ALIGN TECHNOLOGY INC
Form 10-Q/A
August 13, 2003
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q/A

(Mark One)

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

For the quarterly period ended March 31, 2003

OR

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

For the transition period from ______ to ______

Commission file number: 0-32259

Align Technology, Inc.

(Exact name of Registrant as Specified in its Charter)

Delaware	**94-3267295**
(State or Other Jurisdiction of	**(I.R.S. Employer**
Incorporation or Organization)	**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 x No ¨

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

The number of shares outstanding of the registrant s Common Stock, $0.001 par value, as of April 30, 2003 was 57,849,270.

EXPLANATORY NOTE

THIS QUARTERLY REPORT ON FORM 10-Q/A IS BEING FILED FOR THE PURPOSE OF AMENDING AND RESTATING ITEMS 1, 2 AND 4 OF PART 1 AND ITEMS 3 AND 6 OF PART II OF FORM 10-Q (EXCLUDING RISK FACTORS) SOLELY TO THE EXTENT NECESSARY (I) TO REFLECT THE RESTATEMENT OF OUR CONDENSED CONSOLIDATED FINANCIAL STATEMENTS AS OF AND FOR THE PERIODS ENDED MARCH 31, 2003 AND MARCH 31, 2002, AS DESCRIBED IN NOTE 1 TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS, (II) TO MAKE REVISIONS TO MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS , AS WARRANTED BY THE RESTATEMENT, (III) TO INCLUDE THE CERTIFICATIONS REQUIRED BY THE SARBANES-OXLEY ACT OF 2002 AND (IV) TO UPDATE THE EXHIBITS AND REPORTS ON FORM 8-K IN ACCORDANCE WITH THE AMENDMENT. WE HAVE MADE NO FURTHER CHANGES TO THE PREVIOUSLY FILED FORM 10-Q. ALL INFORMATION IN THIS QUARTERLY REPORT ON FORM 10-Q/A IS AS OF MARCH 31, 2003 AND DOES NOT REFLECT ANY SUBSEQUENT INFORMATION OR EVENTS OTHER THAN THOSE REFLECTED IN THE RESTATEMENT.

Align Technology, Inc. (Align) has not amended its Annual Report on Form 10-K for the period ended December 31, 2001 or Quarterly Reports on Form 10-Q for the periods affected by the restatement during the years ended December 31, 2002 or 2001, therefore, the consolidated financial statements and related financial information contained therein should no longer be relied upon. The condensed consolidated balance sheet for the year ended December 31, 2002 and the condensed consolidated statement of operations and cash flows for the period ended March 31, 2002 are included as part of the condensed consolidated financial statements included in this Quarterly Report on Form 10-Q/A. See Align s Annual Report on Form 10-K/A for the period ended December 31, 2002 for more information on the effects of the restatement on prior periods.

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PART I FINANCIAL INFORMATION

ITEM 1 FINANCIAL STATEMENTS

ALIGN TECHNOLOGY, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands)

(unaudited)

	March 31, 2003 Restated	December 31, 2002 Restated
ASSETS		
Current assets:		
Cash and cash equivalents	$ 33,997	$ 35,552
Restricted cash	3,265	3,261
Marketable securities, short-term		2,693
Accounts receivable, net	17,078	16,766
Inventories, net	1,762	1,533
Deferred costs	1,031	1,139
Other current assets	6,650	4,888
Total current assets	63,783	65,832
Property and equipment, net	23,787	25,078
Other assets	2,093	1,946
Total assets	$ 89,663	$ 92,856
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 2,078	$ 1,974
Other accrued liabilities	12,313	11,112
Deferred revenue	11,541	9,403
Current portion of equipment-based term loan	1,667	1,667
Current portion of capital lease obligations	470	516
Total current liabilities	28,069	24,672
Equipment-based term loan, net of current portion	2,917	3,333
Capital lease obligations, net of current portion	425	504
Total liabilities	31,411	28,509
Commitments and contingencies (Note 6)		
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: 57,871 and 57,740 at March 31, 2003 and December 31, 2002, respectively; Outstanding: 57,831 and 57,700	6	6

shares at March 31, 2003 and December 31, 2002, respectively		
Additional paid-in capital	365,117	364,691
Deferred compensation	(14,938)	(19,005)
Notes receivable from stockholders	(792)	(892)
Accumulated other comprehensive income		17
Accumulated deficit	(291,141)	(280,470)
Total stockholders equity	58,252	64,347
Total liabilities and stockholders equity	$ 89,663	$ 92,856

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

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ALIGN TECHNOLOGY, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per share data)

(unaudited)

	Three Months Ended March 31,	
	2003 Restated	2002 Restated
Revenues	$ 22,960	$ 15,858
Cost of revenues	11,924	12,024
Gross profit	11,036	3,834
Operating expenses:		
Sales and marketing	10,630	10,327
General and administrative	7,894	9,871
Research and development	2,985	3,346
Total operating expenses	21,509	23,544
Loss from operations	(10,473)	(19,710)
Interest and other income (expense), net	(198)	406
Net loss	$ (10,671)	$ (19,304)
Net loss per share, basic and diluted	$ (0.19)	$ (0.42)
Shares used in computing net loss per share, basic and diluted	57,189	46,152

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

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ALIGN TECHNOLOGY, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

(unaudited)

	Three Months Ended March 31,	
	2003 Restated	**2002 Restated**
Cash Flows from Operating Activities:		
Net loss	$ (10,671)	$ (19,304)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	2,297	2,913
Amortization of deferred stock compensation	3,641	4,827
Compensation expense for accelerated vesting of stock options	370	118
Stock-based compensation expense	252	653
Loss on retirement, disposal and impairment of fixed assets	145	3
Allowance for doubtful accounts	(4)	(1)
Non-cash interest (income) expense on notes receivable from stockholders	(20)	6
Non-cash accretion on marketable securities	12	25
Changes in operating assets and liabilities:		
Accounts receivable	(308)	(2,916)
Inventories	(229)	95
Deferred costs	108	167
Other current assets	(1,745)	(731)
Accounts payable	(434)	(1,900)
Other accrued liabilities	1,201	(148)
Deferred revenue	2,138	1,510
Net cash used in operating activities	(3,247)	(14,683)
Cash Flows from Investing Activities:		
Purchase of property and equipment	(630)	(2,713)
Restricted cash	(4)	387
Maturities of marketable securities	2,669	2,100
Other assets	(147)	69
Net cash provided by (used in) investing activities	1,888	(157)
Cash Flows from Financing Activities:		
Proceeds from issuance of common stock	225	556
Proceeds from payment on stockholders notes receivable	120	195
Repurchase of common stock		(175)
Payments on debt obligations	(541)	(117)
Net cash (used in) provided by financing activities	(196)	459

Net decrease in cash and cash equivalents	(1,555)	(14,381)
Cash and cash equivalents at beginning of period	35,552	50,550
Cash and cash equivalents at end of period	$ 33,997	$ 36,169

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

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ALIGN TECHNOLOGY, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(unaudited)

Throughout these notes to the condensed consolidated financial statements all referenced amounts reflect the balances and amounts on a restated basis.

1. Restatement of Previously Issued Financial Statements

During the quarter ended June 30, 2003, in conjunction with Align Technology, Inc. s (the Company) 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 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 March 31,			
	2003		2002	
	(in thousands, except per share data)			
	As Previously Reported	As Restated	As Previously Reported	As Restated

Revenues (1)	$ 24,735	$ 22,960	$ 17,141	$ 15,858
Cost of revenues (1)	11,810	11,924	12,505	12,024
Gross profit	12,925	11,036	4,636	3,834
Operating expenses	21,509	21,509	23,544	23,544
Loss from operations	(8,584)	(10,473)	(18,908)	(19,710)
Interest and other income (expense), net	(198)	(198)	406	406
Net loss (2)	$ (8,782)	$ (10,671)	$ (18,502)	$ (19,304)
Net loss per share, basic and diluted (2)	$ (0.15)	$ (0.19)	$ (0.40)	$ (0.42)
Shares used in computing net loss per share, basic and diluted	57,189	57,189	46,152	46,152

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(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 decreased $1,775,000 and $1,283,000 compared to the previously reported amounts for the three months ended March 31, 2003 and 2002, respectively.

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 increased by $114,000 for the three months ended March 31, 2003 and decreased by $481,000 for the three months ended March 31, 2002

(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 $1,889,000 and $802,000 over the amounts previously reported for the three months ended March 31, 2003 and 2002, respectively. Restated net loss per share increased $(0.04) and $(0.02) for the three months ended March 31, 2003 and 2002, respectively.

(3) Liabilities and Stockholders Equity Adjustments

Deferred revenue increased $9,048,000 and $7,273,000 over the amounts previously reported as of March 31, 2003 and December 31, 2002, respectively, due to the deferral of additional case refinement revenue discussed above.

The restated accrued loss decreased by $886,000 and $1,000,000 over previously reported amounts as of March 31, 2003 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 $8,162,000 and $6,273,000 over amounts previously reported as of March 31, 2003 and December 31, 2002, respectively.

2. Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared by the Company 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 March 31, 2003 and December 31, 2002, and its results of operations and cash flows for the three months ended March 31, 2003 and 2002. 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 Annual Report on Form 10-K/A filed with the Securities and Exchange Commission on August 13, 2003.

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The results of operations for the three months ended March 31, 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.

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

Financial instruments which potentially expose the Company to concentrations of credit risk consist primarily of cash equivalents and accounts receivable. The Company invests excess cash primarily in money market funds of major financial institutions, commercial paper and notes. The Company provides credit to customers in the normal course of business. Collateral is not required for accounts receivable, but ongoing evaluations of customers credit worthiness are performed. The Company maintains reserves for potential credit losses and such losses have been within management s expectations. No individual customer accounted for 10% or more of the Company s accounts receivable at March 31, 2003 or at December 31, 2002, or net revenues for the first quarter of 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 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 manufacture, political, social and economic instability, interruptions and limitations in telecommunication services, product and/or material transportation delays or disruption, trade restrictions and changes in tariffs, import and export license

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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 no significant obligations remain, transfer of title has occurred, and collection of the receivables 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. We offer our dental professionals an opportunity to purchase case refinement in advance at a discount. The advance purchase price is non-refundable once Aligners are shipped. 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 does not purchase the case refinements 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 future case refinement sales will be at $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 under agreements with third parties for training of dental professionals and staff for Invisalign are recorded as the services are performed. Charges to third parties are based on negotiated rates, which are intended to approximate a mark-up on 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.

3. Balance Sheet Components

Inventories comprise (in thousands):

	March 31, 2003	December 31, 2002
Raw materials	$ 865	$ 931
Work in process	323	285
Finished goods	574	317
	$ 1,762	$ 1,533

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Other current assets comprise (in thousands):

	March 31, 2003	December 31, 2002
Prepaid expenses	$ 4,735	$ 2,689
Other	1,915	2,199
	$ 6,650	$ 4,888

4. 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 March 31,	
	2003 Restated	2002 Restated
Net loss	$ (10,671)	$ (19,304)
Basic and diluted:		
Weighted-average common shares outstanding	57,766	47,946
Less: Weighted-average shares subject to repurchase	(577)	(1,794)
Weighted-average shares used in basic and diluted net loss per share	57,189	46,152
Net loss per share, basic and diluted	$ (0.19)	$ (0.42)

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

	Three Months Ended March 31,	
	2003	2002
Options to purchase common stock	7,351	5,731
Common stock subject to repurchase	513	1,560
	7,864	7,291

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5. 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 amounts)	Three Months Ended March 31, 2003 Restated	Three Months Ended March 31, 2002 Restated
Net loss, as reported	$ (10,671)	$ (19,304)
Add: Stock-based employee compensation expense included in reported net loss	3,898	4,954
Deduct: Total stock-based employee compensation determined under fair value based method for all awards	(5,874)	(7,680)
Pro forma net loss	$ (12,647)	$ (22,030)
Basic and diluted net loss per common share:		
As reported	$ (0.19)	$ (0.42)
Pro forma	$ (0.22)	$ (0.48)

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 with the following weighted average assumptions:

	Three Months Ended March 31, 2003	Three Months Ended March 31, 2002
Risk free interest rate	3.03	3.03
Expected life	5 years	5 years
Expected volatility	119.8%	119.8%

6. Commitments and Contingencies

During the quarter ended June 30, 2003, as a result of the restatement of its financial statements for fiscal 2001, fiscal 2002 and the first three months of fiscal 2003, the Company determined that for the quarter ended March 31, 2003 the Company was out of compliance with its loan covenants for the accounts receivable-based revolving line of credit and equipment-based term loan requiring certain financial ratios and measurements to be maintained. The Company obtained from its lender a waiver for the loan covenant requirements covering the quarter ended March 31, 2003, and an amendment to exclude from the quick ratio calculation the effect on current liabilities resulting from the restatement of revenues on a prospective basis. As a result of the waiver and amendment, the Company is in full compliance with its loan covenants for the quarter ended March 31, 2003.

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Long-term Obligations

As of March 31, 2003, future minimum long-term obligations are as follows (in thousands):

	2003	2004	2005	2006	2007	Thereafter
Operating leases	$ 2,677	$ 4,219	$ 2,869	$ 1,221	$ 688	$ 597
Capital lease obligations	434	348	187			
Equipment-based term loan	1,250	1,667	1,666			
Total	$ 4,361	$ 6,234	$ 4,722	$ 1,221	$ 688	$ 597

Product Warranty

The following table reflects the change in the Company s warranty accrual during the quarter ended March 31, 2003 (in thousands):

Warranty accrual, December 31, 2002	$ 514
Charged to cost and expenses	316
Actual warranty expenses	(301)
Warranty accrual, March 31, 2003	$ 529

Legal Proceedings

In January 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. In February 2003, we answered the complaint and asserted counterclaims seeking a declaration by the Court of invalidity and non-infringement of the asserted patents. In addition, we counterclaimed for infringement of our U.S. Patent No. 6,398,548, seeking unspecified monetary damages and injunctive relief. Ormco filed a reply to our counterclaims on March 10, 2003 and asserted counterclaims against us seeking a declaration by the Court of invalidity and non-infringement of U.S. Patent No. 6, 398, 548. We responded to Ormco s counterclaims on April 2, 2003. The Court issued an Order setting a Scheduling Conference on June 30, 2003, at which a case schedule is expected to be set.

Three years ago, Ormco filed suit against the Company 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 the Company 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 the Company of the issuance of U.S. Patent No. 6,244,861 and offered a license for this patent. The

Company 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 the Company 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.

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The claims in the Company 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.

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

On April 9, 2002, the Company exercised its right to terminate an Exclusive Marketing Agreement dated October 18, 2001 with Discus Dental Impressions, Inc. (the Marketing Agreement) pursuant to the express terms of the Marketing Agreement and the Company 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 seeks damages of approximately $30 million, including commissions and bonus payments it claims it would have received under the Marketing 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. Prior to terminating the Marketing Agreement, the Company conducted a thorough review of the Marketing Agreement and each party s performance thereunder. Based upon that review of the factual and legal issues, the Company denies 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 the Company submitted a counter-claim against Discus Dental in the arbitration seeking damages of approximately $40 million arising out of our claims for misrepresentation, breach of confidentiality provisions and unfair competition, among others. The three arbitrators have been selected, and the parties are exchanging and reviewing documents in response to document demands. The matter is currently set for arbitration on August 18, 2003.

In February 2001, the Company was named in a class action lawsuit filed on behalf of all licensed dentists (excluding orthodontists) in the U.S. The complaint alleged that the Company s policy of selling Invisalign exclusively to orthodontists violated the U.S. antitrust laws. Without admitting any wrongdoing, the company entered into a Stipulation and Agreement of Settlement with the plaintiffs to settle the lawsuit. The total legal and other settlement costs that the Company agreed to pay were approximately $400,000 in legal fees. In November 2001, the Court approved the Stipulation and Agreement of Settlement. Pursuant to the settlement, the Company trained and certified approximately 5,000 general practitioner dentists in fiscal 2002, and have undertaken to certify 5,000 general practitioner dentists each year over the next three years.

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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.

7. Accumulated Other Comprehensive Income

Accumulated other comprehensive income consists entirely of the change in unrealized gains or losses on available-for-sale securities at December 31, 2002. There were no available-for-sale securities or unrealized gains or losses at March 31, 2003.

8. Recent Accounting Pronouncements

In November 2002, the Emerging Issues Task Force (EITF) reached a consensus on EITF 00-21, which addresses how to account for arrangements that may involve the delivery or performance of multiple products, services, and/or rights to use assets. The final consensus of EITF 00-21 is applicable to agreements entered into in fiscal periods beginning after June 15, 2003, with early adoption permitted. Additionally, companies are permitted to apply the consensus guidance to all existing arrangements as the cumulative effect of a change in accounting principle in accordance with APB Opinion No. 20, Accounting Changes. The Company adopted EITF 00-21 in the second quarter of 2003. The adoption of EITF 00-21 did not have a material impact on the Company s consolidated financial statements.

In January 2003, the 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 beginning after June 15, 2003. The Company does not expect the adoption of FIN 46 to have a material impact on its consolidated financial statements.

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

This Quarterly Report on Form 10-Q/A is being filed for the purpose of amending and restating Items 1, 2 and 4 of Part I and Items 3 and 6 of Part II of Form 10-Q (excluding Risk Factors) solely to the extent necessary (i) to reflect the restatement of our condensed consolidated financial statements as of and for the periods ended March 31, 2003 and March 31, 2002 as described in Note 1 to the condensed consolidated financial statements, (ii) to make revisions to Management s Discussion and Analysis of Financial Condition and Results of Operations as warranted by the restatement, (iii) to include the certifications required by the Sarbanes-Oxley Act of 2002 and (iv) to update the exhibits and reports on Form 8-K in accordance with the Amendment. We have made no further changes to the previously filed Form 10-Q. All information in this Quarterly Report on Form 10-Q/A is as of March 31, 2003 and does not reflect any subsequent information or events other than those reflected in the restatement.

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.

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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.

Invisalign 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 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.

In July 2002, we announced a plan to streamline worldwide operations. The plan included closing our facilities in Pakistan and the United Arab Emirates, or U.A.E. We transitioned the operations performed at these facilities to the United States and Costa Rica. We discontinued operations at our Pakistan and U.A.E. facilities in October and December 2002, respectively. We concluded the remainder of indirect operational activities related to the Costa Rica transition in January 2003 and incurred approximately $0.5 million related to residual facility closure activities. We will cease non-operational closing activities in Pakistan when the land is disposed of at that location and in the U.A.E. when the necessary statutory filings have been completed.

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

From June 2001 until April 2003, Align 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). Align deferred $50 of revenue and accrued the anticipated loss related to the cost 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, Align recognized the revenue associated with the $250 stand-alone case refinement fee upon shipment of the new Aligners.

In May 2003, Align 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 Align believes represents its fair value based on competitive product offerings. Revenue deferrals associated with future case refinement sales will be at $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.

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Service revenues earned under agreements with third parties for training of dental professionals and staff for Invisalign are recorded as the services are performed. Charges to third parties are based on negotiated rates, which are intended to approximate a mark-up on 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 March 31, 2003, we had an accumulated deficit of approximately $291.1 million, as restated.

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 accessed in December 2002. As of March 31, 2003, we had not utilized the accounts receivable-based revolving line of credit. Accessing the accounts receivable-based revolving line of credit is restricted based on qualifying accounts receivable and compliance with certain loan covenants. However, there can be no assurance that such financing will be adequate for us to avoid reducing operating expenses by, including but not limited to, reducing planned capital expenditures relating to enhancing our manufacturing process and reducing worldwide staff.

Results of Operations, as Restated

Revenues. Revenues for the restated quarter ended March 31, 2003 increased 45% to $23.0 million compared to $15.9 million for the restated quarter ended March 31, 2002. Revenues derived from the sale of Invisalign were $21.7 million for the quarter ended March 31, 2003 compared to Invisalign revenues of $13.4 million for the quarter ended March 31, 2002. The increase in Invisalign revenues was primarily the result of an increase in the domestic orthodontic channel of $3.2 million, the domestic general practitioner channel of $3.6 million and the international channel of $1.5 million for the restated quarter ended March 31, 2003 over the restated quarter ended March 31, 2002. Growth in the domestic general practitioner channel resulted primarily from the expanded base of certified clinicians. Growth in the domestic orthodontic and international channels resulted primarily from increased utilization of Invisalign by the existing pool of certified clinicians. All channels benefited from Invisalign marketing promotion programs conducted during the fourth quarter of fiscal 2002 and into the first quarter ended March 31, 2003. The balance of our revenues represented sales of training and ancillary products of $1.3 million for the quarter ended March 31, 2003 and $2.5 million for the quarter ended March 31, 2002.

Cost of revenues. Cost of revenues for the restated quarter ended March 31, 2003 was $11.9 million compared to $12.0 million for the restated quarter ended March 31, 2002. Cost of revenues include the salaries for staff involved in production, the cost of materials and packaging, shipping costs, depreciation on the capital equipment used in the production process, under/over absorbed manufacturing capacity, training costs and the cost of facilities. Also included in cost of revenues are stock-based compensation expenses of $0.7 million and $1.0 million in the first quarters of 2003 and 2002, respectively. Restated gross margin for the quarter ended March 31, 2003 was $11.0 million or 48% of revenue, compared to a restated gross margin of $3.8 million or 24% of revenue for the quarter ended March 31, 2002. The higher gross margin in the first quarter of 2003 as compared to the first quarter of 2002 reflects the benefits of cost reduction initiatives in our manufacturing process and improved fixed cost absorption related to increasing volumes. We believe that gross margins for the remainder of fiscal 2003 will approximate or slightly improve as compared to gross margins for the quarter ended March 31, 2003.

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Sales and marketing. Sales and marketing expenses for the quarter ended March 31, 2003 were $10.6 million compared to $10.3 million for the quarter ended March 31, 2002. Sales and marketing expenses include sales force compensation, together with expenses for professional marketing programs, conducting workshops and market surveys, advertising and attending dental professional trade shows. Included in sales and marketing expenses are stock-based compensation expenses of $0.6 million and $0.8 million in the first quarters of 2003 and 2002, respectively. The increase in sales and marketing expenses for the first quarter of 2003 as compared to the first quarter of 2002 resulted primarily from an increase in spending of $1.2 million related to incremental headcount in our North American sales force and $1.2 million in incremental media and advertisement costs in the U.S., partially offset by a decrease in spending of $2.1 million related to a reduction in our international sales and marketing force.

General and administrative. General and administrative expenses for the quarter ended March 31, 2003 were $7.9 million compared to $9.9 million for the quarter ended March 31, 2002. General and administrative expenses include salaries for administrative personnel, outside consulting services, legal expenses and general corporate expenses. Included in general and administrative expenses are stock-based compensation expenses of $2.2 million for the first quarter of 2003, which decreased from $2.9 million for the first quarter of 2002. The decrease in general and administrative expenses for the first quarter of 2003 over the first quarter of 2002 resulted primarily from decreases in salaries of $0.9 million and $1.3 million related to a reduction in the North American and international administrative work forces, respectively, partially offset by an increase of $0.4 million in outside consultant costs. Offsetting the decreases in general and administrative expenses quarter over quarter were $0.5 million of restructuring charges for the first quarter of 2003, representing the remainder of our indirect operational activities related to the transition of operations from the U.A.E. and Pakistan to Costa Rica. We do not expect to incur restructuring charges during the quarter ending June 30, 2003.

Research and development. Research and development expenses for the quarter ended March 31, 2003 were $3.0 million compared to $3.3 million for the quarter ended March 31, 2002. Research and development expenses include the costs associated with software engineering, the cost of designing, developing and testing our products and the conducting of both clinical and post-marketing trials. We expense our research and development costs as they are incurred. Research and development expenses included $0.7 million of stock-based compensation for the first quarter of 2003, which decreased from $0.9 million of stock-based compensation expense for the first quarter of 2002.

Interest and other income (expense), net. Interest and other income (expense) was ($0.2) million for the first quarter of 2003 compared to $0.4 million for the first quarter of 2002. Interest income decreased in the first quarter of 2003 compared to the first quarter of 2002 by $0.2 million primarily due to the decrease in our cash, cash equivalent and marketable securities balances. Interest expense increased $0.1 million for the first quarter of 2003 compared to the first quarter of 2002 primarily from the interest on the equipment-based term loan.

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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 become exercisable, we revalue the remaining unvested options, with the change in fair value from period to period represented as a change in the deferred compensation charge. This stock-based compensation is amortized as charges to operations over the vesting periods of the options. For the quarters ended March 31, 2003 and 2002, we recorded amortization of deferred compensation of $3.6 million and $4.8 million, respectively. Additionally, we recorded expenses of $0.3 and $0.7 million for the quarters ended March 31, 2003 and 2002, respectively, related to options granted to non-employees.

We have accelerated the vesting of options to several employees in connection with severance packages. This acceleration was accounted for as a charge to the consolidated statements of operations. We recorded charges of $0.4 million and $0.1 million for the quarters ended March 31, 2003 and 2002, respectively. Each respective charge is equal to the intrinsic value difference between the exercise price of the accelerated options and the fair value of the common stock on the date of acceleration.

Liquidity and Capital Resources, as Restated

Historically, we have funded our operations with the proceeds from the sale of our common and preferred stock, equipment leases and bridge loans. As of March 31, 2003, we had $34.0 million of cash and cash equivalents, restricted cash of $3.3 million and an accumulated deficit of $291.1 million, as restated.

Net cash used in operating activities, as restated, totaled $3.2 million and $14.7 million for the quarters ended March 31, 2003 and 2002, respectively. Net cash used by operating activities consisted primarily of operating losses and increases in other current assets and deferred revenue for the first quarter of 2003 and increases in accounts receivable, deferred revenue and payable balances for the first quarter of 2002.

Net cash provided by investing activities totaled $1.9 million for the quarter ended March 31, 2003 and net cash used in investing activities totaled $0.2 million for the quarter ended March 31, 2002. For the quarters ended March 31, 2003 and 2002, net cash provided by (used in) investing activities resulted primarily from the maturity of marketable securities, which was partially offset by purchases of property and equipment.

Net cash used in financing activities was $0.2 million for the quarter ended March 31, 2003 and net cash provided by financing activities was $0.5 million for the quarter ended March 31, 2002. For the quarter ended March 31, 2003, net cash used in financing activities consisted primarily of payments on capital leases and equipment-based term loan payments, partially offset by proceeds from the issuance of common stock. For the quarter ended March 31, 2002, net cash provided by financing activities consisted primarily of proceeds from the issuance of common stock, partially offset by payments on capital leases.

During the quarter ended June 30, 2003, as a result of the restatement of our financial statements for fiscal 2001, fiscal 2002 and the first three months of fiscal 2003, we determined that for the quarter ended March 31, 2003 we were out of compliance with our loan covenants for the accounts receivable-based revolving line of credit and equipment-based term loan requiring certain financial ratios and measurements to be maintained. We obtained from our lender a waiver for the loan covenant requirements covering the quarter ended March 31, 2003, and an amendment to exclude from the quick ratio calculation the effect on current liabilities resulting from our restatement of revenues on a prospective basis. As a result of the waiver and amendment, we are in full compliance with our loan covenants for the quarter ended March 31, 2003.

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 professi