mean the Notice of Grant of Stock Option accompanying the Agreement, pursuant to which Optionee has been informed of the basic terms of the option evidenced hereby.

N. **Incentive Option** shall mean an option which satisfies the requirements of Code Section 422.

O. **Misconduct** shall mean the commission of any act of fraud, embezzlement or dishonesty by Optionee, any unauthorized use or disclosure by Optionee of confidential information or trade secrets of the Corporation (or any Parent or Subsidiary), or any other intentional misconduct by Optionee adversely affecting the business or affairs of the Corporation (or any Parent or Subsidiary) in a material manner. The foregoing definition shall not in any way preclude or restrict the right of the Corporation (or any Parent or Subsidiary) to discharge or dismiss Optionee for any other acts or omissions, but such other acts or omissions shall not be deemed, for purposes of the Plan or this Agreement, to constitute grounds for termination for Misconduct.

P. **Non-Statutory Option** shall mean an option not intended to satisfy the requirements of Code Section 422.

Q. **Notice of Exercise** shall mean the notice of exercise in the form attached hereto as Exhibit I.

R. **Option Shares** shall mean the number of shares of Common Stock subject to the option as specified in the Grant Notice.

S. **Optionee** shall mean the person to whom the option is granted as specified in the Grant Notice.

T. **Parent** shall mean any corporation (other than the Corporation) in an unbroken chain of corporations ending with the Corporation, provided each corporation in the unbroken chain (other than the Corporation) owns, at the time of the determination, stock possessing fifty percent (50%) or more of the total combined voting power of all classes of stock in one of the other corporations in such chain.

U. **Permanent Disability** shall mean the inability of Optionee to engage in any substantial gainful activity by reason of any medically determinable physical or mental impairment which is expected to result in death or has lasted or can be expected to last for a continuous period of twelve (12) months or more.

V. **Plan** shall mean the Corporation's 2001 Stock Incentive Plan.

W. **Plan Administrator** shall mean either the Board or a committee of the Board acting in its capacity as administrator of the Plan.

X. **Service** shall mean the Optionee's performance of services for the Corporation (or any Parent or Subsidiary) in the capacity of an Employee, a non-employee member of the board of directors or a consultant or independent advisor.

Y. **Stock Exchange** shall mean the American Stock Exchange or the New York Stock Exchange.

Z. **Subsidiary** shall mean any corporation (other than the Corporation) in an unbroken chain of corporations beginning with the Corporation, provided each corporation (other than the last corporation) in the unbroken chain owns, at the time of the determination, stock possessing fifty percent (50%) or more of the total combined voting power of all classes of stock in one of the other corporations in such chain.

Exhibit 10.44

EMPLOYMENT AGREEMENT

This AGREEMENT is entered into as of July 12, 2004, by and between Robert D. Mitchell (the “Executive”) and Align Technology, Inc., a Delaware corporation (the “Company”).

1. Duties and Scope of Employment.

(a) Position. For the term of his employment under this Agreement (“Employment”), the Company agrees to employ the Executive in the position of Vice President, Worldwide Sales. 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 his abilities perform such other services consistent with his position as Vice President, Worldwide Sales as may from time to time be assigned to him by the Chief Executive Officer (the “CEO”).

(b) Obligations to the Company. During the term of his Employment, the Executive shall devote his 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 he is under no obligations or commitments, whether contractual or otherwise, that are inconsistent with his obligations under this Agreement. The Executive represents and warrants that he will not use or disclose, in connection with his 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 his 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 he has returned all property and confidential information belonging to any prior employers.

(d) Commencement Date. The Executive commenced full-time Employment on July 12, 2004.

2. Cash and Incentive Compensation.

(a) Salary. The Company shall pay the Executive as compensation for his services a base salary at a gross annual rate of $225,000.00, 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 him with an opportunity to earn a potential annual bonus equal to 60.0% of the Executive's Base Salary. 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 2004, 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 his 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 his 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 his Employment, the Executive shall be authorized to incur necessary and reasonable travel, entertainment and other business expenses in connection with his 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 his Employment by giving the Company fourteen (14) days advance notice in writing. The Executive's Employment shall terminate automatically in the event of his 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 his health insurance coverage under the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended ("COBRA") following the termination of his 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 his 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 his/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 his principal place of employment such that his commuting distance from his 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.

Robert D. Mitchell

ALIGN TECHNOLOGY, INC.

By: Roger E. George
Title: Vice President, Legal Affairs & General Counsel

Exhibit 10.45

EMPLOYMENT AGREEMENT

This AGREEMENT is entered into as of September 13, 2004, by and between Cecilia Claudio (the “Executive”) and Align Technology, Inc., a Delaware corporation (the “Company”).

1. Duties and Scope of Employment.

(a) Position. For the term of his employment under this Agreement (“Employment”), the Company agrees to employ the Executive in the position of Information Technology and Chief Information Officer. 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 his abilities perform such other services consistent with his position as Information Technology and Chief Information Officer as may from time to time be assigned to him by the Chief Executive Officer (the “CEO”).

(b) Obligations to the Company. During the term of his Employment, the Executive shall devote his 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 he is under no obligations or commitments, whether contractual or otherwise, that are inconsistent with his obligations under this Agreement. The Executive represents and warrants that he will not use or disclose, in connection with his 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 his 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 he has returned all property and confidential information belonging to any prior employers.

(d) Commencement Date. The Executive commenced full-time Employment on July 14, 2004.

2. Cash and Incentive Compensation.

(a) Salary. The Company shall pay the Executive as compensation for his services a base salary at a gross annual rate of $224,000.00, 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 him with an opportunity to earn a potential annual bonus equal to 60.0% of the Executive's Base Salary. 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 2004, 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 his 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 his 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 his Employment, the Executive shall be authorized to incur necessary and reasonable travel, entertainment and other business expenses in connection with his 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 his Employment by giving the Company fourteen (14) days advance notice in writing. The Executive's Employment shall terminate automatically in the event of his 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 his health insurance coverage under the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended ("COBRA") following the termination of his 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 his 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 his/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 his principal place of employment such that his commuting distance from his 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.

Cecilia Claudio

ALIGN TECHNOLOGY, INC.

By: Roger E. George
Title: Vice President, Legal Affairs &
General Cousnel

SEPARATION & GENERAL RELEASE AGREEMENT

This Separation and General Release Agreement ("Agreement") is made by and between Jon Fjeld ("Fjeld") and Align Technology, Inc. ("Align"). Fjeld and Align will hereinafter be referred to as the "Parties."

R E C I T A L S

WHEREAS, Fjeld was for a time employed by Align until his employment terminated on July 9, 2004 (the "Termination Date");

WHEREAS, Fjeld and Align (together "the Parties") wish permanently to resolve all disputes that exist or may exist between them in the future arising out of Fjeld's employment with Align and the termination thereof;

NOW, THEREFORE, for and in consideration of the promises and undertakings described below, the Parties agree as follows:

A G R E E M E N T S

A. ALIGN.

1. Payment. Align shall make the following payments to Fjeld:

a. Within thirty (30) business days after the Effective Date of this Agreement (as defined in Section C.8 below), Align shall deliver to Fjeld a check made payable to "Jon Fjeld" in the gross amount of SIXTY SEVEN THOUSAND FOUR HUNDRED DOLLARS ($67,400.00) less applicable deductions and withholdings, for which a 2004 Form W-2 shall be issued to Fjeld. This amount represents Fjeld's calendar year 2004 Target Bonus prorated for the number of days that Fjeld was employed in calendar year 2004.

b. Payable in twenty-six (26) equal installments in accordance with Align's standard payroll schedule and practices, the gross total amount of TWO HUNDRED FIFTEEEN THOUSAND TWO HUNDRED FIFTY FIVE DOLLARS ($215,255.00), less applicable deductions and withholdings, which represents one year of Fjeld's current Base Salary. A Form W-2 shall be issued to Fjeld for each year during which these payments are made.

c. Payable in lump sum on July 9, 2005, less applicable deductions and withholdings, the gross amount of ONE HUNDRED TWENTY NINE THOUSAND ONE HUNDRED FIFTY THREE DOLLARS ($129,153.00), which represents the greater of Fjeld's calendar year 2004 Target Bonus or actual calendar year 2003 Target Bonus, for which a 2005 Form W-2 shall be issued to Fjeld.

2. COBRA Continuation. If Fjeld is eligible and timely elects to continue medical coverage for himself and his eligible dependents under COBRA, Align will pay, on Fjeld's behalf, the premiums to continue this group health insurance, including coverage for Fjeld's eligible dependents; provided, however, that

Align will pay such premiums only for the coverage for which Fjeld and his eligible dependents were enrolled immediately prior to the Termination Date.

Align shall pay the premiums for such coverage until the earlier of (a) July 9, 2005; (b) the effective date of Fjeld's coverage by a health plan of a subsequent employer; or (c) the date Fjeld is no longer eligible for COBRA coverage. For the balance of the period that Fjeld is entitled to coverage under COBRA, he shall be entitled to maintain coverage for himself and his eligible dependents at his own expense.

3. <u>Vesting Acceleration</u>. Align will accelerate the vesting of Sixty Nine Thousand Six Hundred Fifty Seven (69,657) of Fjeld's stock options and/or restricted shares so that on the Effective Date, Fjeld will be vested in the same number of shares Fjeld would have vested in had he remained in service through the one year anniversary of the Termination Date.

B. FJELD.

1. <u>Final Pay</u>. Fjeld represents and warrants that he has received and reviewed his final paycheck and that he has been paid all salary, wages and the like earned by him and owed to him by Align, including, but not limited to, all accrued but unused vacation as well as any reimbursable business expenses. Fjeld further acknowledges and agrees that he is not entitled to any additional payments from Align except as set forth in this Agreement.

2. <u>Consultation/Assistance</u>. Fjeld agrees that for the three (3) month period following the Termination Date, he will make himself available to consult with and assist Align as Align may reasonably request from time to time.

3. <u>General Release</u>. Fjeld hereby fully and forever releases, waives, discharges and promises not to sue or otherwise institute or cause to be instituted any legal or administrative proceedings against Align or any of its current and former officers, directors, attorneys, shareholders, predecessor, successor, affiliated or related companies, agents, employees and assignees thereof (collectively, the "Company"), with respect to any and all liabilities, claims, demands, contracts, debts, obligations and causes of action of any nature, kind, and description, whether in law, equity or otherwise, whether or not now known or ascertained, which currently do or may exist, including without limitation any matter, cause or claim arising out of or related to facts or events occurring prior to the Effective Date of this Agreement, and/or arising from and relating to Fjeld's employment with Align or the termination there from, including, but not limited to any claims for unpaid wages, severance, benefits, penalties, breach of contract, breach of the covenant of good faith and fair dealing, infliction of emotional distress, misrepresentation, claims under Title VII of the Civil Rights Act, under the Age Discrimination in Employment Act, under the California Fair Employment and Housing Act, under the California Labor Code, under the Employment Retirement Income and Security Act and under any other statutory or common law claims relating to employment or the termination thereof, *except* any claims Fjeld may have, which, as a matter of law, are not subject to waiver such as:

a. unemployment insurance benefits pursuant to the terms of applicable law;

b. workers' compensation insurance benefits pursuant to Division 4 of the California Labor Code, under the terms of any workers' compensation insurance policy or fund of Align;

c. continued participation in certain of Align's group benefit plans on a temporary basis pursuant to the federal law known as COBRA; and

d. rights or claims under the Age Discrimination in Employment Act ("ADEA") that may arise after the date this Agreement is signed.

4. Waiver – Civil Code Section 1542. Fjeld understands and agrees that Section B.3., above, applies to claims, known and presently unknown by Fjeld; and that this means that if, hereafter, Fjeld discovers facts different from or in addition to those which Fjeld now knows or believes to be true, that the releases, waivers, discharge and promise not to sue or otherwise institute legal action shall be and remain effective in all respects notwithstanding such different or additional facts or the discovery of such fact. Accordingly, Fjeld hereby agrees that he fully and forever waives any and all rights and benefits conferred upon his by the provision of Section 1542 of the Civil Code of the State of California which states as follows (parentheticals added):

> A general release does not extend to claims which the creditors [*i.e.*, Fjeld] does not know or suspects to exist in his favor at the time of executing the release, which if known by him must have materially affected his settlement with the debtor [*i.e.*, the Company].

5. Confidentiality & Non-Disclosure. Fjeld hereby agrees that he will not, without compulsion of legal process, disclose to any third party any of the terms of this Agreement, including the amount referred to herein, either by specific dollar amounts or by number of "figures" or otherwise, nor shall he disclose that the fact of the payment of said dollar amount, except that he may disclose such information to his spouse and he may disclose such information to his attorneys and accountants to whom, and only to the extent, disclosure is necessary to effect the purposes for which Fjeld has consulted such attorneys and accountants. Fjeld agrees that in connection with any disclosure permitted hereunder, Fjeld shall cause such third party to whom disclosure has been made, including his spouse, to agree to comply with this covenant of confidentiality and non-disclosure, and in the event such third party breaches this covenant of confidentiality and non-disclosure, such breach shall be deemed to have been committed by Fjeld.

6. COBRA Continuation. Fjeld hereby agrees that he will notify Align's human resources department when he becomes eligible for medical coverage with a subsequent employer or otherwise.

7. No Other Pending Claims. Fjeld hereby represents and warrants that he has neither filed nor served any claim, demand, suit or legal proceeding against the Company.

8. No Prior Assignments. Fjeld hereby represents and warrants that he has not assigned or transferred, or purported to assign or transfer, to any third person or entity any claim, right, liability, demand, obligation, expense, action or causes of action being waived or released pursuant to this Agreement.

9. Material Inducements. Fjeld hereby agrees and acknowledges that the releases, waivers and promises contained in this Agreement, including the promises of confidentiality and non-disclosure, are material inducements for the consideration described in Section A., above.

10. Agreement Inures to Align. Fjeld hereby agrees and understands that this Agreement shall bind him, and his heirs, executors, administrators and agents thereof and that it inures to the benefit of Align and its current and former officers, directors, attorneys, shareholders, predecessors, successors, affiliated or related companies, agents, employees and assignees thereof.

11. Proprietary Information. Fjeld hereby acknowledges and agrees that (a) he is bound by, and has continuing obligations under, the Proprietary Information and Inventions Agreement ("PIIA") signed by him on November 10, 2000, and the Employment Agreement by and between Fjeld and Align dated March 1, 2003; (b) he has returned to Align all items of property paid for and/or provided by Align for his use during employment with Align including, but not limited to, any laptops, computer and office equipment, software programs, cell phones, pagers, access cards and keys, credit and calling cards; and

(c) he has returned to Align all documents (electronic and paper) created and received by him during his employment with Align, and he has not retained any such documents, except he may keep his personal copies of (i) documents evidencing his hire, compensation, benefits and termination (including this Agreement); (ii) any materials distributed generally to stockholders of the Company, and (iii) his copy of the PIIA. The PIIA is incorporated herein by this reference.

12. Non-Disparagement. Fjeld agrees not to make any derogatory statements about the Company and/or the Company's officers, directors, employees, investors, stockholders, administrators, affiliates, divisions, subsidiaries, predecessor and successor corporations and assigns.

C. ALIGN AND FJELD.

1. Attorneys Fees and Expenses. Each party to this Agreement shall bear their own respective attorneys' fees and expenses related to the negotiation of this Agreement, and each agrees to hold the other harmless from the payment of all such attorneys' fees and expenses.

2. No Admission. Nothing contained in this Agreement shall constitute, be construed or be treated as an admission of liability or wrongdoing by Fjeld, by Align, or by any current or former employee, officer or director of Align.

3. Governing Law. California law shall govern the construction, interpretation and enforcement of this Agreement.

4. Severability. If any provision, or portion thereof, of this Agreement shall for any reason be held to be invalid or unenforceable or to be contrary to public policy or any law, then the remainder of the Agreement shall not be affected thereby.

5. Arbitration of Disputes Arising from Agreement. Any and all disputes that arise out or relate to this Agreement or any of the subjects hereof shall be resolved through final and binding arbitration. Binding arbitration will be conducted in Santa Clara County in accordance with California Code of Civil Procedure section 1282, *et seq*., and the rules and regulations of the American Arbitration Association then in effect for resolution of commercial disputes. Each of the Parties understands and agrees that arbitration shall be instead of any civil litigation, each waives its right to a jury trial, and each understands and agrees that the arbitrator's decision shall be final and binding to the fullest extent permitted by law and enforceable by any court having jurisdiction thereof. Each of the Parties will bear their own respective attorneys' fees and will equally share the cost of arbitration, although the arbitrator may award the prevailing party his/its reasonable attorneys' fees and costs of arbitration except that such fees and costs may not be recovered by Align that result from Align's defense against any claim by Fjeld challenging the waiver, release and discharge of rights under the Age Discrimination in Employment Act.

6. Counterpart Signatures. Fjeld and Align hereby acknowledge that this Agreement may be executed in counterpart originals with like effect as if executed in a single original document.

7. Time to Consider; Revocation Period; Effective Date. Fjeld understands and agrees that he may have up to a full twenty-one (21) days after receipt of this Agreement within which he may review, consider, and decide whether or not to sign this Agreement, and, if Fjeld has not taken that full time period, that he expressly waives the remaining time period and will not assert the invalidity of this Agreement or any portion thereof on this basis. Fjeld further acknowledges that he should discuss the terms of this Agreement with an attorney of his choosing. Fjeld also understands that, for the period of seven (7) days after the date he signs this Agreement, he may revoke the release of his claims under the Age Discrimination in Employment Act ("ADEA"), in which case this Agreement shall remain effective and

enforceable in all other respects but the payments in Section A.1. will each be reduced by 40%. Fjeld understands that if he wishes to revoke his release of claims under the ADEA, he must deliver written notice of revocation, no later than the seventh day after he signs this Agreement, to:

Align Technology, Inc.
Attn. Human Resources
881 Martin Ave.
Santa Clara, CA 95050
Facsimile: (408) 470-1207

Fjeld further understands that the Effective Date of this General Release will be the eighth day after both of the Parties have signed it and it has been delivered to Align. Fjeld understands that he should deliver his signed General Release to Align via the address, above.

8. Results of Negotiation; Knowing and Voluntary Execution. The Parties hereby acknowledge that this Agreement is the result of negotiation between them, that each were represented by an attorney of their own choosing in deciding whether or not to sign this Agreement and that each has read and understands the foregoing Agreement and that each affixes their respective signature to this Agreement knowingly, voluntarily and without coercion.

9. Entire Agreement; Modification. The Parties hereby acknowledge and agree that except for any pre-existing stock, stock option and/or purchase agreement(s) between Fjeld and Align, and any amendments and waivers thereto, no promises or representations were or are made which do not appear written in this Agreement. The Parties agree that this Agreement contains the entire agreement by Fjeld and Align, and that neither is relying on any representation or promise that does not appear in this Agreement. The Parties further agree that the benefits provided in this Agreement fully satisfy any obligations Align may have to provide any severance or other benefits to Fjeld under that certain employment offer letter by and between Fjeld and Align dated November 6, 2000, and the Employment Agreement by and between Fjeld and Align dated March 1, 2003. This Agreement may be changed only by another written agreement signed by Fjeld and the Chief Executive Officer of Align.

10. Enforcement Costs. If an action is brought by either party for breach of any provision of this Agreement, the non-breaching party shall be entitled to recover all reasonable attorneys' fees and costs in defending or bringing such an action.

Date: July 14, 2004

/s/ John Fjeld

Align Technology Inc.:

Date: July 9, 2004

By: /s/ Pat Wadors
Name Pat Wadors
Title Vice President
Human Resources

Exhibit 31.1

CERTIFICATION

I, Thomas M. Prescott, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Align Technology, Inc.;
2. Based on my knowledge, this 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 officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and we 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 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: November 5, 2004

/s/ THOMAS M. PRESCOTT

Thomas M. Prescott
President and Chief Executive Officer

I, Eldon M. Bullington, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Align Technology, Inc.;

2. Based on my knowledge, this 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 officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and we 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 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: November 5, 2004

/s/ ELDON M. BULLINGTON

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

Exhibit 32.1

**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 Quarterly Report of Align Technology, Inc. on Form 10-Q for the quarter ended September 30, 2004 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in such Quarterly Report on Form 10-Q fairly presents in all material respects the financial condition and results of operations of Align Technology, Inc.

	By:	/s/ THOMAS M. PRESCOTT
Date: November 5, 2004	**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 Quarterly Report of Align Technology, Inc. on Form 10-Q for the quarter ended September 30, 2004 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in such Quarterly Report on Form 10-Q fairly presents in all material respects the financial condition and results of operations of Align Technology, Inc.

	By:	/s/ ELDON M. BULLINGTON
Date: November 5, 2004	**Name:**	**Eldon M. Bullington**
	Title:	Vice President of Finance and Chief Financial Officer