ALIGN TECHNOLOGY INC
Form 10-Q/A
August 13, 2003
Table of Contents

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 Incorporation or Organization)	**(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 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.

Table of Contents

Table Of Contents

ALIGN TECHNOLOGY, INC.

INDEX

Table of Contents

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.

Table of Contents

ALIGN TECHNOLOGY, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per share data)

(unaudited)

	Three Months Ended March 31,	
	2003	2002
	Restated	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.

Table of Contents

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.

Table of Contents

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

Table of Contents

(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.

Table of Contents

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

8

Table of Contents

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

Table of Contents

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	2002
	Restated	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

Table of Contents

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.

Table of Contents

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.

Table of Contents

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.

Table of Contents

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.

Table of Contents

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.

Table of Contents

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.

16

Table of Contents

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.

Table of Contents

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.

Table of Contents

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 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.

Table of Contents

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

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 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.

Table of Contents

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.

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.

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.

21

Table of Contents

Legal contingencies

We are currently involved in certain legal proceedings as discussed in Note 6 to our condensed consolidated financial statements. Because of uncertainties related to both the potential amount and range of loss from pending litigation, management is unable to make a reasonable estimate of the liability that could result if there is an unfavorable outcome in these legal proceedings. As additional information becomes available, we will assess the potential liability related to this pending litigation and revise our estimates accordingly. Revisions of our estimates of such potential liability could materially impact our results of operations and financial condition.

Deferred Tax Valuation Allowance

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 November 2002, the Emerging Issues Task Force (EITF) reached 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.

Table of Contents

RISK FACTORS

The statements contained below and elsewhere in this report on Form 10-Q/A 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/A, 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 all or a portion of fiscal 2003 and we may not achieve or maintain profitability in the future.

We have incurred significant operating losses, negative operating cash flows and 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. It is possible that we will not achieve profitability in the near future, if at all, and even if we do achieve profitability, we may not sustain or increase profitability in the future.

Table of Contents

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 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 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 shareholders, raising $18.1 million, net of issuance costs. In December 2002, we secured an accounts receivable-based revolving line of credit of up to $10.0 million and a 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 customary loan covenants. 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.

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.

24

Table of Contents

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

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

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

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

Table of Contents

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.

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.

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, particularly in light of the terrorist attacks of September 11, 2001;
- difficulties in staffing and managing international operations;
- controlling quality of manufacture;
- 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.

Table of Contents

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 March 31, 2003, we had 29 issued U.S. patents, 20 issued foreign patents, 69 pending U.S. patent applications, and numerous 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. 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 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.

Table of Contents

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 our counterclaim of infringement will be successful. However, the outcome of a lawsuit is inherently unpredictable. Should our technology be found to infringe any one of Ormco s asserted patents, we would have to seek a license from Ormco, which 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 which 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.

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. 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.

Table of Contents

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 702 employees as of March 31, 2003. This expansion will continue to place significant demands on our management and other resources and will require us to continue to develop and improve our operational, financial and other internal controls, both in the U.S. and internationally. In particular, rapid growth increases the challenges involved in a number of areas, including recruiting and retaining sufficient skilled personnel, providing adequate training and supervision to maintain our high quality standards, and preserving our culture and values. Also, recent reductions in our workforce, although designed to not affect service levels and demand generation, may adversely affect these areas of our business. Our inability to effectively manage this level of growth could harm our business.

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

We are highly dependent on the key employees in our clinical engineering and management teams. The loss of the services of those individuals may significantly delay or prevent the achievement of our product development and other business objectives and could harm our business. Our future success will also depend on our ability to identify, recruit, train and retain additional qualified personnel. In addition, few orthodontists are 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 Specialities. In addition, manufacturers of traditional braces, such as 3M Company, Sybron Dental Specialities 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.

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:

Table of Contents

product design, development, manufacture and testing;

product labeling;

product storage;

pre-market clearance or approval;

advertising and promotion; and

product sales and distribution.

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

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

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

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

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

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

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

Table of Contents

The healthcare market itself is highly regulated and subject to changing political, economic and regulatory influences. Regulations implemented pursuant to 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.

Table of Contents

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 increased during the first quarter of 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 increased during the first quarter of 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, following periods of volatility in the market price of a company s securities, class action litigation has often been brought against the issuing company. 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.

Table of Contents

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 March 31, 2003, our executive officers, directors and principal stockholders beneficially owned an aggregate of approximately 60.5% 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 March 31, 2003 consists of outstanding principle balances on lease obligations and an equipment-based term loan of $0.9 million and $4.9 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 and the interest rates are primarily fixed. Our capital lease obligations of $0.9 million at March 31, 2003 carry fixed interest rates of 6.53% and 11.15% per annum with principle payments due in 60 and 48 monthly installments, respectively, beginning in 2000.

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

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

Our ability to pay long-term debts at maturity; and

The impact of interest rate movements on our ability to obtain adequate financing to fund future operations.

We have the ability to hold at least a portion of the fixed income investments until maturity. As a result, we 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.

Table of Contents

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.*

Within the 90 days prior to the filing of this Quarterly Report on Form 10-Q/A (the Evaluation Date), we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-14(c) and 15d-14(c) under the Exchange Act). Based upon that evaluation, our Chief Executive Officer and our Chief Financial Officer concluded that our disclosure controls and procedures are effective to ensure that material information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission rules and forms. It should be noted, however, that the design of any system of controls is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions, regardless of how remote.

(b) *Changes in internal controls.*

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

PART II OTHER INFORMATION

ITEM 1. 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 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 Align 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.

Table of Contents

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 our counterclaim of infringement will be successful. However, the outcome of a lawsuit is inherently unpredictable. Should our technology be found to infringe any one of Ormco s asserted patents, 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, we could be subject to damages or an injunction which could materially adversely affect its business.

On April 9, 2002, we exercised our right to terminate an Exclusive Marketing Agreement dated October 18, 2001 with Discus Dental Impressions, Inc. (the Marketing Agreement) pursuant to the express terms of the Marketing Agreement and we 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 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 us from selling Invisalign to dentists in the U.S. and Canada. Prior to terminating the Marketing Agreement, we conducted a thorough review of the Marketing Agreement and each party s performance thereunder. Based upon that 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 counterclaim 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, we were named in a class action lawsuit filed on behalf of all licensed dentists (excluding orthodontists) in the U.S. The complaint alleged that our policy of selling Invisalign exclusively to orthodontists violated the U.S. antitrust laws. Without admitting any wrongdoing, we entered into a Stipulation and Agreement of Settlement with the plaintiffs to settle the lawsuit. The total legal and other settlement costs that we 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, we 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.

Table of Contents

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

ITEM 2. CHANGES IN SECURITIES AND USE OF PROCEEDS

Not applicable.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

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.

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:

Exhibit 10.36*	Lease Agreement dated February 26, 2003 between KPMG FIDES (COSTA RICA) S.A., PARQUE GLOBAL S.A. and Align Technology, Inc.
Exhibit 99.1	Certifications Pursuant To 18 U.S.C. Section 1350, As Adopted Pursuant To Section 906 Of The Sarbanes-Oxley Act Of 2002

* Previously filed.

(b) Reports on Form 8-K:

None.

Table of Contents

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.

ALIGN TECHNOLOGY, INC.

By: /s/ THOMAS M. PRESCOTT

Thomas M. Prescott
President and Chief Executive Officer

By: /s/ ELDON M. BULLINGTON

ELDON M. BULLINGTON
Chief Financial Officer and

Vice President of Finance

Date: August 13, 2003

Table of Contents

CERTIFICATION PURSUANT TO

18 U.S.C. SECTION 1350,

AS ADOPTED PURSUANT TO SECTION 302

OF THE SARBANES-OXLEY ACT OF 2002

I, Thomas M. Prescott, certify that:

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

2. Based on my knowledge, this quarterly 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 quarterly report;

3. Based on my knowledge, the financial statements, and other financial information included in this quarterly 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 quarterly report;

4. The registrant s other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:

   a) designed such disclosure controls and procedures 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 quarterly report is being prepared;

   b) evaluated the effectiveness of the registrant s disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the Evaluation Date); and

   c) presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5. The registrant s other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant s auditors and the audit committee of registrant s board of directors (or persons performing the equivalent functions):

   a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant s ability to record, process, summarize and report financial data and have identified for the registrant s auditors any material weaknesses in internal controls; and

   b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant s internal controls; and

6. The registrant s other certifying officers and I have indicated in this quarterly report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: August 13, 2003

/s/ THOMAS M. PRESCOTT

Thomas M. Prescott
President and Chief Executive Officer

Table of Contents

I, Eldon M. Bullington, certify that:

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

2. Based on my knowledge, this quarterly 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 quarterly report;

3. Based on my knowledge, the financial statements, and other financial information included in this quarterly 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 quarterly report;

4. The registrant s other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:

   a) designed such disclosure controls and procedures 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 quarterly report is being prepared;

   b) evaluated the effectiveness of the registrant s disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the Evaluation Date); and

   c) presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5. The registrant s other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant s auditors and the audit committee of registrant s board of directors (or persons performing the equivalent functions):

   a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant s ability to record, process, summarize and report financial data and have identified for the registrant s auditors any material weaknesses in internal controls; and

   b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant s internal controls; and

6. The registrant s other certifying officers and I have indicated in this quarterly report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: August 13, 2003

/s/ ELDON M. BULLINGTON

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

Table of Contents

EXHIBIT INDEX

Exhibit Number	Description of Exhibit
10.36*	Lease Agreement dated February 26, 2003 between KPMG FIDES (COSTA RICA) S.A., PARQUE GLOBAL S.A. and Align Technology, Inc.
99.1	Certifications Pursuant to 18 U.S.C. Section 1350, As Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

* Previously filed.