

**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, 2003

OR

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

For the transition period from _____ to _____

Commission file number: 0-32259

Align Technology, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(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, \$0.001 par value, as of October 31, 2003 was 58,557,101.

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ALIGN TECHNOLOGY, INC.

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

	September 30, 2003	December 31, 2002
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 37,250	\$ 35,552
Restricted cash	3,420	3,261
Marketable securities, short-term	1,998	2,693
Accounts receivable, net	20,794	16,766
Inventories, net	1,578	1,533
Deferred costs	768	1,139
Prepaid expenses and other current assets	5,751	4,888
	<hr/>	<hr/>
Total current assets	71,559	65,832
Property and equipment, net	22,331	25,078
Other assets	1,960	1,946
	<hr/>	<hr/>
Total assets	\$ 95,850	\$ 92,856
	<hr/>	<hr/>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 1,755	\$ 1,974
Other accrued liabilities	18,319	11,112
Deferred revenue	13,301	9,403
Current portion of equipment-based term loan	1,667	1,667
Current portion of capital lease obligations	373	516
	<hr/>	<hr/>
Total current liabilities	35,415	24,672
Equipment-based term loan, net of current portion	2,083	3,333
Capital lease obligations, net of current portion	265	504
	<hr/>	<hr/>
Total liabilities	37,763	28,509
	<hr/>	<hr/>
Commitments and contingencies (Note 5)		
Stockholders' equity:		
Preferred stock: \$0.0001 par value; Authorized: 5,000 shares; Issued and outstanding: none	—	—
Common stock: \$0.0001 par value; Authorized: 200,000; Issued: 58,518 and 57,740 at September 30, 2003 and December 31, 2002, respectively; Outstanding: 58,478 and 57,700 shares at September 30, 2003 and December 31, 2002, respectively	6	6
Additional paid-in capital	367,526	364,691
Deferred compensation	(8,057)	(19,005)
Notes receivable from stockholders	(344)	(892)
Accumulated other comprehensive income	—	17
Accumulated deficit	(301,044)	(280,470)
	<hr/>	<hr/>
Total stockholders' equity	58,087	64,347
	<hr/>	<hr/>
Total liabilities and stockholders' equity	\$ 95,850	\$ 92,856
	<hr/>	<hr/>

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,	
	2003	2002 As Restated	2003	2002 As Restated
Revenues	\$ 34,038	\$ 17,375	\$ 86,223	\$ 48,947
Cost of revenues	13,446	10,598	38,639	33,352
Gross profit	20,592	6,777	47,584	15,595
Operating expenses:				
Sales and marketing	10,505	11,459	32,551	33,780
General and administrative	8,722	9,899	25,630	29,727
Research and development	3,113	3,208	9,810	9,829
Total operating expenses	22,340	24,566	67,991	73,336
Loss from operations	(1,748)	(17,789)	(20,407)	(57,741)
Interest and other income (expense), net	(396)	(17)	(167)	318
Net loss	\$ (2,144)	\$ (17,806)	\$ (20,574)	\$ (57,423)
Net loss per share, basic and diluted	\$ (0.04)	\$ (0.38)	\$ (0.36)	\$ (1.23)
Shares used in computing net loss per share, basic and diluted	57,948	46,934	57,543	46,556

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,	
	2003	2002 As Restated
Cash Flows from Operating Activities:		
Net loss	\$ (20,574)	\$ (57,423)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation and amortization	6,927	10,078
Amortization of deferred stock compensation	10,228	12,447
Compensation expense for accelerated vesting of stock options	820	2,240
Stock-based compensation expense	942	1,781
Loss on retirement and disposal of fixed assets	195	3
Provision for doubtful accounts	229	712
Non-cash interest income on notes receivable from stockholders	(43)	(45)
Non-cash accretion on marketable securities	(2)	66
Changes in operating assets and liabilities:		
Accounts receivable	(4,257)	(5,228)
Inventories	(45)	88
Deferred costs	371	(244)
Other current assets	(846)	(2,346)
Accounts payable	(157)	(2,435)
Other accrued liabilities	7,207	(1,041)
Deferred revenue	3,898	4,487
	<u>4,893</u>	<u>(36,860)</u>
Cash Flows from Investing Activities:		
Purchase of property and equipment	(4,496)	(6,794)
Proceeds from sale of equipment	42	—
Restricted cash	(159)	350
Purchases of marketable securities	(5,390)	(1,972)
Maturities of marketable securities	6,069	11,169
Other assets	(14)	(250)
	<u>(3,948)</u>	<u>2,503</u>
Cash Flows from Financing Activities:		
Proceeds from issuance of common stock	1,799	917
Proceeds from payment on stockholders' notes receivable	591	225
Repurchase of common stock	(6)	(275)
Payments on debt obligations	(1,631)	(314)
	<u>753</u>	<u>553</u>
Net increase (decrease) in cash and cash equivalents	1,698	(33,804)
Cash and cash equivalents at beginning of period	35,552	50,550
Cash and cash equivalents at end of period	<u>\$ 37,250</u>	<u>\$ 16,746</u>

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, 2003 and December 31, 2002, its results of operations for the three and nine months ended September 30, 2003 and 2002, and its cash flows for the nine months ended September 30, 2003 and 2002. The December 31, 2002 balance sheet was restated and has been derived from the audited balance sheet included on Form 10-K/A. 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, 2002 included in the Company's amended Annual Report on Form 10-K/A filed with the Securities and Exchange Commission on August 13, 2003.

The results of operations for the three and nine months ended September 30, 2003 are not necessarily indicative of the results that may be expected for the year ending December 31, 2003 or any other interim period, and the Company makes no representations related thereto.

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

Restatement of Previously Issued Financial Statements

During the quarter ended June 30, 2003, in conjunction with Align's adoption of Emerging Issues Task Force Issue No. 00-21, Accounting for Revenue Arrangements with Multiple Deliverables (EITF 00-21), which addresses the issue of accounting for arrangements that involve the delivery of multiple products or services, the Company re-evaluated its prior accounting treatment for case refinement revenues under the principles contained in Staff Accounting Bulletin No. 101, Revenue Recognition in Financial Statements, (SAB 101) and related guidance. The Company determined that under SAB 101 the revenue amount deferred on advance sales of case refinement should be based on the stand-alone value of case refinement rather than the published discounted price for advance purchase. On July 24, 2003, the Company announced that, as a result of its review, it would restate its financial statements for fiscal 2001, fiscal 2002 and the first three months of fiscal 2003.

From June 2001 until April 2003, the Company offered customers the option to purchase a one-time, non-refundable case refinement at the time of the initial treatment plan purchase at a discounted price of \$50. Customers not electing to purchase the upfront case refinement (or requiring additional refinements i.e. in addition to the one purchased in advance) could subsequently purchase a case refinement at a price of \$250 (stand-alone value). The Company deferred \$50 of revenue and accrued the anticipated loss related to the cost

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of producing and delivering the related Aligners for discounted case refinements sold at the beginning of the treatment period. These deferred amounts were recognized when either the case refinement shipped or upon case expiration. Where the customer declined to purchase the \$50 upfront case refinement but subsequently purchased the \$250 stand-alone case refinement, the Company recognized the revenue associated with the \$250 stand-alone case refinement fee upon shipment of the new Aligners.

The following tables present amounts from operations as previously reported and as restated:

	Three Months Ended September 30, 2002		Nine Months Ended September 30, 2002	
	As Previously Reported	As Restated	As Previously Reported	As Restated
	(in thousands, except per share data)			
Revenues ⁽¹⁾	\$ 18,573	\$ 17,375	\$ 52,969	\$ 48,947
Cost of revenues ⁽¹⁾	10,880	10,598	34,159	33,352
Gross profit	7,693	6,777	18,810	15,595
Operating expenses	24,566	24,566	73,336	73,336
Loss from operations	(16,873)	(17,789)	(54,526)	(57,741)
Interest and other income (expense), net	(17)	(17)	318	318
Net loss ⁽²⁾	\$ (16,890)	\$ (17,806)	\$ (54,208)	\$ (57,423)
Net loss per share, basic and diluted ⁽²⁾	\$ (0.36)	\$ (0.38)	\$ (1.16)	\$ (1.23)
Shares used in computing net loss per share, basic and diluted	46,934	46,934	46,556	46,556

⁽¹⁾ Revenue and Cost of Revenue Adjustments:

The restatement of revenue from the additional deferral of case refinement revenue of \$200 per discounted case refinement purchased, due to the re-evaluation of the fair value of case refinement, resulted in a decrease of revenue related to these advance sales. Revenue for the three and nine-months ended September 30, 2002 decreased \$1,198,000 and \$4,022,000, respectively, compared to the previously reported amounts for the same time periods.

The restatement of revenue resulted in a corresponding adjustment to the cost of revenues due to the effect of the increased valuation of advance case refinement sales on the provision for estimated loss on sales i.e. no accrual for loss was required. Compared to amounts previously reported, the cost of revenues decreased by \$282,000 and \$807,000 for the three and nine months ended September 30, 2002, respectively.

⁽²⁾ Net Loss and Per Share Adjustments:

The adjustments in revenues and cost of revenue resulted in a net increase in net loss available to stockholders of \$916,000 and \$3,215,000 over the amounts previously reported for the three and nine months ended September 30 2002, respectively. Restated net loss per share increased \$(0.02) and \$(0.07) for the three and nine months ended September 30, 2002, respectively.

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Liabilities and Stockholders' Equity Adjustments

Deferred revenue increased \$5,598,000 and \$7,273,000 over the amounts previously reported as of September 30, 2002 and December 31, 2002, respectively, due to the deferral of additional case refinement revenue discussed above.

The restated accrued loss decreased by \$808,000 and \$1,000,000 over previously reported amounts as of September 30, 2002 and December 31, 2002, respectively.

The restated increase in deferred revenue and related decrease in accrued loss resulted in a net increase in accumulated deficit of \$4,790,000 and \$6,273,000 over amounts previously reported as of September 30, 2002 and December 31, 2002, respectively.

Reclassifications

In 2002, the Company made the decision to reclassify certain costs and expenses within the consolidated statements of operations. These reclassifications do not change net loss. The nature of the change centers around the classification of order administration expenses, bank processing fees and information technology costs among cost categories. The Company has historically expensed these costs in general and administrative expenses and other expense in the consolidated statements of operations. Current and future presentation of these expenses will be to allocate them to the functions utilizing the services.

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, 2003 or at December 31, 2002, or net revenues for the three and nine months ended September 30, 2003 or 2002.

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

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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.

Revenue Recognition

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

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

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

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.

The Company estimates and records 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.

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2. Balance Sheet Components

Inventories comprise (in thousands):

	September 30, 2003	December 31, 2002
Raw materials	\$ 973	\$ 931
Work in process	182	285
Finished goods	423	317
	<u>\$ 1,578</u>	<u>\$ 1,533</u>

Prepaid expenses and other current assets comprise (in thousands):

	September 30, 2003	December 31, 2002
Prepaid expenses	\$ 3,848	\$ 2,352
Other	1,903	2,536
	<u>\$ 5,751</u>	<u>\$ 4,888</u>

3. Net Loss Per Share

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2003	2002 As Restated	2003	2002 As Restated
Net loss	\$ (2,144)	\$ (17,806)	\$ (20,574)	\$ (57,423)
Basic and diluted:				
Weighted-average common shares outstanding	58,300	47,988	58,001	47,950
Less: Weighted-average shares subject to repurchase	(352)	(1,054)	(458)	(1,394)
Weighted-average shares used in basic and diluted net loss per share	<u>57,948</u>	<u>46,934</u>	<u>57,543</u>	<u>46,556</u>
Net loss per share, basic and diluted	<u>\$ (0.04)</u>	<u>\$ (0.38)</u>	<u>\$ (0.36)</u>	<u>\$ (1.23)</u>

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

	September 30,	
	2003	2002
Options to purchase common stock	8,575	7,650
Common stock subject to repurchase	312	953
	<u>8,887</u>	<u>8,603</u>

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. The following table illustrates the effect on net loss and net loss per common share if the Company had applied the fair value recognition provisions of SFAS 123 to stock-based employee compensation (in thousands, except per share data):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2003	2002 As Restated	2003	2002 As Restated
Net loss, as reported	\$ (2,144)	\$ (17,806)	\$ (20,574)	\$ (57,423)
Add: Stock-based employee compensation expense included in reported net loss	3,051	4,861	10,736	15,146
Deduct: Total stock-based employee compensation determined under fair value based method for all awards	(6,967)	(7,502)	(18,981)	(23,123)
Pro forma net loss	<u>\$ (6,060)</u>	<u>\$ (20,447)</u>	<u>\$ (28,819)</u>	<u>\$ (65,400)</u>
Basic and diluted net loss per common share:				
As reported	<u>\$ (0.04)</u>	<u>\$ (0.38)</u>	<u>\$ (0.36)</u>	<u>\$ (1.23)</u>
Pro forma	<u>\$ (0.10)</u>	<u>\$ (0.44)</u>	<u>\$ (0.50)</u>	<u>\$ (1.40)</u>

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 and Nine Months Ended September 30,	
	2003	2002
Risk free interest rate	2.96%	3.03%
Expected life	5 years	5 years
Expected volatility	90%	119.8%

5. Commitments and Contingencies

Short-term and Long-term Obligations

As of September 30, 2003, future minimum payments under lease obligations and financing agreements are as follows (in thousands):

	2003	2004	2005	2006	2007	Thereafter	Total
Operating leases	\$ 1,015	\$ 4,080	\$ 2,746	\$ 1,142	\$ 746	\$ 600	\$ 10,329
Capital lease obligations	145	348	187	—	—	—	680
Equipment-based term loan	417	1,667	1,666	—	—	—	3,750
Total	<u>\$ 1,577</u>	<u>\$ 6,095</u>	<u>\$ 4,599</u>	<u>\$ 1,142</u>	<u>\$ 746</u>	<u>\$ 600</u>	<u>\$ 14,759</u>

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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, 2003 (in thousands):

Warranty accrual, December 31, 2002	\$ 514
Charged to cost and expenses	1,278
Actual warranty expenses	(1,132)
	<hr/>
Warranty accrual, September 30, 2003	\$ 660

Legal Proceedings

On January 6, 2003, Ormco Corporation filed suit against Align 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, Align answered the complaint and asserted counterclaims seeking a declaration by the Court of invalidity and non-infringement of the asserted patents. In addition, Align counterclaimed for infringement of its U.S. Patent No. 6,398,548, seeking unspecified monetary damages and injunctive relief. Ormco filed a reply to Align's counterclaims on March 10, 2003 and asserted counterclaims against Align seeking a declaration by the Court of invalidity and non-infringement of U.S. Patent No. 6,398,548. Align responded to Ormco's counterclaims on April 2, 2003. At a Scheduling Conference held on June 30, 2003, the Court set a January 2, 2004, discovery cutoff and a May 2004 trial date. The Court also granted leave for Align to amend its counterclaim to add Allesee Orthodontic Appliances, Inc. ("AOA"), a wholly-owned subsidiary of Ormco, as a defendant in regard to the Company's claim of infringement of U.S. Patent No. 6,398,548. Align filed its amended answer and counterclaim on July 7, 2003.

On June 11, 2003, Ormco's wholly-owned subsidiary, AOA, filed a declaratory judgment action against Align in the Eastern District of Wisconsin, seeking a determination that U.S. Patent No. 6,398,548 (the same patent the Company is asserting against Ormco and AOA in the Central District of California) is invalid and/or not infringed. On July 9, 2003, Align answered the Wisconsin complaint and counterclaimed for infringement of U.S. Patent No. 6,398,548, seeking unspecified monetary damages and injunctive relief.

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On July 7, 2003, Ormco filed a motion in the Central District of California to sever Align's counterclaims and a motion to transfer those counterclaims to the Eastern District of Wisconsin. Also on July 7, 2003, Align filed a motion in the Central District of California to enjoin Ormco and AOA from proceeding with the action filed in the Eastern District of Wisconsin. The Central District of California denied Ormco's motion to sever, did not decide Ormco's motion to transfer and found Align's counterclaims were properly filed in the Central District of California, but denied Align's motion to enjoin without prejudice to renew, deferring to the Eastern District of Wisconsin to stay or dismiss the case pending in that District. Shortly thereafter, the parties stipulated to the dismissal of AOA's Wisconsin action. Currently pending before the Court is Ormco's motion to amend its complaint to add its newly-issued U.S. Patent No. 6,616,444 to this case. Align also seeks to add U.S. Patent No. 6,554,611 to this case.

Three years ago, Ormco filed suit against Align asserting infringement of U.S. Patent Nos. 5,447,432 and 5,683,243. In June 2000, the parties entered into a Stipulation of Dismissal with Ormco. Ormco agreed for a period of at least two years not to pursue litigation with respect to these patents, except as set forth below. Further, Ormco agreed that it would not bring any patent action against Align for at least a period of one year with respect to any as yet unissued patents. If Ormco were to bring such an action concerning as yet unissued patents after one year, the Stipulation of Dismissal would allow Ormco to include in such an action claims involving U.S. Patent Nos. 5,447,432 and 5,683,243. In August 2001, Ormco notified Align of the issuance of U.S. Patent No. 6,244,861 and offered a license for this patent. Align did not take a license to this patent. Five months after Ormco's notification, it filed the lawsuit that is currently pending.

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

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

Align strongly believes that Ormco's claims of infringement lack merit and that Align's counterclaim of infringement will be successful. However, the outcome of a lawsuit is inherently unpredictable. Should Align's technology be found to infringe any one of Ormco's asserted patents, Align would have to seek a license from Ormco, which license might not be available on commercially reasonable terms or at all. In that event, Align could be subject to damages or an injunction, which could materially adversely affect its business.

From time to time, we have received and may in the future receive letters from third parties drawing our attention to their patent rights. While we do not believe that we infringe upon any valid and enforceable rights that have been brought to our attention, there may be other more pertinent rights of which we are presently unaware. The defense and prosecution of intellectual property suits, interference proceedings and related legal and administrative proceedings could result in substantial expense to us and significant diversion of effort by our technical and management personnel. An adverse determination in a patent suit by Ormco or

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in any other litigation or interference proceeding to which we may become a party could subject us to significant liabilities. An adverse determination of this nature could also put our patents at risk of being invalidated or interpreted narrowly or require us to seek licenses from third parties. Licenses may not be available on commercially reasonable terms or at all, in which event, our business would be materially adversely affected.

On April 9, 2002, the Company exercised its right to terminate an Exclusive Marketing Agreement dated October 18, 2001 with Discus Dental Impressions, Inc. pursuant to the express terms of the agreement and issued a press release reporting this termination. On or about May 14, 2002 the Company received a demand for arbitration submitted by Discus Dental with the American Arbitration Association in San Jose, California. In its arbitration demand, Discus Dental sought damages of approximately \$30 million, including commissions and bonus payments it claims it would have allegedly received under the agreement as well as other expenses, attorneys' fees and injunctive relief to prevent the Company from selling Invisalign to dentists in the U.S. and Canada. Based on a review of the factual and legal issues, the Company denies all claims made by Discus Dental in its demand and contends that such claims are entirely without merit. In addition, on or about June 13, 2002 the Company submitted a counter-claim against Discus in the arbitration seeking damages of approximately \$40 million arising out of the Company's claims for misrepresentation, breach of confidentiality provisions, and unfair competition, among others. Three arbitrators were selected, and the arbitration hearing commenced in San Francisco on August 18, 2003. The parties completed presenting witness testimony on September 9, 2003. The parties completed all post-hearing legal briefing on October 10, 2003, and the closing argument was heard on October 29, 2003. Discus now seeks lost profit damages of \$46.5 million or loss of goodwill/out of pocket damages of \$13.5 million. Align previously and voluntarily dismissed its damage counter-claims but maintained its counter-claim for declaratory relief, seeking a judicial declaration that Align properly terminated the agreement with Discus. The arbitrators are expected to issue a ruling by the end of November, 2003.

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

6. Accumulated Other Comprehensive Income

Accumulated other comprehensive income consists entirely of unrealized gains and losses on available-for-sale securities as of December 31, 2002. There were no unrealized gains or losses as of September 30, 2003.

7. Recent Accounting Pronouncements

In January 2003, the Financial Accounting Standards Board ("FASB") issued FASB Interpretation No. 46 ("FIN 46"), "Consolidation of Variable Interest Entities, an Interpretation of ARB No. 51." FIN 46 requires certain variable interest entities to be consolidated by the primary beneficiary of the entity if the equity investors in the entity do not have the characteristics of a controlling financial interest or do not have sufficient equity at risk for the entity to finance its activities without additional subordinated financial support

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from other parties. FIN 46 is effective immediately for all new variable interest entities created or acquired after January 31, 2003. For variable interest entities created or acquired prior to February 1, 2003, the provisions of FIN 46 must be applied for the first interim or annual period ending after December 31, 2003. The Company does not expect the adoption of FIN 46 to have a material impact on its consolidated financial statements.

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

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

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

The following contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Words such as "anticipates," "expects," "intends," "plans," "believes," "seeks," "estimates" and similar expressions identify such forward-looking statements. These forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially from those indicated in the forward-looking statements. Factors which could cause actual results to differ materially include those set forth 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. Unless required by law, the Company undertakes no obligation to update publicly any forward-looking statements.

During the quarter ended June 30, 2003, in conjunction with Align's adoption of Emerging Issues Task Force Issue No. 00-21, Accounting for Revenue Arrangements with Multiple Deliverables (EITF 00-21), which addresses the issue of accounting for arrangements that involve the delivery of multiple products or services, Align re-evaluated its prior accounting treatment for case refinement revenues under the principles contained in Staff Accounting Bulletin No. 101, Revenue Recognition in Financial Statements, (SAB 101) and related guidance. Align determined that under SAB 101 the revenue amount deferred on advance sales of case refinement should be based on the stand-alone value of case refinement rather than the published discounted price for advance purchase. On July 24, 2003, Align announced that, as a result of its review, it would restate its financial statements for fiscal 2001, fiscal 2002 and the first three months of fiscal 2003.

Throughout the following analysis, all referenced amounts reflect the balances and amounts on a restated basis.

Overview

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

Two of our key production steps are performed in operations located outside of the U.S. At our facility in Costa Rica, technicians use a sophisticated, internally developed computer-modeling program to prepare electronic treatment plans, which are transmitted electronically back to the U.S. These electronic files form the basis of ClinCheck™ and are used to manufacture Aligner molds. A third party manufacturer in Mexico fabricates Aligners and ships the completed products to our customers.

Revenue from the sale of Invisalign and ancillary products is recognized upon product shipment, provided that no significant obligations remain, transfer of title has occurred and collection of the receivable

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is deemed probable. The costs of producing the ClinCheck™ treatment plan, which are incurred prior to the production of Aligners, are deferred and recognized as related revenues are earned, i.e. upon shipment of the Aligners.

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

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

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

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

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

We expect to expend significant capital to continue to build our national brand, expand our dental professional channel, automate our manufacturing processes and develop both product and process technology. In November 2002, we completed a private placement of common stock to a group of investors led by existing shareholders, raising \$18.1 million, net of issuance costs. In December 2002, we secured an accounts receivable-based revolving line of credit of up to \$10 million and an equipment-based term loan of \$5.0 million, which was fully drawn down in December 2002. As of September 30, 2003, we had not utilized the accounts receivable-based revolving line of credit. As of September 30, 2003, the equipment-based term loan had an outstanding balance of \$3.8 million. Accessing the accounts receivable-based revolving line of credit is restricted based on qualifying accounts receivable and compliance with certain loan covenants. However, there can be no assurance that such financing will be adequate for us to avoid reducing operating expenses by, among other things, reducing planned capital expenditures relating to enhancing our manufacturing process and reducing worldwide staff.

Results of Operations

As discussed in Note 1 to the condensed consolidated financial statements, we have restated our results for the three and nine-month periods ended September 30, 2002. All of the following analyses apply the basis of the restated amounts.

Revenues. Revenues for the quarter ended September 30, 2003 increased 95% to \$34.0 million from \$17.4 million for the quarter ended September 30, 2002. Revenues for the nine-month period ended September 30, 2003 increased 76% to \$86.2 million from \$48.9 million for the nine-month period ended September 30, 2002. Revenues derived from the sale of Invisalign were \$32.0 million for the quarter ended September 30, 2003 compared to Invisalign revenues of \$16.4 million for the quarter ended September 30, 2002. The increase in Invisalign revenues for the quarter ended September 30, 2003 as compared to the quarter ended September 30, 2002 was primarily the result of an increase in the domestic orthodontic channel of \$7.1 million, the domestic general practitioner channel of \$6.9 million and the international channel of \$1.6 million. Revenues derived from the sale of Invisalign were \$80.9 million for the nine-month period ended September 30, 2003 compared to Invisalign revenues of \$44.5 million for the nine-month period ended September 30, 2002. The increase in Invisalign revenues for the nine-month period ended September 30, 2003 as compared to the nine-month period ended September 30, 2002 was primarily the result of an increase in the domestic orthodontic channel of \$16.7 million, the domestic general practitioner channel of \$14.8 million and the international channel of \$4.9 million. For the three and nine-month periods ended September 30, 2003, growth in the domestic orthodontic and general practitioner channels resulted primarily from an increase in a growing number of participating clinicians and utilization within their practices. All channels benefited from Invisalign marketing promotion programs conducted during the nine-month period ended September 30, 2003. The balance of our revenues represented sales of training and ancillary products of \$2.0 million for the quarter ended September 30, 2003 and \$1.0 million for the quarter ended September 30, 2002. Sales of training and ancillary products were \$5.3 million and \$4.4 million for the nine-month periods ended September 30, 2003 and 2002, respectively.

Cost of revenues. Cost of revenues for the quarter ended September 30, 2003 was \$13.4 million compared to \$10.6 million for the quarter ended September 30, 2002. Cost of revenues for the nine-month period ended September 30, 2003 was \$38.6 million compared to \$33.4 million for the nine-month period ended September 30, 2002. Cost of revenues include the salaries for staff involved in production, the cost of materials and packaging, shipping costs, depreciation on the capital equipment used in the production process, under/over absorbed manufacturing capacity, training costs and the cost of facilities. Also included in cost of revenues are stock-based compensation expenses of \$0.6 million and \$0.8 million for the third quarters of fiscal 2003 and 2002, respectively. Included in cost of revenues are stock-based compensation expenses of \$2.0 million and \$2.7 million for the nine-month periods ended September 30, 2003 and 2002, respectively. Cost of revenues for the nine-month period ended September 30, 2003 also included approximately a \$0.4 million charge for use tax on production materials resulting from a state tax audit. Gross profit for the three-month period ended September 30, 2003 was \$20.6 million or 61% of revenue, compared to a gross profit of \$6.8 million or 39% of revenue for the three-month period ended September 30, 2002. Gross profit for the nine-month period ended September 30, 2003 was \$47.6 million or 55% of revenue, compared to a gross profit of \$15.6 million or 32% of revenue for the nine-month period ended September 30, 2002. The higher gross profit in the three-month and nine-month periods ended September 30, 2003 as compared to the same periods of fiscal 2002 reflects the benefits of cost reduction initiatives in our manufacturing process and

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improved fixed cost absorption related to increasing volumes. We believe that the gross profit percentage for fiscal 2003 will approximate the gross profit percentage for the nine-month period ended September 30, 2003.

Sales and marketing. Sales and marketing expenses for the quarter ended September 30, 2003 were \$10.5 million compared to \$11.5 million for the three-month period ended September 30, 2002. Sales and marketing expenses for the nine-month period ended September 30, 2003 were \$32.6 million compared to \$33.8 million for the nine-month period ended September 30, 2002. Sales and marketing expenses include sales force compensation (combined with expenses for professional marketing programs), conducting workshops and market surveys, advertising and attending dental professional trade shows. Sales and marketing expenses include stock-based compensation expenses of \$0.5 million and \$0.6 million in the third quarters of fiscal 2003 and 2002, respectively. Sales and marketing expenses for the nine-month periods ended September 30, 2003 and 2002 include stock-based compensation expenses of \$1.8 million and \$2.1 million, respectively. The decrease in sales and marketing expenses for the third quarter of 2003 as compared to the third quarter of 2002 resulted primarily from a decrease in spending of \$1.5 million for advertising and media in the U.S. Spending also decreased by \$0.2 million related to a reduction in our international sales and marketing work force in the third quarter of 2003 as compared to the third quarter of 2002. Decreases in sales and marketing spending were partially offset by an increase in spending of \$0.8 million related to incremental headcount in our North American sales work force. The decrease in sales and marketing expenses for the nine-month period ended September 30, 2003 as compared to the nine-month period ended September 30, 2002 resulted primarily from a decrease in spending of \$4.6 million in 2003 related to our reduction in our international sales and marketing work force. The reduction of the international sales and marketing work force was part of the plan during the second half of fiscal 2002 to streamline worldwide operations. The decrease in sales and marketing spending was offset by an increase in spending of \$2.7 million related to incremental headcount in our North American sales force and \$0.9 million in incremental media and advertisement costs for the nine-month period ended September 30, 2003 as compared to the nine-month period ended September 30, 2002.

General and administrative. General and administrative expenses for the quarter ended September 30, 2003 were \$8.7 million compared to \$9.9 million for the three-month period ended September 30, 2002. General and administrative expenses for the nine-month period ended September 30, 2003 were \$25.6 million compared to \$29.7 million for the nine-month period ended September 30, 2002. 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 \$1.6 million and \$2.9 million for the third quarters of fiscal 2003 and 2002, respectively. The decrease in general and administrative expenses for the three-month period ended September 30, 2003 over the three-month period ended September 30, 2002 resulted primarily from decreases in stock-based compensation of \$1.3 million and salaries of \$1.3 million related to a reduction in the worldwide administrative work force. Partially offsetting the decreases in spending was \$1.0 million of incremental legal expenses related to litigation matters in the third quarter of fiscal 2003 and \$0.4 million of incremental outside professional services. General and administrative expenses for the nine-month periods ended September 30, 2003 and 2002 include stock-based compensation expenses of \$5.7 million and \$9.3 million, respectively. The decrease in general and administrative expenses for the nine-month period ended September 30, 2003 over the nine-month period ended September 30, 2002 resulted primarily from decreases in stock-based compensation of \$3.6 million, and salaries of \$2.9 million and \$1.1 million related to reductions in the North American and international administrative work forces, respectively. Partially offsetting the decreases in spending were an increase of \$1.1 million in outside consultant costs, incremental legal expenses of \$1.0 million related to litigation matters, and a sales tax charge of \$1.4 million incurred during the second quarter of fiscal 2003. The

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sales tax charge of \$1.4 million was in connection with sales tax for which Align decided not to pursue collection from its customers.

Research and development. Research and development expenses for the quarter ended September 30, 2003 were \$3.1 million and \$3.2 million for the quarter ended September 30, 2002. Research and development expenses for both the nine-month periods ended September 30, 2003 and 2002 were \$9.8 million. 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 \$0.6 million and \$0.8 million of stock-based compensation for the third quarters of fiscal 2003 and 2002, respectively. Research and development expenses included \$2.5 million of stock-based compensation for both the nine-month periods ended September 30, 2003 and 2002, respectively.

Interest and other income (expense), net. Interest and other income (expense) was (\$0.4) million for the quarter ended September 30, 2003 compared to \$17,000 for the quarter ended September 30, 2002. Interest and other income (expense) was (\$0.2) million for the nine-month period ended September 30, 2003 and \$0.3 million for the nine-month period ended September 30, 2002. Interest and other expenses increased by \$0.2 million for the three and nine-month periods ended September 30, 2003 compared to the three and nine-month periods ended September 30, 2002. Interest income decreased by \$0.1 million and \$0.5 million for the three and nine-month periods ended September 30, 2003, respectively, primarily due to lower interest rates paid on cash, cash equivalent and marketable securities balances as compared to the three and nine-month periods ended September 30, 2002. Foreign currency translation gain increased \$0.2 million for the nine-month periods ended September 30, 2003 compared to the nine-month periods ended September 30, 2002.

Stock-based compensation. In connection with the grant of stock options to employees and non-employees prior to 2001, we recorded deferred stock-based compensation as a component of stockholders' equity. Deferred stock-based compensation for options granted to employees is the difference between the fair value of our common stock on the date such options were granted and their exercise price. For stock options granted to non-employees, the fair value of the options, estimated using the Black-Scholes valuation model, is initially recorded on the date of grant. As the non-employee options vest, we revalue the remaining unvested options, with the change in fair value from period to period represented as a change in deferred compensation. This stock-based compensation is amortized as charges to operations over the vesting periods of the options. For the quarters ended September 30, 2003 and 2002, we recorded amortization of deferred compensation of \$3.1 million and \$3.8 million, respectively. Additionally, we recorded expenses of \$0.3 million for each of the quarters ended September 30, 2003 and 2002, related to options granted to non-employees. For the nine-month periods ended September 30, 2003 and 2002, we recorded amortization of deferred compensation of \$10.2 million and \$12.4 million, respectively. Additionally, we recorded expenses of \$0.9 million and \$1.8 million for the nine-month periods ended September 30, 2003 and 2002, respectively, related to options granted to non-employees.

We have accelerated the vesting of options to several employees in connection with severance packages. This acceleration was accounted for as a charge to the condensed consolidated statements of operations. We had no such charge for the quarter ended September 30, 2003. We recorded a charge of \$0.9 million for the quarter ended September 30, 2002. We recorded charges of \$0.8 million and \$2.2 million for the nine-month periods ended September 30, 2003 and 2002, respectively. Each respective charge is equal to

the intrinsic value difference between the exercise price of the accelerated options and the fair value of the common stock on the date of acceleration.

Liquidity and Capital Resources

Historically, we have funded our operations with the proceeds from the sale of our common and preferred stock, an equipment-based term loan and bridge loans. As of September 30, 2003, we had \$37.3 million of cash and cash equivalents, restricted cash of \$3.4 million and short-term marketable securities of \$2.0 million. We had an accumulated deficit of \$301.0 million as of September 30, 2003.

Net cash provided by (used in) operating activities totaled \$4.9 million and (\$36.9) million for the nine-month periods ended September 30, 2003 and 2002, respectively. Net cash provided by operating activities for the nine-month period ended September 30, 2003 consisted primarily of increases in accrued liabilities and deferred revenue, partially offset by operating losses and increases in accounts receivable. For the nine-month period ended September 30, 2002, net cash used in operating activities resulted primarily from operating losses and increases in accounts receivable balances.

Net cash used in investing activities totaled \$3.9 million for the nine-month period ended September 30, 2003 and net cash provided by investing activities totaled \$2.5 million for the nine-month period ended September 30, 2002. 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 operating activities. For the nine-month period ended September 30, 2002, net cash provided by investing activities resulted primarily from the maturities of marketable securities, partially offset by the purchases of property and equipment.

Net cash provided by financing activities was \$0.8 million and \$0.6 million for the nine-month periods ended September 30, 2003 and 2002, respectively. For both the nine-month periods ended September 30, 2003 and 2002, net cash provided by financing activities consisted of proceeds from the issuance of common stock, partially offset by payments on debt obligations.

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

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Short-term and Long-term Obligations

As of September 30, 2003, future minimum payments under lease obligations and financing agreements are as follows (in thousands):

	2003	2004	2005	2006	2007	Thereafter	Total
Operating leases	\$ 1,015	\$ 4,080	\$ 2,746	\$ 1,142	\$ 746	\$ 600	\$ 10,329
Capital lease obligations	145	348	187	—	—	—	680
Equipment-based term loan	417	1,667	1,666	—	—	—	3,750
Total	\$ 1,577	\$ 6,095	\$ 4,599	\$ 1,142	\$ 746	\$ 600	\$ 14,759

Critical Accounting Policies

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

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

Revenue Recognition

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

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

In May 2003, we updated our domestic pricing policy to include the future delivery of one case refinement in the price of each case and to offer additional case refinements at a price of \$125 each, which we

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believe represents its fair value based on competitive product offerings. Revenue deferrals associated with future case refinement after May 1, 2003 are \$125 per case. This revenue deferral amount represents the fair value of a case refinement as determined in accordance with the newly adopted rules contained in EITF 00-21, which addresses the issue of accounting for arrangements that involve the delivery of multiple products or services. These revenue deferrals will be recognized when the case refinement has been utilized or upon case expiration.

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

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

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 known to us. 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.

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 considered important which 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.

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

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accordingly. Revisions of our estimates of such potential liability could materially impact our results of operations and financial condition.

Deferred Tax Valuation Allowance

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

Recent Accounting Pronouncements

In January 2003, the Financial Accounting Standards Board (“FASB”) issued FASB Interpretation No. 46 (“FIN 46”), “Consolidation of Variable Interest Entities, an Interpretation of ARB No. 51.” FIN 46 requires certain variable interest entities to be consolidated by the primary beneficiary of the entity if the equity investors in the entity do not have the characteristics of a controlling financial interest or do not have sufficient equity at risk for the entity to finance its activities without additional subordinated financial support from other parties. FIN 46 is effective immediately for all new variable interest entities created or acquired after January 31, 2003. For variable interest entities created or acquired prior to February 1, 2003, the provisions of FIN 46 must be applied for the first interim or annual period ending after December 31, 2003. Align does not expect the adoption of FIN 46 to have a material impact on its consolidated financial statements.

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

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

RISK FACTORS

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

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

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

We continue to incur significant operating expenses to:

- develop new software and increase the automation of our manufacturing processes;
- execute our consumer advertising campaign and dental professional marketing efforts;
- increase the size of our sales force and dental professional training staff;
- execute clinical research and education plans;
- develop technological improvements to our products;
- continue our international sales and marketing efforts; and
- undertake quality assurance and improvement initiatives.

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

in the future, if at all, and even if we do achieve profitability, we may not be able to sustain or increase profitability in future periods.

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

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

- changes in the timing of product orders;
- unanticipated delays in production caused by insufficient capacity, any disruptions in the manufacturing process or the introduction of new production processes;
- inaccurate forecasting of revenue, production and other operating costs; and
- the development and marketing of directly competitive products by potential competitors.

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

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

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

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

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

Our success depends upon increasing acceptance of Invisalign by dental professionals. Invisalign requires dental professionals and their staff to undergo special training and learn to interact with patients in new ways. In addition, because Invisalign has only been in clinical testing since July 1997 and commercially available only since July 1999, dental professionals may be reluctant to adopt it until more historical clinical

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results are available. Also, increasing adoption and cumulative use by dental professionals will depend on factors such as the capability, safety, efficacy, ease of use, price, quality and reliability of our products and our provision of effective sales support, training and service. In the future, unanticipated poor clinical performance of Invisalign could result in significant adverse publicity and, consequently, reduced acceptance by dental professionals. If Invisalign does not achieve growing acceptance in the orthodontic and dental communities, our operating results will be harmed.

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

Invisalign represents a significant change from traditional orthodontic treatment, and patients may be reluctant to accept it or may not find it preferable to conventional treatment. In addition, patients may not comply with recommended treatment guidelines for Invisalign, which could compromise the effectiveness of their treatment. We have generally received positive feedback from both dental professionals and patients regarding Invisalign as both an alternative to braces and as a clinical method for treatment of malocclusion, but a number of dental professionals believe that Invisalign is appropriate for only a limited percentage of their patients. Our success will depend upon the acceptance of Invisalign by a substantially larger number of dental professionals and potential patients to whom we are now actively marketing. We have had a limited number of complaints from patients and prospective patients generally related to shipping delays and minor manufacturing irregularities. Market acceptance will depend in part upon the recommendations of dental professionals, as well as other factors including effectiveness, safety, reliability, improved treatment aesthetics and greater comfort and hygiene compared to conventional orthodontic products. Furthermore, consumers may not respond to our direct marketing campaigns or we may be unsuccessful in reaching our target audience. Adoption by consumers may also be impacted by general macroeconomic conditions, including the economic downturn and increased unemployment levels in the United States of America, levels of consumer confidence and consumer spending, all of which fluctuate and could be affected by unstable global economic, political or other conditions. If orthodontists and dentists experience a reduction in consumer demand for orthodontic services or consumers prove unwilling to adopt Invisalign as rapidly as we anticipate or in the volume that we anticipate, our operating results will be harmed.

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

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

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

- political, social and economic instability;
- acts of terrorism and acts of war;

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- difficulties in staffing and managing international operations;
- controlling quality of the manufacturing process;
- interruptions and limitations in telecommunication services;
- product or material transportation delays or disruption;
- burdens of complying with a wide variety of local country and regional laws;
- trade restrictions and changes in tariffs;
- import and export license requirements and restrictions;
- fluctuations in currency exchange rates; and
- potential adverse tax consequences.

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

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

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

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

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

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

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

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

Three years ago, Ormco filed suit against us asserting infringement of U.S. Patent Nos. 5,447,432 and 5,683,243. In June 2000, the parties entered into a Stipulation of Dismissal with Ormco. Ormco agreed for a period of at least two years not to pursue litigation with respect to these patents, except as set forth below. Further, Ormco agreed that it would not bring any patent action against us for at least a period of one year with respect to any as yet unissued patents. If Ormco were to bring such an action concerning as yet unissued patents after one year, the Stipulation of Dismissal would allow Ormco to include in such an action claims involving U.S. Patent Nos. 5,447,432 and 5,683,243. In August 2001, Ormco notified us of the issuance of U.S. Patent No. 6,244,861 and offered a license for this patent. We did not take a license to this patent. Five months after Ormco's notification, it filed the lawsuit that is currently pending.

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

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

We strongly believe that Ormco's claims of infringement lack merit and that Align's counterclaim of infringement will be successful. However, the outcome of a lawsuit is inherently unpredictable. Should our technology be found to infringe any one of Ormco's asserted patents, we would have to seek a license from Ormco, which license might not be available on commercially reasonable terms or at all. In that event, we could be subject to damages or an injunction, which could materially adversely affect its business.

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

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

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

On April 9, 2002, we exercised our right to terminate an Exclusive Marketing Agreement dated October 18, 2001 with Discus Dental Impressions, Inc. pursuant to the express terms of the Agreement and issued a press release reporting this termination. On or about May 14, 2002 we received a demand for arbitration submitted by Discus Dental with the American Arbitration Association in San Jose, California. In its arbitration demand, Discus Dental sought damages of approximately \$30 million, including commissions and bonus payments it claims it would have allegedly received under the Agreement as well as other

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

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

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

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

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

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

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

We are highly dependent on the key employees in our clinical engineering and management teams. The loss of the services of those individuals may significantly delay or prevent the achievement of our

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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, Inc. have substantially greater financial resources and manufacturing and marketing experience than we do and may, in the future, attempt to develop an orthodontic system similar to ours. Large consumer product companies may also enter the orthodontic supply market. Furthermore, we may face competition in the future from new companies that may introduce new technologies. We may be unable to compete with these competitors and one or more of these competitors may render our technology obsolete or economically unattractive. If we are unable to compete effectively with existing products or respond effectively to any products developed by our competitors, our business could be harmed.

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

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

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

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

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

- product design, development, manufacture and testing;

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- product labeling;
- product storage;
- pre-market clearance or approval;
- advertising and promotion; and
- product sales and distribution.

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

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

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

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

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

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

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

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

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

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

- storage, transmission and disclosure of medical information and healthcare records;
- prohibitions against the offer, payment or receipt of remuneration to induce referrals to entities providing healthcare services or goods; and
- the marketing and advertising of our products.

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

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

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

consumers outside our domestic market will adopt Invisalign in sufficient numbers or as rapidly as we anticipate.

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

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

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

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

- quarterly variations in our results of operations and liquidity;
- changes in recommendations by the investment community or in their estimates of our revenues or operating results;
- speculation in the press or investment community concerning our business and results of operations;
- strategic actions by our competitors, such as product announcements or acquisitions; and
- announcements of technological innovations or new products by us, our customers or competitors; and general market conditions.

In addition, the stock market in general, and the market for technology and medical device companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated to or disproportionate to the operating performance of those companies. These broad market and industry factors may seriously harm the market price of our common stock, regardless of our operating performance. In the past, class action litigation has often been brought against the issuing company following periods of volatility in the market price of a company's securities. If a securities class action suit is filed against us in the future, we would incur substantial legal fees, and our management's attention and resources would be diverted from operating our business in order to respond to the litigation.

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

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

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

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

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

Interest Rate Risk. We are subject to interest rate risks on cash and cash equivalents, available-for-sale marketable securities, existing long-term debts and any future financing requirements. Interest rate risks related to marketable securities are managed by managing maturities in our marketable securities portfolio. The long-term debt at September 30, 2003 consists of outstanding principal balances on lease obligations and an equipment-based term loan of \$0.6 million and \$3.8 million, respectively.

The fair value of our investment portfolio or related income would not be significantly impacted by changes in interest rates since the marketable securities maturities do not exceed fiscal year 2003. Our capital lease obligations of \$0.6 million at September 30, 2003 carry fixed interest rates of 6.53% and 11.15% per annum with principal payments due in 60 and 48 monthly installments, respectively, beginning in 2000.

Our primary interest rate risk exposures relate to:

- The available-for-sale securities will fall in value if market interest rates increase;

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- Our ability to pay long-term debts at maturity; and
- The impact of interest rate movements on our ability to obtain adequate financing to fund future operations.

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

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

Currency Rate Risk. Our primary currency rate risk exposures relate to our decentralized or outsourced operations, whereby, based on fiscal 2002 results, approximately \$18.2 million of our annual expenses are related to operations outside the United States, denominated in currencies other than the U.S. dollar.

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

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-14(c) and 15d-14(c) 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 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 significant 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 affect, our internal controls over financial reporting.

PART II—OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

On January 6, 2003, Ormco Corporation filed suit against Align 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, Align answered the complaint and asserted counterclaims seeking a declaration by the Court of invalidity and non-infringement of the asserted patents. In addition, Align counterclaimed for infringement of its U.S. Patent No. 6,398,548, seeking unspecified monetary damages and injunctive relief. Ormco filed a reply to Align's counterclaims on March 10, 2003 and asserted counterclaims against Align seeking a declaration by the Court of invalidity and non-infringement of U.S. Patent No. 6,398,548. Align responded to Ormco's counterclaims on April 2, 2003. At a Scheduling Conference held on June 30, 2003, the Court set a January 2, 2004, discovery cutoff and a May 2004 trial date. The Court also granted leave for Align to amend its counterclaim to add Allesee Orthodontic Appliances, Inc. ("AOA"), a wholly-owned subsidiary of Ormco, as a defendant in regard to the Company's claim of infringement of U.S. Patent No. 6,398,548. Align filed its amended answer and counterclaim on July 7, 2003.

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

Three years ago, Ormco filed suit against Align asserting infringement of U.S. Patent Nos. 5,447,432 and 5,683,243. In June 2000, the parties entered into a Stipulation of Dismissal with Ormco. Ormco agreed for a period of at least two years not to pursue litigation with respect to these patents, except as set forth below. Further, Ormco agreed that it would not bring any patent action against Align for at least a period of one year with respect to any as yet unissued patents. If Ormco were to bring such an action concerning as yet unissued patents after one year, the Stipulation of Dismissal would allow Ormco to include in such an action claims involving U.S. Patent Nos. 5,447,432 and 5,683,243. In August 2001, Ormco notified Align of the issuance of U.S. Patent No. 6,244,861 and offered a license for this patent. Align did not take a license to this patent. Five months after Ormco's notification, it filed the lawsuit that is currently pending.

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

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

Align strongly believes that Ormco's claims of infringement lack merit and that Align's counterclaim of infringement will be successful. However, the outcome of a lawsuit is inherently unpredictable. Should Align's technology be found to infringe any one of Ormco's asserted patents, Align would have to seek a license from Ormco, which license might not be available on commercially reasonable terms or at all. In that event, Align could be subject to damages or an injunction, which could materially adversely affect its business.

On April 9, 2002, Align exercised its right to terminate an Exclusive Marketing Agreement dated October 18, 2001 with Discus Dental Impressions, Inc. pursuant to the express terms of the agreement and issued a press release reporting this termination. On or about May 14, 2002 Align received a demand for arbitration submitted by Discus Dental with the American Arbitration Association in San Jose, California. In its arbitration demand, Discus Dental sought damages of approximately \$30 million, including commissions and bonus payments it claims it would have allegedly received under the agreement as well as other expenses, attorneys' fees and injunctive relief to prevent Align from selling Invisalign to dentists in the U.S. and Canada. Based on a review of the factual and legal issues, Align denies all claims made by Discus Dental in its demand and contends that such claims are entirely without merit. In addition, on or about June 13, 2002 Align submitted a counter-claim against Discus in the arbitration seeking damages of approximately \$40 million arising out of Align's claims for misrepresentation, breach of confidentiality provisions, and unfair competition, among others. Three arbitrators were selected, and the arbitration hearing commenced in San Francisco on August 18, 2003. The parties completed presenting witness testimony on September 9, 2003. The parties completed all post-hearing legal briefing on October 10, 2003, and the closing argument was heard on October 29, 2003. Discus now seeks lost profit damages of \$46.5 million or loss of goodwill/out of pocket damages of \$13.5 million. Align previously and voluntarily dismissed its damage counter-claims but maintained its counter-claim for declaratory relief, seeking a judicial declaration that Align properly terminated the agreement with Discus. The arbitrators are expected to issue a ruling by the end of November, 2003.

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

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ITEM 2. CHANGES IN SECURITIES AND USE OF PROCEEDS

Not applicable.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

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

Not applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K

(a) Exhibits:

<u>Exhibit Number</u>	<u>Description</u>
10.37	Director Offer Letter dated July 18, 2003 for Gregory J. Santora.
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.

(b) Reports on Form 8-K:

On October 23, 2003, Align filed a report on Form 8-K, reporting under Item 5 the announcement that on October 23, 2003 Align issued a press release announcing financial results for the third quarter of fiscal 2003, which ended on September 30, 2003.

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 12, 2003

ALIGN TECHNOLOGY, INC.

By: /s/ THOMAS M. PRESCOTT

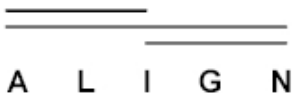
Thomas M. Prescott
President and Chief Executive Officer

By: /s/ ELDON M. BULLINGTON

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

EXHIBIT INDEX

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July 18, 2003

Via Federal Express Delivery

Mr. Gregory J. Santora
4201 Grant Court
Pleasanton, CA 94566

Re: Offer to join the Board of Directors

Dear Greg:

On behalf of Align Technology, Inc. (the "Company"), I am extremely pleased to invite you to become a member of the Company's Board of Directors (the "Board"). We believe that your skills, expertise and knowledge will prove very helpful to the Company's progress.

In connection with your service as a director, we will recommend to the Board that you be granted a stock option entitling you to purchase up to 75,000 shares of the Company's Common Stock. We will recommend that the shares become vested as follows: 25% of the option shall vest on the 12 month anniversary of the commencement of your service as a director, and the remaining 75% shall vest in 36 equal monthly installments. In addition, the option will fully accelerate upon the occurrence of a Change in Control of the Company (as that term is defined in the Company's 2001 Stock Incentive Plan (the "Plan")). Each option granted to you will be subject to the terms and conditions of the Plan and the stock option agreement evidencing the option. The exercise price per share will be equal to the fair market value of the Company's common stock on the date of grant, as determined by the Board.

In addition, you will be entitled to receive cash compensation in accordance with Schedule A attached hereto. You will be reimbursed for reasonable expenses incurred by you in connection with your services to the Company in accordance with the Company's established policies.

The Board currently meets once every two months at our offices in Santa Clara. The various committees of the Board to which you may be appointed also meet frequently. It is our expectation that you will participate in those meetings in person to the extent possible. We also ask that you make yourself available to participate in various telephonic meetings from time to time.

Please note that this offer is contingent upon your qualification as an independent director under applicable NASDAQ rules. Also, please note that this offer and any rights to purchase shares of the Company's capital stock referenced in this offer letter are contingent upon approval of the Board and the Company's stockholders.

Your service on the Board of Directors will be in accordance with, and subject to, the Company's Bylaws and the Certificate of Incorporation, as such may be amended from time to time. In accepting this offer, you are representing to us that (i) you do not know of any conflict that would

restrict you from becoming a director of the Company and (ii) you will not provide the Company with any documents, records or other confidential information belonging to any other parties.

This offer is considered confidential information and we trust that you will treat it as such. If you wish to accept this offer, please sign below and return the fully executed letter to us. You should keep one copy of this letter for your own records. This letter sets forth the terms of your service with the Company and supersedes any prior representations or agreements, whether written or oral. This letter may not be modified or amended except by a written agreement, signed by an officer of the Company and by you.

We are looking forward to having you join us at the Company. We believe that your enthusiasm and past experience will be an asset to the Company and that you will have a positive impact on the organization. If you have any questions, please call me at (408) 470-1112.

Sincerely,

Align Technology, Inc.

/s/ THOMAS M. PRESCOTT

Thomas M. Prescott

Accepted and agreed to this

19th day of July, 2003

/s/ GREGORY J. SANTORA

Gregory J. Santora

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 12, 2003

/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 12, 2003

/s/ ELDON M. BULLINGTON

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

**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, 2003 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in 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 12, 2003

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, 2003 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in 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 12, 2003

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