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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2005

OR

o **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 ☒ No o

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes o No ☒

The number of shares outstanding of the registrant's Common Stock, $0.0001 par value, as of October 31, 2005 was 62,053,554.

Table Of Contents

ALIGN TECHNOLOGY, INC.

INDEX

PART I—FINANCIAL INFORMATION

ITEM 1 FINANCIAL STATEMENTS
ALIGN TECHNOLOGY, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except per share data)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2005	2004	2005	2004
Revenues	$ 50,866	$ 45,766	$ 155,961	$ 129,175
Cost of revenues	14,975	14,922	47,073	42,565
Gross profit	35,891	30,844	108,888	86,610
Operating expenses:				
Sales and marketing	21,315	13,884	61,498	40,555
General and administrative	11,715	8,263	30,949	25,196
Research and development	4,400	4,846	14,658	11,750
Total operating expenses	37,430	26,993	107,105	77,501
Profit (loss) from operations	(1,539)	3,851	1,783	9,109
Interest and other, net	326	(217)	28	(619)
Net profit (loss) before income tax provision	(1,213)	3,634	1,811	8,490
Income tax provision	(303)	(316)	(926)	(843)
Net profit (loss)	$ (1,516)	$ 3,318	$ 885	$ 7,647
Net profit (loss) per share:				
Basic	$ (0.02)	$ 0.06	$ 0.01	$ 0.13
Diluted	$ (0.02)	$ 0.05	$ 0.01	$ 0.12
Shares used in computing net profit (loss) per share:				
Basic	61,788	60,319	61,509	59,703
Diluted	61,788	64,055	63,129	64,298

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

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

	September 30, 2005	December 31, 2004
ASSETS		
Current assets:		
Cash and cash equivalents	$ 77,354	$ 69,659
Restricted cash	265	303
Marketable securities, short-term	1,990	—
Accounts receivable, net of allowance	29,155	28,809
Inventories	3,594	2,852
Prepaid expenses and other current assets	5,039	5,211

Total current assets	117,397	106,834
Property and equipment, net	24,326	21,702
Goodwill	478	—
Intangible assets, net	805	—
Other assets	2,008	2,176
Total assets	$ 145,014	$ 130,712
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 3,653	$ 3,361
Accrued liabilities	28,870	23,481
Deferred revenues	19,705	16,257
Debt	417	1,849
Total current liabilities	52,645	44,948
Other long-term liabilities	54	25
Total liabilities	52,699	44,973
Commitments and contingencies (Note 7)		
Stockholders' equity:		
Preferred stock: $0.0001 par value; Authorized: 5,000 shares; Issued and outstanding: none at September 30, 2005 and December 31, 2004	—	—
Common stock: $0.0001 par value; Authorized: 200,000 shares; Issued: 62,013 and 60,916 shares at September 30, 2005 and December 31, 2004, respectively; Outstanding: 61,973 and 60,876 shares at September 30, 2005 and December 31, 2004, respectively	6	6
Additional paid-in capital	383,207	377,559
Accumulated other comprehensive income (loss)	41	(2)
Accumulated deficit	(290,939)	(291,824)
Total stockholders' equity	92,315	85,739
Total liabilities and stockholders' equity	$ 145,014	$ 130,712

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

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

	Nine Months Ended September 30,	
	2005	**2004**
Cash Flows from Operating Activities:		
Net profit	$ 885	$ 7,647
Adjustments to reconcile net profit to net cash provided by operating activities:		
Depreciation and amortization	7,543	6,628
Amortization of intangibles	230	—
Stock-based compensation expense	99	5,665
Loss on retirement and disposal of fixed assets	28	63
Provision for doubtful accounts	504	266
Changes in assets and liabilities, net of acquisition effects:		
Accounts receivable	(836)	(6,664)
Inventories	(742)	184
Other current assets	172	(10)
Accounts payable	443	663
Accrued liabilities	5,872	2,362
Deferred revenue	2,813	685
Net cash provided by operating activities	17,011	17,489
Cash Flows from Investing Activities:		
Purchase of property and equipment	(10,314)	(7,399)
Proceeds from sale of property and equipment	—	851
Decrease in restricted cash	38	158
Purchases of marketable securities	(2,240)	(519)
Maturities of marketable securities	250	2,292
Acquisition, net of cash acquired	(856)	—
Other assets	168	(230)
Net cash used in investing activities	(12,954)	(4,847)
Cash Flows from Financing Activities:		
Proceeds from issuance of common stock	5,070	7,095
Proceeds from payment on stockholders' notes receivable	—	17
Payments on debt obligations	(1,432)	(1,478)
Net cash provided by financing activities	3,638	5,634
Net increase in cash and cash equivalents	7,695	18,276
Cash and cash equivalents at beginning of period	69,659	44,939
Cash and cash equivalents at end of period	$ 77,354	$ 63,215

ALIGN TECHNOLOGY, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(unaudited)

1. Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared by Align Technology, Inc. (the "Company" or "Align") in accordance with the rules and regulations of the Securities and Exchange Commission. Certain information and footnote disclosures normally included in consolidated financial statements prepared in accordance with accounting principles generally accepted in the United States of America have been condensed or omitted in accordance with such rules and regulations. In the opinion of management, the accompanying unaudited condensed consolidated financial statements reflect all adjustments, consisting only of normal recurring adjustments, necessary to present fairly the financial position of the Company as of September 30, 2005 and December 31, 2004, its results of operations for the three and nine months ended September 30, 2005 and 2004, and its cash flows for the nine months ended September 30, 2005 and 2004.

The results of operations for the three and nine months ended September 30, 2005 are not necessarily indicative of the results that may be expected for the year ending December 31, 2005 and the Company makes no representations related thereto. The information included in this Quarterly Report on Form 10-Q should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations," "Quantitative and Qualitative Disclosures About Market Risk" and the Consolidated Financial Statements and notes thereto included in Items 7, 7A and 8, respectively, of the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2004.

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

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

2. Net Profit (Loss) Per Share

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2005	2004	2005	2004
Numerator:				
Net profit (loss)	$ (1,516)	$ 3,318	$ 885	$ 7,647
Denominator:				
Weighted-average common shares outstanding	61,788	60,348	61,509	59,797
Less: Unvested common shares subject to repurchase	—	(29)	—	(94)
Total shares, basic	61,788	60,319	61,509	59,703
Effect of dilutive securities:				
Add: Dilutive common stock equivalents	—	3,707	1,620	4,501
Unvested common shares subject to repurchase	—	29	—	94
Total shares, diluted	61,788	64,055	63,129	64,298
Basic net profit (loss) per share	$ (0.02)	$ 0.06	$ 0.01	$ 0.13
Diluted net profit (loss) per share	$ (0.02)	$ 0.05	$ 0.01	$ 0.12

Options to purchase common stock of 8.5 million and 2.3 million for the three months ended September 30, 2005 and 2004, respectively, and 4.7 million and 1.2 million for the nine months ended September 30, 2005 and 2004, respectively, are not included in the diluted net profit (loss) per share because to do so would be anti-dilutive.

There was no common stock subject to repurchase for the three and nine months ended September 30, 2005. Common stock subject to repurchase was included in dilutive securities for the three and nine months ended September 30, 2004.

3. 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 Statement of Financial

Accounting Standards ("SFAS") No. 148, "Accounting for Stock-Based Compensation—Transition and Disclosure—an amendment of FASB Statement No. 123" ("SFAS 148").

In December 2004, the FASB issued SFAS 123 (revised 2004), "Share-Based Payment" ("SFAS 123R"), which is a revision of SFAS 123. SFAS 123R supersedes APB 25 and amends FASB Statement No. 95, "Statement of Cash Flows." Generally, the approach in SFAS 123R is similar to the approach described in SFAS 123. However, SFAS 123R generally requires share-based payments to employees, including grants of employee stock options and purchases under employee stock purchase plans, to be recognized in the statement of operations based on fair values. Pro forma disclosure of fair value recognition will no longer be an alternative.

Statement 123R permits public companies to adopt its requirements using one of two methods:

1. Modified prospective method: Compensation cost is recognized beginning with the effective date of the adoption (a) based on the requirements of SFAS 123R for all share-based payments granted after the effective date of adoption and (b) based on the requirements of SFAS 123 for all awards granted to employees prior to the effective date of adoption that remain unvested on the date of adoption.

2. Modified retrospective method: Includes the requirements of the modified prospective method described above, but also permits restatement using amounts previously disclosed under pro forma provision of SFAS 123 either for (a) all prior periods presented or (b) prior interim periods of the year of adoption.

SFAS 123R is effective for public companies for interim and annual periods beginning after December 15, 2005.

As noted above, the Company currently accounts for share-based payments to employees using APB 25's intrinsic value method. As a result, the Company generally recognizes no compensation cost for employee stock options and purchases under the Employee Stock Purchase Plan. Although the adoption of SFAS 123R's fair value method will have no adverse impact on the Company's balance sheet or cash flows, it will affect the Company's net profit (loss) and earnings (loss) per share.

SFAS 123R also requires the benefits of tax deductions in excess of recognized compensation expense to be reported as a financing cash flow, rather than as an operating cash flow as prescribed under current accounting rules. Total cash flow will remain unchanged from cash flow as prescribed under current accounting rules.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2005	2004	2005	2004
Net profit (loss), as reported	$ (1,516)	$ 3,318	$ 885	$ 7,647
Add: Stock-based employee compensation expense included in reported net profit (loss), net of related tax effects	—	1,754	70	5,383
Deduct: Total stock-based employee compensation determined under fair value based method for all awards, net of related tax effects	(4,556)	(4,271)	(14,382)	(14,173)
Pro forma net profit (loss)	$ (6,072)	$ 801	$ (13,427)	$ (1,143)
Basic net profit (loss) per common share:				
As reported	$ (0.02)	$ 0.06	$ 0.01	$ 0.13
Pro forma	$ (0.10)	$ 0.01	$ (0.22)	$ (0.02)
Diluted net profit (loss) per common share:				
As reported	$ (0.02)	$ 0.05	$ 0.01	$ 0.12
Pro forma	$ (0.10)	$ 0.01	$ (0.22)	$ (0.02)

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2005	2004	2005	2004
Risk free interest rate	4.03%	4.32%	3.78%	3.36%
Expected life	3.2 years	5.0 years	2.3 years	5.0 years
Expected volatility	72%	51%	71%	56%
Weighted average fair value	$ 3.57	$ 8.02	$ 3.13	$ 9.41

The decrease to the expected life assumption used in the Black-Scholes option pricing model to 3.2 years and 2.3 years for the three and nine months ended September 30, 2005, respectively, as compared to 5.0 years for the three and nine months ended September 30, 2004 is the result of granting options with shorter vesting in 2005.

On October 6, 2005, the Compensation Committee of the Company's Board of Directors approved the acceleration of vesting for all unvested stock options with exercise prices greater than $7.10. Options held by non-employee directors are excluded from the vesting acceleration. See Note 9 for further discussion.

4. Acquisitions

In January 2005, the Company acquired all of the membership interests of privately held General Orthodontics, LLC ("GO"). GO is the sole premier provider of consulting and education services to general practitioner dentists ("GP") and orthodontists using the Invisalign orthodontic appliance. The condensed consolidated financial statements include the operating results of GO from the date of acquisition.

The purchase price of $1.3 million was accounted for as a business combination and allocated to the acquired assets, goodwill and other identified intangibles, as follows (in thousands):

Fair value of net liabilities assumed	$ (174)
Identified intangible assets acquired:	
Consultant relationships	980
Other	55
Goodwill	478
Total	$ 1,339

The valuation of the consultant relationships represent the fair value of consultant services which include direct consulting services to GO's customers on the use of the Invisalign technology and training of GP dentists and orthodontists at the Company's certification training sessions. Consultant relationships and other intangible assets are being amortized on a straight-line basis over the estimated useful life of three years.

In accordance with the Membership Interest Purchase Agreement, the Company agreed to contingent earn-outs of up to $1.0 million payable to certain former holders of GO membership interests upon the achievement of milestones defined in the agreement. These contingent payments are accrued on a straight-line basis based on the estimated completion dates. The Company paid $0.5 million related to milestone completion in July 2005.

5. Goodwill and Other Intangible Assets

In January 2005, the Company completed the acquisition of GO (See Note 4) and recorded $0.5 million of goodwill. Goodwill is the difference between the purchase price and the fair value of the acquired net assets and the identified intangible assets. Upon the integration of GO, Align included GO's consulting services in its clinical education and training programs under the name of Invisalign Consulting Services.

As required by SFAS 142, the Company will perform its annual impairment test in the fourth quarter of 2005 or if events or changes in circumstances indicate the assets may be impaired.

The following is a summary of the Company's purchased intangible assets as of September 30, 2005 (in thousands):

	Gross Carrying Value	Estimated Useful Life (in years)	Accumulated Amortization	Net Carrying Value
Consultant relationships	$ 980	3	$ 218	$ 762
Other	55	3	12	43
Total	$ 1,035		$ 230	$ 805

Estimated future amortization expense for purchased intangible assets as of September 30, 2005 is $86 thousand, $345 thousand, $345 thousand and $29 thousand in 2005, 2006, 2007 and 2008, respectively.

6. Inventories

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

Inventories comprise (in thousands):

	September 30, 2005	December 31, 2004
Raw materials	$ 1,539	$ 953
Work in process	1,803	1,547
Finished goods	252	352
	$ 3,594	$ 2,852

7. Commitments and Contingencies

Short-term and Long-term Obligations

As of September 30, 2005, future minimum payments under lease obligations and financing agreements are as follows (in thousands):

	2005	2006	2007	2008	2009	Thereafter	Total
Operating leases	$ 607	$ 2,265	$ 1,880	$ 1,698	$ 1,057	$ 466	$ 7,973
Equipment-based term loan	417	—	—	—	—	—	417

Total	$ 1,024	$ 2,265	$ 1,880	$ 1,698	$ 1,057	$ 466	$ 8,390

Product Warranty

Aligners are subject to the Invisalign product warranty, which covers defects in materials and workmanship, and is contingent upon proper use of the Aligners. The Invisalign product warranty is in force until the case is completed. In the event the Aligners fall within the scope of the Invisalign product warranty, the Company will replace the Aligners at its expense. If a patient chooses not to wear the Aligners, and as a result, requests additional Invisalign treatment, the dental professional pays for the additional expense. The Invisalign product warranty does not provide any assurances regarding the outcome of treatment using Invisalign. The Company provides for the estimated future costs of warranty obligations in costs of revenues when the related product is shipped. Accrued estimated warranty costs are primarily based on historical experience as to product failures as well as current information on replacement costs. Management periodically reviews the accrued balances and updates the historical warranty cost trends. Actual warranty costs incurred have not materially differed from those accrued.

The following table reflects the change in the Company's warranty accrual during the nine months ended September 30, 2005 and September 30, 2004, respectively (in thousands):

	Nine months ended September 30,	
	2005	2004
Balance at beginning of period	$ 1,616	$ 862
Charged to cost and expenses	1,972	1,996
Actual warranty expenses	(1,582)	(1,480)
Balance at end of period	$ 2,006	$ 1,378

Contingencies

In December 2003, the Company negotiated a $15.0 million revolving line of credit based on domestic accounts receivable which accrues interest at a rate of 0.5% above prime. Accessing the accounts receivable based revolving line of credit is subject to qualifying accounts receivable and the Company's compliance with certain loan covenants. The line of credit expires in December 2005. As of September 30, 2005, the Company had not accessed the revolving line of credit.

In December 2002, the Company obtained and accessed a $5.0 million equipment-based term loan, which accrues interest at a rate of 2.25% above prime. The Company did not draw down on any new funds in fiscal 2004 or during the first nine months of fiscal 2005. Principal payments are due in 36 monthly installments beginning in January 2003. The loan balance was $0.4 million as of September 30, 2005.

During the quarter ended September 30, 2005, the Company determined it was out of compliance with its loan covenants for the accounts receivable-based revolving line of credit, which requires certain financial ratios and measurements to be maintained. The loan covenants were amended on October 27, 2005 for the purpose of decreasing the minimum Earnings Before Income Taxes, Depreciation and Amortization (EBITDA) amount that the Company must maintain for the fiscal quarter ended September 30, 2005 and each fiscal quarter ending thereafter from $2.0 million to zero. As a result of the amendment, the Company is in compliance with its loan covenants for the quarter ended September 30, 2005.

Legal Proceedings

OrthoClear

On February 2, 2005, the Company filed a multi-claim lawsuit in San Francisco County Superior Court against defendants OrthoClear, Inc., OrthoClear Holdings, Inc., Muhammad Ziaullah Chishti, Bao Tran, Peter Riepenhausen, Joe Breeland, Jeff Tunnell, Christopher Kawaja, and Charles Wen. Among other things, the complaint alleges tort, contract, statutory and common law causes of action arising from OrthoClear and the individual defendants' alleged plan to unlawfully utilize our intellectual property, confidential information and employees. The complaint also alleges that OrthoClear, Chishti and other defendants are in breach of contractual obligations, statutory law and common law for attempting to intentionally interfere and disrupt the Company's ongoing business operations and improperly gain access to our customer relationships and trade secrets. The complaint seeks injunctive relief and monetary damages in an amount to be determined.

On February 15, 2005, OrthoClear, Chishti, Riepenhausen, Breeland, Tunnell, Kawaja and Wen filed a multi-claim cross-complaint against the Company, Thomas Prescott, Roger George, Eldon Bullington, David Thrower, Patricia Wadors, Gil Laks and Kelsey Wirth (collectively, the "Align Parties") alleging conspiracy, breach of contract, libel, slander, unjust enrichment, intentional interference with prospective economic advantage, and unfair competition. The cross-complaint seeks injunctive relief and monetary damages in an amount to be determined.

On February 18, 2005, the Court granted the Company's request for and issued a Temporary Restraining Order ("TRO") prohibiting OrthoClear and the individual OrthoClear defendants from engaging, assisting, or participating, directly or indirectly, in soliciting, inducing to leave, recruiting, or encouraging any current Align employee or consultant to terminate or alter his or her employment or business relationship with Align or attempting to do the same. The Court also granted the Company's request and issued a TRO prohibiting OrthoClear and the individual OrthoClear defendants from disclosing, using, lecturing upon or publishing any of our proprietary information without our express prior written permission. In addition, in response to a cross-application for TRO filed by certain OrthoClear defendants, the Court enjoined Chishti and the Align Parties from disparaging each other in such a manner as to violate the mutual non-disparagement clause contained in the Separation Agreement between Align and Chishti dated as of March 27, 2002. The Court also enjoined the Align Parties from advising any Align employee or consultant that he or she will be subject to criminal charges or a civil lawsuit if that person elects to change his or her employment status with Align, unless Align has good cause to believe criminal conduct has been or will be committed or that a civil cause of action will lie against the employee or consultant. The Court also required the Align Parties to refrain from taking any actions inconsistent with Federal or State securities laws relating to the issuance or redemption of Align stock. On March 1, 2005, the Court signed a Stipulated Preliminary Injunction Order, whereby the Court ordered that the express terms of the TRO remain in place until the earlier of (i) trial, (ii) written agreement of the parties or further Court order setting an earlier termination, or (iii) as to the preliminary injunction regarding non-solicitation or recruiting of Align employees or consultants only, October 27, 2005.

The defendants and the Align Parties filed demurrers to the complaint and the cross-complaint, respectively. On June 6, the Court ruled on demurrers on the complaint filed by OrthoClear and denied OrthoClear's challenges to the core of Align's complaint — Align's claims of Misappropriation of Trade Secrets and Breach of Contract — by overruling the OrthoClear demurrers to these causes of action. In addition, the Court granted Align's request for permission to amend its original complaint to consolidate several duplicative causes of action and to add specific evidence not available to Align when the original complaint was filed. OrthoClear did not oppose the demurrer filed by Align and amended its original pleading by filing a first supplemental and amended cross-complaint.

On July 6, 2005, OrthoClear filed a demurrer to Align's first amended complaint. On August 23, 2005, the Court issued an order overruling all of OrthoClear's demurrers. As a result, on September 9, 2005, OrthoClear filed answers to eleven causes of action brought by Align. In September 2005, Align presented demurrers to OrthoClear's first supplemental and amended cross-complaint. As of the date of this Form 10-Q, the Court has not ruled on Align's demurrers. Align denies the allegations in the amended cross-complaint, and will vigorously defend against such claims that survive Align's demurrers. No trial date has been set in the case.

On July 19, 2005, Align filed a multi-claim lawsuit in the United States District Court for the Northern District of California against OrthoClear. The complaint alleges numerous violations of the federal Lanham Act (15 U.S.C. §1051 et seq.) by OrthoClear and its officers and employees. These violations include unfair competition, trademark infringement and false advertising. The complaint also alleges violations by OrthoClear of California's Unfair Practices Act (California Business and Professions Code §17200 et seq.). A trial date has been scheduled for October 30, 2006.

The complaint seeks monetary damages according to proof at trial and an injunction preventing OrthoClear from further false advertising and unfair competition including any use of Align's trademarks or any advertising which deceives

consumers into incorrectly believing that OrthoClear has a program for training and certifying dentists and orthodontists or that OrthoClear has successfully treated patients.

Ormco

On January 6, 2003, Ormco Corporation ("Ormco") filed suit against the Company in the United States District Court for the Central District, Orange County Division, asserting infringement of U.S. Patent Nos. 5,447,432, 5,683,243 and 6,244,861. The complaint sought unspecified monetary damages and injunctive relief. On February 18, 2003, the Company answered the complaint and asserted counterclaims seeking a declaration by the Court of invalidity and non-infringement of the asserted patents. In addition, the Company counterclaimed for infringement of its U.S. Patent No. 6,398,548, seeking unspecified monetary damages and injunctive relief. Ormco filed a reply to the Company's counterclaims on March 10, 2003 and asserted counterclaims against the Company seeking a declaration by the Court of invalidity and non-infringement of U.S. Patent No. 6,398,548. The Company amended its counterclaim to add Allesee Orthodontic Appliances, Inc. ("AOA"), a wholly-owned subsidiary of Ormco, as a counterdefendant in regard to the Company's counterclaim of infringement of U.S. Patent No. 6,398,548. The Court then permitted Ormco to amend its Complaint and permitted the Company to amend its counterclaim to add an additional patent each. Ormco filed a first amended complaint for infringement of U.S. Patent No. 6,616,444 on October 15, 2003. On October 27, 2003, the Company filed an answer to Ormco's first amended complaint and a counterclaim for invalidity and non-infringement of U.S. Patent No. 6,616,444 and for infringement of U.S. Patent No. 6,554,611.

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

On December 20, 2004, the Company filed a further summary judgment motion that the Company's asserted claims are not invalid based on Ormco's and AOA's new evidence. Ormco and AOA filed a counter-summary judgment motion that the Company's asserted claims are invalid based on this new evidence. The motions were heard by the Court on February 7, 2005. On February 24, 2005, the Court granted the Company's motion in part, confirming the validity of all of the asserted claims of the Company's 6,554,611 patent and two of the asserted claims of the Company's 6,398,548 patent. The Court also granted Ormco's and AOA's motion in part, finding certain claims of the Company's 6,398,548 patent to be invalid in view of prior use evidence. On March 10, 2005, Ormco and AOA moved for reconsideration of the Court's ruling that Claims 10 and 17 of the Company's U.S. Patent No. 6,398,548 are not invalid. On April 8, 2005, upon a motion for reconsideration made by Ormco and AOA, the Court advised that it would adhere to its previous ruling that Claims 10 and 17 of the Company's 6,398,548 patent are not invalid.

On March 28, 2005, the Company filed a motion for permanent injunction to prevent Ormco and AOA from selling the infringing Red, White & Blue system. On May 26, 2005, the Court issued a permanent injunction (the "Permanent Injunction") to enjoin Ormco and AOA from further infringement of Claims 10 and 17 of the Company's 6,398,548 patent and Claims 1-3 and 7 of the Company's 6,554,611 patent. On May 31, 2005, Ormco and AOA noticed an appeal to the Federal Circuit from the Permanent Injunction. As of the date of this Form 10-Q, the Permanent Injunction remains in full force and effect.

As of the date of this Form 10-Q, only the Company's remedies for Ormco's and AOA's adjudged infringement remain at issue. A trial date has been scheduled for February 28, 2006.

Other matters

In the second quarter and third quarter of 2005, requests were filed with the United States Patent and Trademark Office ("USPTO") by a San Francisco, California, law firm, acting on behalf of an unnamed party, requesting reexamination of five of the Company's patents (U.S. Patent Nos. 5,975,893, 6,398,548, 6,309,215, 6,705,863 and 6,217,325 (collectively, the "Reexam Patents")). The USPTO has granted the request to reexamine each of the Reexam Patents. The reexamination proceedings are currently pending. While the pending reexaminations are in a preliminary stage and the Company is still evaluating all issues, the Company believes that the Reexam Patents are valid. However, there can be no assurance that the Company will prevail, and an adverse outcome of the reexamination proceedings could cause some or all of the Reexam Patent claims to have a narrower scope of coverage or even to be invalidated.

On July 25, 2005, Bay Materials, LLC ("Bay") filed suit against the Company in the Superior Court of the State of California for the County of San Mateo. The complaint, as amended, asserts, among other things, breach of contract, promissory estoppel, fraud and negligent misrepresentation by the Company. Bay alleges that the Company breached the terms of a purchase order by failing to pay for unshipped goods manufactured by Bay pursuant to such order. Bay further alleges that the Company promised to purchase from Bay an alternative polyurethane product and Bay relied on this representation to develop such an alternative product which the Company determined not to use. The complaint seeks monetary damages of $1.1 million related to breach of contract and research and development costs incurred plus unspecified damages related to lost profit, punitive and exemplary damages, and legal expenses. The Company intends to vigorously defend itself.

8. Information about Geographic Areas

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

Revenues by geography are based on billing address of customers. The following table sets forth revenues and long-lived assets by geographic area (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2005	2004	2005	2004
Revenues:				
United States and Canada	$ 45,253	$ 41,574	$ 138,744	$ 117,020
International	5,613	4,192	17,217	12,155
Total revenues	$ 50,866	$ 45,766	$ 155,961	$ 129,175

	As of September 30, 2005	As of December 31, 2004
Long-lived assets:		
United States and Canada	$ 24,550	$ 20,627
International	3,067	3,251
Total long-lived assets	$ 27,617	$ 23,878

9. Subsequent Events

Stock Option Acceleration

On October 6, 2005, the Compensation Committee of the Company's Board of Directors, approved the acceleration of vesting for all unvested stock options with exercise prices greater than $7.10. Options held by non-employee directors are excluded from the vesting acceleration. Because the exercise price of all options subject to acceleration was greater than the fair market value of the Company's underlying common stock on the date of acceleration, in accordance with generally accepted accounting principles, the Company did not record any compensation expense. As a result of the acceleration, approximately 3.8 million options or 35% of the total outstanding options became immediately exercisable as of October 6, 2005. Of the aggregate number of options subject to the acceleration, approximately 1.2 million options or 32% of the total accelerated options are held by executive officers of the Company.

The Compensation Committee also required that, as a condition to the acceleration of options held by executive officers, each officer agree to refrain from selling common stock acquired upon the exercise of accelerated options until the date on which the exercise would have been permitted under the options' pre-acceleration vesting terms or, if earlier, the executive officer's last day of employment or upon a "change in control" as defined in the 2001 Incentive Plan, the 2005 Incentive Plan or any employment agreement between the individual and the Company.

Preferred Stock Rights Agreement

On October 25, 2005, pursuant to a Preferred Stock Rights Agreement (the "Rights Agreement") between the Company and EquiServe Trust Company, N.A. as Rights Agent (the "Rights Agent"), the Company's Board of Directors declared a dividend of one right (a "Right") to purchase one one-thousandth share of the Company's Series A Participating Preferred Stock ("Series A Preferred") for each outstanding share of Common Stock, par value $0.0001 per share of the Company. The dividend is payable on November 22, 2005 to stockholders of record as of the close of business on that date. Each Right entitles the registered holder, subject to the terms of the Rights Agreement, to purchase from the Company one one-thousandth of a share of Series A Preferred at an exercise price of $37.00, subject to adjustment.

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

In addition to historical information, this Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. These statements include, among other things, statements concerning our expectations of increased collaboration between orthodontists and general practitioner dentists and the impact this collaboration will have on sales of Invisalign and on our revenue, our expectation that the percentage of revenue generated by general practitioner dentists will represent an increasingly larger percentage of our revenue, our expectations regarding further expansion into North American and international markets, including Japan, the number of new general practitioner dentists we anticipate training in 2005, our anticipated revenue, gross margin and volume growth in fiscal 2005, our expectation regarding costs, our expectation regarding relocation of our stereolithography mold fabrication operations to Mexico, as well as our expectations regarding the timing of such relocation, our expectations regarding sales and marketing and research and development expenses in the fourth quarter of 2005, our expectations regarding estimated incremental costs, including legal fees, that we may incur as a result of the OrthoClear litigation, our statement that we intend to introduce Invisalign to the curriculums of additional universities, our estimate of the future expense we expect to eliminate as a result of the stock option acceleration program, as well as other statements regarding our future operations, financial condition and prospects and business strategies. These statements may contain words such as "expects," "anticipates," "intends," "plans," "believes," "estimates," or other words indicating future results. These forward-looking statements are subject to certain risks and uncertainties that could cause actual results to differ materially from those reflected in the forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the following discussion, and in particular, the risks discussed below under the subheading "Risk Factors" and in other documents we file with the Securities and Exchange Commission. We undertake no obligation to revise or publicly update the results of these forward-looking statements. Given these risks and uncertainties, readers are cautioned not to place undue reliance on such forward-looking statements.

The following discussion and analysis of our financial condition and results of operations should be read together with our condensed consolidated financial statements and related notes included elsewhere in this Quarterly Report on Form 10-Q.

Overview

Align Technology, founded in April 1997, designs, manufactures and markets Invisalign, a proprietary method for treating malocclusion, or the misalignment of teeth. Invisalign treats malocclusion using a series of clear, nearly invisible, removable appliances that gently move teeth to a desired final position. Because it does not rely on the use of metal or ceramic brackets and wires, Invisalign significantly reduces the aesthetic and certain other limitations associated with braces. Invisalign is appropriate for treating adults and teens with mature dentition. We received FDA clearance to market Invisalign in 1998, and we began commercial operations in July 1999.

The Invisalign system is manufactured in phases. The initial step in our manufacturing process is the creation of electronic treatment plans using ClinCheck™, an internally developed computer-modeling program. These treatment plans are developed at our operations facility in Costa Rica and are transmitted electronically back to our customers, the prescribing orthodontist or general practitioner dentist (GP) via ClinCheck™. ClinCheck™ allows the orthodontist or GP to simulate treatment in three dimensions by modeling two-week stages of tooth movement. Upon the dental professional's approval of the ClinCheck™ simulation, we use the data underlying the simulation, in conjunction with stereolithography (SLA) technology, to manufacture Aligner molds. A third party manufacturer in Mexico uses these molds to fabricate Aligners. Aligners are thin, clear plastic, removable dental appliances that are manufactured in a series to correspond to each two-week stage of the ClinCheck™ simulation. Aligners are customized to perform the treatment prescribed for an individual patient by a dental professional using ClinCheck™. After the Aligners are produced, the third party manufacturer ships the finished products to our customers.

We generate the vast majority of our revenues from the sales of the Invisalign system to orthodontists and GPs in the United States and Canada, our domestic market. In the first nine months of 2005, sales of Invisalign in our domestic GP channel and our domestic orthodontist channel represented approximately 42% and 43% of our total revenues, respectively.

A number of factors, the most important of which are set forth below, may affect our success during the remainder of 2005 and beyond.

- *Increased Competition.* In May 2005, OrthoClear, Inc. announced the commercial launch of the OrthoClear

System, a product that is intended to compete directly with our Invisalign system. We believe that OrthoClear's product infringes on our intellectual property, and prior to OrthoClear's commercial launch, we filed a multi-claim lawsuit alleging, among other things, OrthoClear's unlawful use of our intellectual property. We are in the early stages of evaluating the impact the events underlying this litigation may have on our business, competitive position in the market and other matters related to the sale of our product. *See Part II Item 1 of this Form 10-Q for a more complete summary of the OrthoClear litigation.* If OrthoClear is ultimately successful in gaining broad market acceptance of its product, our business could be adversely affected. To date, the presence of OrthoClear in the marketplace has impacted our business by consuming management and technical personnel's attention and resources from normal business operations, disrupting sales coverage and customer relationships, and introducing pricing pressure. Each of these disruptions from the presence of OrthoClear in the marketplace have adversely affected our revenue, volume growth, gross margins, net profits and stock price.

- Resources from Normal Business Operations: We have included estimated incremental OrthoClear related expenses of $10 million to $12 million in our financial plan expectations for fiscal 2005. As of the date of this Quarterly Report on Form 10-Q, the launch of the OrthoClear product has not caused us to change this estimate.

- Disruption in Sales Coverage and Customer Relationships: In the first half of 2005, 17 orthodontic sales representatives, representing approximately 50% of our orthodontic sales force, left Align and joined OrthoClear. We have replaced the majority of these individuals with new sales representatives. Case submissions in our orthodontic channel were slightly lower in the third quarter of 2005 compared to the previous quarter due to the disruption in our sales force and the resulting disruption to many of our key customer relationships. We are committed to train and successfully deploy our new sales team and rebuild these disrupted customer relationships. *See "Risk Factors – We rely on our direct sales force to sell our products, any failure to maintain our direct sales force could harm our business."*

- Increased Pricing Pressure:

- In addition, in response to OrthoClear's launch and in an effort to simplify our pricing structure, on November 1, 2005, we announced that all Invisalign cases (other than Invisalign Express) in our domestic market have a list price of $1,495 per case. This pricing initiative is effective for all domestic cases ordered on and after November 1, 2005. Previously, list prices ranged from $1,195 to $1,895 per case depending on the treatment option selected.

- In response to OrthoClear's launch and in order to encourage continued use of our products we implemented a volume based discount program directed to our highest performing customers, in the third quarter of 2005.

We expect each of these programs to adversely affect our revenue, gross margin and net profit.

- *Increased Collaboration and Referral Relationships Between Orthodontists and GPs.* Although we have historically generated a majority of our revenues from orthodontists, there exists a significantly greater number of GPs in North America than orthodontists. As the primary provider of dental care, GPs have access to a greater number of patients than orthodontists, and possess a unique opportunity to educate these patients on the benefits of oral care and introduce them to Invisalign. GPs also have the ability to refer appropriate cases to orthodontists and may choose to treat less complex cases themselves. We are committed to improving the collaboration and referral relationships between orthodontists and GPs. We believe that improved collaboration is beneficial to the orthodontist and the GP and will accelerate growth in Invisalign cases and consequently increase our revenues. As specialists, orthodontists are a critical part of our business, and we expect that orthodontists will continue to treat the majority of complex cases and continue to drive research for expanding Invisalign applications. We expect, however, that the percentage of revenues generated by GPs will increase, largely due to the fact that there are significantly more GPs than orthodontists. In fact, in the third quarter and first nine months of 2005, our domestic GP channel generated 45% and 42% of our total revenues, respectively. We believe the expected increase in the number of cases treated by GPs will result in an increase in the overall market for Invisalign, as patients who would not have otherwise sought orthodontic treatment are introduced to Invisalign by their GPs.

- *Penetration into our Domestic Market.* We expect to continue to increase our penetration into our domestic market. Clinical education and ongoing training are critical to our customers' success with Invisalign. Each year, we provide numerous clinical education and training programs, which include certification classes, conference calls, seminars and workshops. Since 2001, the Invisalign Summit has been Align's premiere clinical education and motivation event for orthodontists. In the second quarter of 2005, we hosted our first Invisalign Summit for GPs, which was the first time a corresponding summit program was held exclusively for GPs. By participating in these events, we believe that our customers will emerge with a better understanding of the product and its applicability. We expect to train approximately 4,000 GPs to use the Invisalign system during fiscal 2005. In addition, by educating dental students and orthodontic students on the benefits of the Invisalign technique, we believe they will be more likely to use this technology in their future practices which we expect to increase our revenues. During the first nine months of 2005, four dental schools, the Pankey Institute, Harvard, Columbia and the University of Texas at San Antonio, announced the integration of the Invisalign technique into their curriculums. We expect additional dental schools to integrate the Invisalign technique into their curriculums in the future.

- *Expansion of International Markets.* We continue to focus our efforts towards the expansion of our international markets. We expect to increase our infrastructure and support in key countries in Europe in order to take advantage of these emerging opportunities. In October 2005, we announced the launch of Invisalign in Japan. We plan to hold certification courses for orthodontists in Japan and offer Japanese versions of Virtual Invisalign Practice (VIP), our proprietary customer interfacing software, and ClinCheck. In addition, in the second quarter of 2005, we hosted our first Invisalign Summit for European doctors, which was the first time a summit program was held exclusively for our international customers.

- *Demand for Invisalign Treatment*. Our market research indicates that the vast majority of people with malocclusion who desire treatment do not elect traditional treatment because of its many limitations, such as compromised aesthetics and oral discomfort. By communicating the benefits of Invisalign to both dental professionals and consumers, we intend to increase the number of patients who seek orthodontic treatment annually. In the second quarter of 2005, we launched a new consumer marketing campaign designed to raise the profile of Invisalign and drive more consumers to our most experienced dental professionals.

Financial highlights. Revenues for the third quarter and first nine months of 2005 increased from $45.8 to $50.9 million and from $129.2 million to $156.0 million or 11.1% and 20.7%, respectively, compared to the third quarter and first nine months of 2004. The increases were driven by higher case volumes resulting from growth in our customer base, primarily in our domestic GP and international channels.

Our operating expenses for the third quarter and first nine months of 2005 increased from $27.0 million to $37.4 million and from $77.5 million to $107.1 million or 38.5% and 38.2%, respectively, compared to the third quarter and first nine months of 2004. The increase in operating expenses primarily resulted from increases in sales and marketing expenses, as further described below in Results of Operations.

Stock-based compensation. In connection with the grant of stock options prior to 2001, we recorded deferred stock-based compensation as a component of stockholders' equity. This stock-based compensation was amortized as charges to operations over the vesting periods of the options. For the third quarter and first nine months of 2004, we recorded amortization of deferred compensation of $1.0 million and $4.7 million, respectively. Deferred stock-based compensation was fully amortized as of December 31, 2004.

Option Acceleration. On October 6, 2005, the Compensation Committee of our Board of Directors approved acceleration of the vesting for all unvested stock options with exercise prices greater than $7.10. Options held by non-employee directors are excluded from the vesting acceleration. As a result of the acceleration, approximately 3.8 million options or 35% of the total outstanding options became immediately exercisable as of October 6, 2005. Of the aggregate number of options subject to the acceleration, approximately 1.2 million options or 32% of the total accelerated options are held by our executive officers. Because the exercise price of all options subject to acceleration was greater than the fair market value of our underlying common stock on the date of acceleration, in accordance with generally accepted accounting principles, we did not record any compensation expense.

The primary purpose of the acceleration is to eliminate future compensation expense we would otherwise recognize in our statement of operations with respect to these accelerated options upon the adoption of FAS 123R. FAS 123R is effective for us beginning in the first quarter of 2006, and will require that compensation expense associated with stock options be recognized in the statement of operations, rather than as a footnote disclosure in our consolidated financial statements. We estimate that the aggregate future expense that will be eliminated over the next four years as a result of the acceleration of the vesting of these options is approximately $15.2 million, as follows:

Fiscal Year Ended	Approximate Amount of Expense Eliminated (millions)
2006	$ 7.9
2007	$ 5.9
2008	$ 1.3
2009	$ 0.1
Total:	**$ 15.2**

Results of Operations

Revenues.

Invisalign product revenues by channel and other revenues, which represented training and sales of ancillary products, for the three and nine months ended September 30, 2005 and 2004 were as follows:

	Three Months Ended				Nine Months Ended			
(Amounts in $ million)	September 30, 2005	September 30, 2004	Change*	Percent	September 30, 2005	September30, 2004	Change*	Percent
Domestic:								
Orthodontic	$ 20.3	$ 22.2	$ (1.9)	(8.5)%	$ 66.7	$ 66.4	$ 0.3	0.5%
GP	22.9	17.4	5.5	31.6%	65.9	45.0	20.9	46.4%
International	5.7	4.1	1.6	39.0%	16.6	11.8	4.8	40.7%
Total Product	48.9	43.7	5.2	11.9%	149.2	123.2	26.0	21.1%
Other revenues	2.0	2.1	(0.1)	(4.8)%	6.7	6.0	0.7	11.7%
Total Revenues	$ 50.9	$ 45.8	$ 5.1	11.1%	$ 155.9	$ 129.2	$ 26.7	20.7%

* **Primary reasons for change**: For the quarter and the nine-months ended September 30, 2005, revenue growth was primarily due to higher case volumes for the domestic GP and international channels compared to the three and nine months ended September 30, 2004. The increase in the number of cases submitted was driven by an increase in the number of participating clinicians in our domestic GP and international channels.

We expect revenues for the fourth quarter of 2005 to remain consistent with the third quarter of 2005 primarily due to recently announced pricing initiatives, competitive pressure and promotional programs.

	Three months ended September 30,				Nine months ended September 30,			
(Amounts in $ million)	2005	2004	Change	Percent	2005	2004	Change	Percent
Cost of revenues	$ 15.0	$ 14.9	$ 0.1	0.7%	$ 47.0	$ 42.6	$ 4.4	10.3%
Sales and marketing	21.3	13.9	7.4	53.2%	61.5	40.6	20.9	51.5%
General and administrative	11.7	8.3	3.4	41.0%	30.9	25.2	5.7	22.6%
Research and development	4.4	4.8	(0.4)	(8.3)%	14.7	11.8	2.9	24.6%
Interest and other	(0.3)	0.2	(0.5)	(250.0)%	0.0	0.6	(0.6)	(100.0)%
Income tax provision	0.3	0.3	—	0.0%	0.9	0.8	0.1	12.5%

Cost of revenues. Cost of revenues include the salaries for staff involved in the production process, the cost of materials and packaging, shipping costs, depreciation on the capital equipment used in the production process, training costs and the cost of facilities. Cost of revenues for the three months ended September 30, 2005 increased by $0.1 million compared to the three months ended September 30, 2004. Cost of revenues for the nine months ended September 30, 2005 increased by $4.4 million compared to the nine months ended September 30, 2004. Gross profit for the three months ended September 30, 2005 was $35.9 million or 70.6% of revenues, compared to a gross profit of $30.8 million or 67.4% of revenues for the three months ended September 30, 2004. Gross profit for the nine months ended September 30, 2005 was $108.9 million or 69.8% of revenues, compared to a gross profit of $86.6 million or 67.1% of revenues for the nine months ended September 30, 2004. The higher gross profit for the three and nine month periods ended September 30, 2005 as compared to the three and nine month periods ended September 30, 2004 is primarily attributable to improved fixed cost absorption related to increasing volumes and continued manufacturing process improvements in both our treatment operations facility in Costa Rica and in the Aligner fabrication process.

We expect gross margin percentage for the fourth quarter of 2005 to remain consistent with or be slightly less than the third quarter of 2005 primarily due to recently announced pricing initiatives, competitive pressure and promotional programs.

Sales and marketing. Sales and marketing expenses include sales force compensation (including travel related costs and expenses for professional sales training programs), costs associated with conducting workshops and market surveys, advertising and dental professional trade show attendance. Sales and marketing expenses for the three months ended September 30, 2005 increased by $7.4 million compared to the three months ended September 30, 2004. Sales and marketing expenses for the nine months ended September 30, 2005 increased by $20.9 million compared to the nine months ended September 30, 2004. The increase in sales and marketing expense of $7.4 million for the three months ended September 30, 2005, as compared to the three months ended September 30, 2004 resulted primarily from increases of $2.9 million in media, advertising and marketing expenses, an increase of $2.7 million in the compensation of our North American sales, sales training and marketing workforce, and $0.5 million related to retention incentives and guarantees to our sales force. The increase in sales and marketing expense of $20.9 million for the nine months ended September 30, 2005 as compared to the nine months ended September 30, 2004 resulted primarily from increases of $9.1 million in media, advertising and marketing expenses, an increase of $7.3 million in the

compensation of our North American sales, sales training and marketing workforce and $2.1 million related to retention incentives and guarantees to our sales force. For 2005, sales retention incentives and guarantees were put in place in response to the solicitation of our sales force by OrthoClear during the first quarter.

The increases in sales and marketing expenses during the first nine months of fiscal 2005 have been consistent with our marketing and sales initiatives, which we expect to continue. We expect sales and marketing expenses in the fourth quarter of 2005 to decline slightly compared to the first nine months due to seasonal reductions in media and advertising spending.

General and administrative. General and administrative expenses include salaries for administrative personnel, outside consulting services, legal expenses and general corporate expenses. General and administrative expenses for the three months ended September 30, 2005 increased by $3.4 million compared to the three months ended September 30, 2004. General and administrative expenses for the nine months ended September 30, 2005 increased by $5.7 million compared to the nine months ended September 30, 2004. The $3.4 million and $5.7 million increase in general and administrative expenses for the three and nine months ended September 30, 2005 as compared to the three and nine months ended September 30, 2004 was primarily due to increases in the number of administrative employees, as well as, outside legal and professional fees, including $2.0 million and $4.2 million related to OrthoClear litigation, respectively.

We expect to continue to incur significant legal fees as a result of the OrthoClear litigation. See Part II Item 1 of this Form 10-Q for a summary of our material pending legal proceedings.

Research and development. Research and development expenses include the costs associated with software engineering, the cost of designing, developing and testing our products and conducting clinical and post-marketing trials. We expense our research and development costs as incurred. Research and development expenses for the three months ended September 30, 2005 decreased by $0.4 million compared to the three months ended September 30, 2004. Research and development expenses for the nine months ended September 30, 2005 increased by $2.9 million compared to the nine months ended September 30, 2004. The decrease of $0.4 million in research and development for the three months ended September 30, 2005 resulted from a reduction in outside consulting fees as compared to the three months ended September 30, 2004. The increase of $2.9 in research and development for the nine months ended September 30, 2005 resulted from increased headcount and spending for product improvement initiatives as compared to the nine months ended September 30, 2004.

We expect to increase research and development spending in the fourth quarter of 2005 for new products and enhancements to our existing product, including spending related to the development of a next generation Aligner material, the development of a patient compliance indicator and the early testing of a bracket positioning template, and conducting clinical research.

Interest and other, net. Interest and other, net include interest income earned on cash balances, interest expense on debt, foreign currency translation gains and losses for the dollar against other currencies related to international businesses and other miscellaneous charges. Interest and other, net for the three months ended September 30, 2005 decreased $0.5 million as compared to the three months ended September 30, 2004 primarily resulted from increased interest income as a result of higher cash balances. Interest and other, net for the nine months ended September 30, 2005 decreased by $0.6 million compared to the nine months ended September 30, 2004. The decrease of $0.6 million in interest and other expense for the nine months ended September 30, 2005 as compared to the nine months ended September 30, 2004 primarily resulted from increased interest income as a result of higher cash balances, primarily offset by translation loss associated with our foreign operations.

Income tax provision. We recorded an income tax provision of $0.3 million on a net loss before income tax provision of $1.2 million and $0.9 million on a net profit before income tax provision of $1.8 million for the three and nine months ended September 30, 2005, respectively. The income tax provision recorded in the third quarter of 2005 included the amount of statutory tax that we expect to incur for the nine months ended September 30, 2005. Our effective tax rate for the remainder of 2005 may fluctuate based upon our operating results for each taxable jurisdiction in which we operate and the amount of statutory tax that we incur in each jurisdiction. As of September 30, 2005, we have recorded a full valuation allowance for our existing deferred tax assets due to uncertainties about whether we will be able to utilize these assets before they expire.

We recorded an income tax provision of $0.3 million and $0.8 million for the three and nine months ended September 30, 2004, respectively.

Liquidity and Capital Resources

Historically, we have funded our operations with cash generated from operations and the proceeds from the sale of our common stock. As of September 30, 2005, we had $77.4 million of cash and cash equivalents and $0.3 million of restricted cash. We had an accumulated deficit of $290.9 million as of September 30, 2005.

Net cash provided by operating activities was $17.0 million and $17.5 million for the nine months ended September 30, 2005 and September 30, 2004, respectively. Net cash provided by operating activities for the nine months ended September 30, 2005 resulted primarily from operating profit adjusted for non cash items and increased accrued liabilities. For the nine months ended September 30, 2004, net cash provided by operating activities resulted primarily from operating profit adjusted for non cash items and increases in accounts receivable partially offset by increases in current liabilities.

Net cash used in investing activities was $13.0 million and $4.8 million for the nine months ended September 30, 2005 and September 30, 2004, respectively. For the nine months ended September 30, 2005, net cash used in investing activities resulted primarily from the purchase of property and equipment for capacity expansion, manufacturing improvements, purchases of marketable securities and the purchase of General Orthodontics, LLC. For the nine months ended September 30, 2004, net cash used in investing activities resulted primarily from the purchase of property and equipment for capacity expansion and manufacturing improvements, partially offset by proceeds from the sale of equipment and maturities of marketable securities.

Net cash provided by financing activities was $3.6 million and $5.6 million for the nine months ended September 30, 2005 and 2004, respectively. For the nine month periods ended September 30, 2005 and 2004, net cash provided by financing activities consisted of proceeds from the issuance of common stock, primarily from exercises of employee stock options, partially offset by payments on debt obligations related to the equipment-based term loan and capital lease obligations.

Contractual Obligations. As of September 30, 2005, there have been no material changes to our contractual obligations outside the ordinary course of business from those disclosed in our annual report on Form 10-K for the fiscal year ended December 31, 2004.

In December 2003, we negotiated a $15.0 million revolving line of credit based on domestic accounts receivable which accrues interest at a rate of 0.5% above prime. Accessing the accounts receivable based revolving line of credit is restricted based on qualifying accounts receivable and compliance with certain loan covenants. The line of credit expires in December 2005. As of September 30, 2005, we had not accessed the revolving line of credit.

In December 2002, we obtained and accessed a $5.0 million equipment-based term loan, which accrues interest at a rate of 2.25% above prime. We did not draw down on any new funds in fiscal 2004 or during the first nine months of fiscal 2005. Principal payments are due in 36 monthly installments beginning in January 2003. The loan balance was $0.4 million as of September 30, 2005.

During the quarter ended September 30, 2005, we determined that we were out of compliance with our loan covenants for the accounts receivable-based revolving line of credit, which requires certain financial ratios and measurements to be maintained. The loan covenants were amended on October 27, 2005 for the purpose of decreasing the minimum Earnings Before Income Taxes, Depreciation and Amortization (EBITDA) amount that we must maintain for the fiscal quarter ended September 30, 2005 and each fiscal quarter ending thereafter from $2.0 million to zero. As a result of the amendment, we were in compliance with our loan covenants for the quarter ended September 30, 2005.

We expect that our operating expense levels for 2006 will remain consistent with or be slightly less than 2005, dependent on our level of business activity with increases, if needed, focused on; continuing efforts to automate our manufacturing processes, capacity expansion requirements, the size of our sales force and dental professional training staff, continued international sales and marketing efforts, legal expenses, and research and development expenses as we develop new products and improvements to our existing 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, and reduce our expenditures in general. Accordingly, the failure to obtain sufficient funds on acceptable terms when needed could have a material adverse effect on our business, results of operations and financial condition.

Critical Accounting Policies

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

We believe the following critical accounting policies reflect our most significant estimates, judgments and assumptions used in the preparation of our consolidated financial statements. These critical accounting policies and related disclosures appear in our Annual Report on Form 10-K for the year ended December 31, 2004.

- Recognition of revenues
- Warranty expense
- Allowance for doubtful accounts
- Accounting for long-lived assets
- Legal contingencies
- Deferred tax valuation allowance

Except as set forth below, there have been no significant changes in our critical accounting policies during the nine months ended September 30, 2005 compared to what was previously disclosed in Item 7. *Management's Discussion and Analysis of Financial Condition and Results of Operations* included in our Annual Report on Form 10-K for the year ended December 31, 2004.

Revenue Recognition

Revenue is recognized when persuasive evidence of an arrangement exists, delivery has occurred, the fee is fixed or determinable, and collectibility is probable. We enter into transactions where we are obligated to deliver multiple products and/or services (multiple elements). In recording these transactions, we generally allocate the total revenue among the elements based on the stand-alone sales price of each element when sold separately (vendor-specific objective evidence).

Revenue from the sale of the Invisalign system and ancillary products generally is recognized upon product shipment, with a portion of the revenue from sales of the Invisalign system recorded as deferred revenue due to undelivered elements related to case refinement. Case refinement is a finishing

treatment tool using newly manufactured Aligners, not previously provided with the initial Aligners, to move a patient's teeth to the final desired positions. Align's case refinement policy

allows doctors to order three case refinement as part of their original lab fee, provided they submit the order prior case expiration. Case expiration is defined as the point in time when the case is deemed complete. Case expiration date is calculated by the number of stages in a treatment plan multiplied by two weeks plus an additional one hundred and eighty days to allow for patient and doctor scheduling during or at the end of the case treatment period. Prior to our policy change during the fourth quarter of fiscal 2004, we deemed the case expiration date to occur on the ninetieth day after the expected end of treatment.

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

We updated our domestic and international pricing policies in May 2003 and January 2004, respectively, to include the future delivery of one case refinement in the price of each case and to offer additional case refinements at a price of $125 each and at a comparable price internationally, which we believe represents its fair value based on competitive product offerings. Revenue deferrals associated with future case refinement from May 1, 2003 to June 30, 2005 were $125 per case and a comparable price internationally after January 2004. These revenue deferrals are recognized when the case refinement is shipped or upon case expiration, whichever is earliest.

For Aligner cases shipped after July 1, 2005, we further modified our domestic case refinement policy to include up to three case refinements in the price of each case, provided the case refinement orders are received prior to case expiration. In addition to including more case refinements in the price of each case, we also changed our method of deferring case refinement revenue effective July 1, 2005. Between May 1, 2003 and June 30, 2005, we deferred the fair value of case refinement on 100% of Aligner cases shipped. Beginning in the third quarter of fiscal 2005, we now defer the $125 fair value of case refinement based on the historical usage rate, or "breakage factor." The breakage factor is the percentage of case refinement utilized by dental professionals over the trailing eight quarters.

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

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

Goodwill

As a result of the acquisition of GO, we recorded $0.5 million of goodwill. See Notes 4 and 5 for further information. We monitor the recoverability of goodwill annually or sooner if events or changes in circumstances indicate that the carrying amount may not be recoverable. Impairment, if any, would be determined in accordance with SFAS No. 142 "Goodwill and Other Intangible Assets", which uses a fair value model for determining the carrying value of goodwill. The impairment test is a two-step process. The first step requires comparing the fair value to its net book value. The second step is only performed if impairment is indicated after the first step is performed, as it involves measuring the actual impairment to goodwill.

RISK FACTORS

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

You should consider our business and prospects in light of the risks, expenses and difficulties encountered by a company in an early stage of operations. Since inception, we incurred significant operating losses. While we achieved profitability beginning in the fourth quarter of fiscal 2003, we experienced a net loss in the third quarter of 2005. 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 marketing campaign and dental professional marketing efforts;
- increase the size of our sales force and clinical education support staff;
- execute clinical research and education plans;
- develop technological improvements to our products;
- continue our international sales and marketing efforts;
- protect our intellectual property, including trade secrets; and

- undertake quality assurance and improvement initiatives.

As noted above, we experienced a net loss in the third quarter of 2005. As a result, if we are to return to profitability in future periods, we will need to continue to increase our revenues, while controlling our expenses. We generated positive operating cash flow for the first time during fiscal year 2003, and we cannot be certain that we will be able to sustain or increase such positive cash flow from operations, from period to period, in the future. Our net loss in the third quarter of 2005 was primarily attributable to increased sales and marketing expenses as a result of several factors, including our consumer marketing campaign, dental professional marketing efforts, continued international sales and marketing efforts and increases in the size of our sales force and dental professional training staff. For instance, in the second quarter of 2005, we launched a new consumer marketing campaign involving television, radio and print media. This marketing program is designed to raise the profile of Invisalign and drive prospective patients to our most experienced dental professionals. Marketing programs of this nature are expensive and may have limited success, if any, and the program may not result in revenue generation commensurate with its costs. In addition, legal expenses associated with the OrthoClear litigation resulted in an additional increase to our general and administrative expenses in the first nine months of 2005.

Because our business is evolving, it is difficult to predict our future operating results or levels of growth, and we may not be able to sustain our historical growth rates in future periods. If we do not increase profitability or revenue growth or otherwise meet the expectations of securities analysts or investors, the market price of our common stock will likely decline.

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

We were incorporated in April 1997 and began sales of Invisalign in July 1999. Thus, we have a limited operating history, which makes it difficult to evaluate our future prospects. In addition, we expect our future quarterly and annual operating results to fluctuate as we focus on increasing 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:

- the development and marketing of directly competitive products by potential competitors, such as OrthoClear Inc.;

- aggressive price competition from competitors, including OrthoClear;
- 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 revenues, production and other operating costs;
- costs and expenditures in connection with ongoing litigation, in particular the litigation related to OrthoClear;
- increased expenses resulting from several factors, including increased headcount in our sales and marketing department; and
- investments in research and development to develop new products and enhancements to Invisalign.

To respond to these and other factors, we may need to make business decisions that could adversely affect our operating results such as modifications to our pricing policy, business structure or operations. 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 revenues for a particular period fall below our expectations, we may be unable to adjust spending quickly enough to offset any shortfall in revenues.

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

We are currently involved in litigation with several former employees stemming from our efforts to protect our intellectual property. This litigation may be costly and could distract our management and cause a decline in our results of operations and stock price.

We seek to diligently protect our intellectual property rights. On February 2, 2005 we filed a complaint against OrthoClear, Inc., OrthoClear Holdings, Inc., Mr. Chishti, one of our founders, and several former employees. Among other things, the complaint alleges tort, contract, statutory and common law causes of action arising from OrthoClear and the individual defendants' alleged plan to unlawfully utilize our intellectual property, confidential information and employees. The complaint also alleges that OrthoClear, Mr. Chishti, and other defendants are in breach of contractual obligations, statutory law and common law for attempting to intentionally interfere and disrupt our ongoing business operations and improperly gain access to our customer relationships and trade secrets. The complaint seeks injunctive relief and monetary damages in an amount to be determined. On February 15, 2005, OrthoClear, Mr. Chishti and certain other defendants filed a multiclaim Cross-Complaint against Align and certain of our executive officers, senior management and directors alleging conspiracy, breach of contract, libel, slander, unjust enrichment, intentional interference with prospective economic advantage, and unfair competition. On July 19, 2005, Align filed a multi-claim lawsuit in the United States District Court for the Northern District of California against OrthoClear. The complaint alleges numerous violations of the federal Lanham Act (15 U.S.C. §1051 et seq.) by OrthoClear and its officers and employees. These violations include unfair competition, trademark infringement and false advertising. The complaint also alleges violations by OrthoClear of California's Unfair Practices Act (California Business and Professions Code §17200 et seq.).

Although this lawsuit is in the early stages, litigating claims of this type, whether or not ultimately determined in our favor or settled by us, is costly and diverts the efforts and attention of our management and technical personnel from normal business operations. Any of these results from our litigation could adversely affect our results of operations and stock price. See Part II Item 1 of this Form 10-Q for a summary of the OrthoClear litigation.

In addition, we are currently a party to various other legal proceedings and claims. Management does not believe that the ultimate outcome of these other legal proceedings and claims will have a material adverse effect on our financial position or results of operations. However, in the Ormco litigation,

there is no assurance that the court's decision will not be overturned on appeal. In addition, litigation is subject to inherent uncertainties and unfavorable rulings could occur. An unfavorable ruling could include monetary damages or, in cases where injunctive relief is sought, an injunction prohibiting us from selling our products. Any of these results from our litigation could adversely affect our results of operations and stock price.

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

We experience competition from manufacturers of traditional braces and expect aggressive competition from these and other companies who may introduce new technologies in the future.

Currently, our Invisalign product competes directly against a product called Red, White and Blue, which is manufactured and distributed by Ormco, a subsidiary of Sybron Dental Specialties, and an aligner product manufactured by OrthoClear, Inc. In addition, manufacturers of traditional braces, such as 3M Company, Sybron Dental Specialties and Dentsply International have substantially greater financial resources and manufacturing and marketing experience than we do and may, in the future, attempt to develop an orthodontic system similar to ours. Large consumer product companies may also enter the orthodontic supply market. Furthermore, we may face competition in the future from new companies that may introduce new technologies. We may be unable to compete with these competitors and one or more of these competitors may render our technology obsolete or economically unattractive. If we are unable to compete effectively with existing products or respond effectively to any products developed by new or existing competitors, our business could be harmed. In May 2005, OrthoClear announced the launch of the OrthoClear system, a product that is intended to compete directly with our Invisalign system. Although we intend to vigorously defend our intellectual property rights and prevent OrthoClear from continuing to market any product that infringes on our intellectual property, if OrthoClear is successful in gaining broad market acceptance of its product, our business could be adversely affected. *See Part II Item 1 of this Form 10-Q for a more complete summary of the OrthoClear litigation.* Increased competition from OrthoClear or other competitors may result in volume discounting, price reductions, reduced gross margins, reduced profitability and loss of market share, any of which could have a material adverse effect on our revenue, volume growth, net profit and stock price. For instance, in the third quarter of 2005, in order to encourage continued use of our products, we implemented a volume based discount program directed to our highest performing customers. In addition, in the fourth quarter of 2005, we introduced a new pricing initiative reducing our average price per case. We expect these programs to adversely affect our revenues, gross margin and net profit. We cannot assure you that we will be able to compete successfully against our current or future competitors or that competitive pressures will not have a material adverse effect on our business, results of operations and financial condition.

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

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

In October 2004, we implemented a new version of our enterprise resource planning system and new software for our manufacturing execution system. Throughout 2005 we intend to integrate additional functionality into our manufacturing execution system, which will more efficiently integrate this system with our other system applications, such as customer facing and manufacturing tools. System upgrades and enhancements require significant expenditures and allocation of valuable employee resources. Delays in integration or disruptions to our business from implementation of these new or upgraded systems could have a material adverse impact on our financial condition and operating results. Furthermore, we continuously upgrade our customer facing software applications, specifically our ClinCheck™ and VIP product. Software products frequently contain errors or defects, especially when they are first introduced or when new versions are released. Although we have not experienced any substantial problems to date from potential defects and errors, there is no assurance that our customer facing software is or in the future will be completely free of defects and errors. The discovery of a defect or error in a new upgraded version may result in the following consequences, among others: loss of revenue or delay in market acceptance, damage to our reputation or increased service costs, any of which could have a material adverse effect upon our business, financial condition or results of operations. Further, in the third quarter of 2005, we changed our information technology outsourcing provider. Delays in transition and failure to migrate smoothly to our new vendor could cause business disruptions.

In addition, experienced computer programmers and hackers may be able to penetrate our network security and misappropriate our confidential information or that of third parties, create system disruptions or cause shutdowns. Furthermore, sophisticated hardware and operating system software and applications that we either internally produce or procure from third parties may contain defects in design and manufacture, including "bugs" and other problems that can unexpectedly interfere with the operation of the system. The costs to eliminate or alleviate security problems, viruses and

bugs could be significant, and the efforts to address these problems could result in interruptions that may have a material adverse impact on our operations, sales and operating results.

While we believe we currently have adequate internal control over financial reporting, we are required to assess our internal control over financial reporting on an annual basis and any future adverse results from such assessment could result in a loss of investor confidence in our financial reports and have an adverse effect on our stock price.

Pursuant to the Sarbanes-Oxley Act of 2002 and the rules and regulations promulgated by the SEC, we are required to furnish in our Form 10-K an annual report by our management regarding the effectiveness of our internal control over financial reporting. The report, which was included in our most recent Form 10-K, includes, among other things, an assessment of the effectiveness of our internal control over financial reporting as of the end of our fiscal year, including a statement as to whether or not our internal control over financial reporting is effective. This assessment must include disclosure of any material weaknesses in our internal control over financial reporting identified by management. While we currently believe our internal control over financial reporting is effective, the effectiveness of our internal controls to future periods is subject to the risk that our controls may become inadequate because of changes in conditions, and, as a result, the degree of compliance of our internal control over financial reporting with the policies or procedures may deteriorate. If we are unable to assert that our internal control over financial reporting is effective in any future period (or if our auditors are unable to express

an opinion on the effectiveness of our internal controls), we could lose investor confidence in the accuracy and completeness of our financial reports, which would have an adverse effect on our stock price.

We depend on the sale of Invisalign for the vast majority of our revenues, and any decline in sales of Invisalign would adversely affect our business and results of operations.

We expect that revenues from the sale of Invisalign will continue to account for the vast majority of our total revenues for the foreseeable future. Continued and widespread market acceptance of Invisalign by orthodontists, GPs and consumers is critical to our future success. If orthodontists and GPs experience a reduction in consumer demand for orthodontic services or consumers prove unwilling to adopt Invisalign as rapidly as we anticipate or in the volume that we anticipate, or if orthodontists and GPs do not collaborate as we expect, our operating results could be harmed. Factors that could cause Invisalign not to achieve market acceptance at the rate at which we expect, or at all, are described more fully below.

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

Our success depends upon increasing acceptance of Invisalign by dental professionals. Invisalign requires orthodontists, GPs 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, orthodontists and GPs may be reluctant to adopt it until more historical clinical results are available. Also, increasing adoption and cumulative use by orthodontists and GPs will depend on factors such as the capability, safety, efficacy, ease of use, price, quality and reliability of our products, our ability to provide effective sales support, training and service and the availability of competing products, technologies and alternative treatments. In the future, unanticipated poor clinical performance of Invisalign could result in significant adverse publicity and, consequently, reduced acceptance by dental professionals. In addition, increased competition from direct competitors could cause us to lose market share and reduce customers efforts and commitment to expand their Invisalign practice. If Invisalign does not achieve growing acceptance in the orthodontic and GP communities, our operating results will be harmed.

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

In addition, our success depends upon the acceptance of Invisalign by a substantially larger number of dental professionals as well as potential consumers to whom we are now actively marketing. Invisalign represents a significant change from traditional orthodontic treatment, and consumers may be reluctant to accept it or may not find it preferable to conventional treatment. In addition, consumers 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 orthodontists, GPs and consumers regarding Invisalign as both an alternative to braces and as a clinical method for treatment of malocclusion, but a number of dental professionals believe that Invisalign is appropriate for only a limited percentage of their patients. Market acceptance will depend in part upon the recommendations of dental professionals, as well as other factors including effectiveness, safety, reliability, improved treatment, aesthetics, greater comfort and hygiene compared to conventional orthodontic products and price for Invisalign compared to competing 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 in North America and internationally, which fluctuate and could be affected by unstable global economic, political or other conditions.

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

Our success depends in part upon improving the collaboration and referral relationships between orthodontists and GP dentists. As specialists, orthodontists are a critical part of our business, and we expect that orthodontists will continue to treat the majority of complex cases and continue to drive research for expanding Invisalign applications. We expect, however, that the percentage of revenues generated by GPs will increase, largely due to the fact that there are significantly more GPs than orthodontists. As the primary provider of dental care, GPs have access to a greater number of patients than orthodontists, possess a unique opportunity to educate these patients and introduce them to Invisalign, have the ability to refer appropriate cases to orthodontists and, in certain instances, may chose to treat less complex cases themselves. If this collaboration and increase in referrals does not occur or occurs more slowly than we anticipate, our operating results could be harmed.

Our future success may depend on our ability to develop and successfully introduce new products.

Our future success may depend on our ability to develop, obtain regulatory approval or clearance of, manufacture and market new products. In the second half of 2005, we launched Invisalign Express™, a value based Aligner system to be used for less complex cases, and we are in early testing of a bracket positioning template. There can be no assurance that we will be able to successfully sell and achieve market acceptance of these and other new products and applications and enhanced versions of our existing product. The extent of, and rate at which, market acceptance and penetration are achieved by future products is a function of many variables, which include, among other things, price, safety, efficacy, reliability, marketing and sales efforts, the availability of third-party reimbursement of procedures using our new products, the existence of competing products and general economic conditions affecting purchasing patterns. Our ability to market and sell new products may also be subject to government regulation, including approval or clearance by the United States Food and Drug Administration, or FDA, and foreign government agencies. Any failure in our ability to successfully develop and introduce new products or enhanced versions of existing products and achieve market acceptance of new products and new applications could have a material adverse effect on our operating results and could cause our revenues to decline.

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 ClinCheck™ and are used to manufacture Aligner molds. A third party manufacturer in Mexico fabricates Aligners and ships the completed products to our customers. Our costs associated with these operations are denominated in Costa Rican colons, Mexican pesos and U.S. dollars.

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

- political, social and economic instability;
- acts of terrorism and acts of war;
- difficulties in staffing and managing international operations; import and export license requirements and restrictions;
- controlling quality of the manufacturing process;
- interruptions and limitations in telecommunication services;
- product or material transportation delays or disruption;
- burdens of complying with a wide variety of local country and regional laws;

- trade restrictions and changes in tariffs;
- 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.

In addition, by the second quarter of fiscal 2006, we expect to have completed the relocation of our stereolithography (SLA) mold fabrication operations from our Santa Clara facility to Mexico. Upon completion of this relocation, our SLA mold fabrication operations and our Aligner fabrication operations will be conducted by a third party manufacturer in Mexico. In addition to the risks set forth above, if we do not successfully coordinate the relocation and consolidation of our SLA mold fabrication operations, we may be unable to produce sufficient volume of molds to meet customer demand, which would harm our results of operations.

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. As of September 30, 2005, we had 62 issued U.S. patents, 92 pending U.S. patent applications, and numerous foreign issued patents, as well as pending foreign patent applications.

We intend to rely on our portfolio of issued and pending patent applications in the U.S. and in other countries to protect a large part of our intellectual property and our competitive position. However, our currently pending or future patent filings may not result in the issuance of 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 the second quarter and third quarter of 2005, requests were filed with the United States Patent and Trademark Office ("USPTO") by a San Francisco, California, law firm, acting on behalf of an unnamed party, requesting reexamination of five of our patents (U.S. Patent Nos. 5,975,893, 6,398,548, 6,309,215, 6,705,863 and 6,217,325, (collectively, the "Reexam Patents")). The USPTO has granted the request to reexamine each of the Reexam Patents. The reexamination proceedings on these patents are currently pending. While the pending reexaminations are in a preliminary stage and we are still evaluating all issues, we believe that the Reexam Patents are valid. However, there can be no assurance that we will prevail, and an adverse outcome of the reexamination proceedings could cause some or all of the Reexam Patent claims to have a narrower scope of coverage or even to be invalidated. See Part II Item 1 of this Form 10-Q. 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. See Part II Item 1 of this Form 10-Q for a summary of the OrthoClear litigation.

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 our pricing and market share.

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

Extensive litigation over patents and other intellectual property rights is common in the medical device industry. We have been sued for infringement of third party's patents in the past and we may be the subject of patent or other litigation in the future. From time to time, we have received and may in the future receive letters from third parties drawing our attention to their patent rights. While we do not believe that we infringe upon any valid and enforceable rights that have been brought to our attention, there may be other more pertinent rights of which we are presently unaware. The defense and prosecution of intellectual property suits, interference proceedings and related legal and administrative proceedings could result in substantial expense to us and significant diversion of effort by our technical and management personnel. An adverse determination of any litigation or interference proceeding to which we may become a party could subject us to significant

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

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

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. In addition, by the second quarter of fiscal 2006, we expect to outsource our SLA mold fabrication process to the same third party manufacturer in Mexico. As a result, if this third party manufacturer fails to deliver its components or if we lose its services, we may be unable to deliver our products in a timely manner, and our business may be harmed. Any difficulties encountered by the third party manufacturer with respect to hiring personnel, and maintaining acceptable manufacturing standards, controls, procedures and policies could disrupt our ability to deliver our products in a timely manner. Finding a substitute manufacturer may be expensive, time-consuming or impossible.

We maintain single supply relationships for certain of our key machines and materials technologies, and our business and operating results could be harmed if supply is restricted or ends.

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. In particular, we are committed to purchase all of our resin from a single-source and our scanning and stereolithography equipment are provided by single suppliers. Technology changes by our vendors could disrupt access to required manufacturing capacity or require expensive, time consuming development efforts to adapt and integrate new equipment or processes. 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 technology changes, delivery delays or shortages of these items, our business and growth prospects may be harmed.

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

We have expanded rapidly since we commenced commercial sales in 1999. Our headcount increased from approximately 50 employees as of December 31, 1999 to approximately 1,098 employees as of September 30, 2005. 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 sufficiently skilled personnel, providing adequate training and supervision to maintain our high quality standards, and preserving our culture and values. Our inability to effectively manage this level of growth could harm our business.

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

We are highly dependent on the key employees in our clinical engineering, technology development, sales and marketing personnel 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, including orthodontists. 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. Finally, we currently do not have a Vice President of Marketing or a Vice President of Information Technology. We are currently engaged in a search for people to fill these positions. If we are unable to attract and retain key personnel, our business could be materially harmed.

We rely on our direct sales force to sell our products, and any failure to maintain our direct sales force could harm our business.

Our ability to sell our products and generate revenues depends upon our direct sales force within our domestic market and internationally. As of September 30, 2005 our direct sales force consisted of 103 employees. We do not have any

long-term employment contracts with the members of our direct sales force. The loss of the services of these key personnel may harm our business. In the first half of 2005, approximately 17 orthodontic sales representatives, representing approximately 50% of our orthodontic sales force, left Align and joined OrthoClear. Although we have replaced the majority of these individuals with new sales representatives, to adequately train and successfully deploy new representatives into effected regions and to reestablish strong customer relationships takes time. If we are unable to replace our direct sales force personnel with individuals of equivalent technical expertise and qualifications, or if we are unable to successfully instill such technical expertise or if we fail to reestablish strong relationships with our customers within a relatively short period of time, our revenues and our ability to maintain market share could be materially harmed.

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

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

- product design, development, manufacture and testing;
- product labeling;
- product storage;

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

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

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

If any of these events were to occur, they could harm our business. We must comply with facility registration and product listing requirements of the FDA and adhere to applicable Quality System regulations. The FDA enforces its Quality System regulations through periodic unannounced inspections. We have not yet been subject to an FDA inspection, and we cannot assure you we will successfully pass such an inspection in the future. Our failure to take satisfactory corrective action in response to an adverse inspection or our failure to comply with applicable manufacturing regulations could result in enforcement action, and we may be required to find alternative manufacturers, which could be a long and costly process.

Before we can sell a new medical device in the U.S., or market a new use of or claim for an existing product we must obtain FDA clearance or approval, unless an exemption applies. Obtaining regulatory clearances or approvals can be a lengthy and time-consuming process. Even though the devices we market have obtained the necessary clearances from the FDA, we may be unable to maintain such clearances in the future. Furthermore, we may be unable to obtain the necessary clearances for new devices that we intend to market in the future. Our inability to maintain or obtain regulatory clearances or approvals could materially harm our business.

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

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

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

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

The healthcare market itself is highly regulated and subject to changing political, economic and regulatory influences. Regulations implemented pursuant to the Health Insurance Portability and Accountability Act (HIPAA), including regulations affecting the security and privacy of patient healthcare information held by healthcare providers and the business associates may require us to make significant and unplanned enhancements of software applications or services, result in delays or cancellations of orders, or result in the revocation of endorsement of our products and services by healthcare participants. The effect of HIPAA and newly enacted regulations on our business is difficult to predict, and there can be no assurance that we will adequately address the business risks created by HIPAA and its implementation or that we will be able to take advantage of any resulting business opportunities. Additionally, the HIPAA Security Standard, which went into effect in April 2005, requires that we implement safeguards that reasonably and appropriately protect the confidentiality, integrity and availability of the electronic protected health information that we create, receive, maintain or transmit pursuant to our Business Associate Agreements with healthcare professionals. Compliance with the Security Standard could require complex changes in our internal systems and services and could be costly.

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

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

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

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

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

We currently sell our products in Europe, Canada, the United Kingdom, Mexico, Brazil, Australia and Hong Kong, and may expand into other countries from time to time. Recently, we announced our intention to launch sales of Invisalign in Japan. We do not know whether orthodontists, GPs and consumers outside our domestic market will adopt Invisalign in sufficient numbers or as rapidly as we anticipate. In addition, sales of our products outside the U.S. are subject to foreign regulatory requirements that vary widely from country to country. The time required to obtain clearances or approvals required by other countries may be longer than that required for FDA clearance or approval, and requirements for such approvals may differ from FDA requirements. We may be unable to obtain regulatory approvals in one or more of the other

countries in which we do business or in which we may do business in the future. We may also incur significant costs in attempting to obtain and maintain foreign regulatory approvals. If we experience delays in receipt of approvals to market our products outside of the U.S., 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.

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 2004 and during the first nine months of fiscal 2005, the market price for our common stock was volatile.

The market price of our common stock could be subject to wide price fluctuations in response to various factors, many of which are beyond our control. The factors include:

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

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

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

A large percentage of our outstanding common stock is currently owned by a small number of significant stockholders. These stockholders have sold in the past, and may sell in the future, large amounts of common stock over relatively short periods of time. Sales of substantial amounts of our common stock in the public market by our existing stockholders may adversely affect the market price of our common stock. Such sales could create public perception of difficulties or problems with our business and may depress our stock price.

Changes in, or interpretations of, accounting rules and regulations, such as expensing of stock options, could result in unfavorable accounting charges.

We prepare our consolidated financial statements in conformity with accounting principles generally accepted in the United States of America. These principles are subject to interpretation by the SEC and various bodies formed to interpret and create appropriate accounting policies. A change in these policies can have a significant effect on our reported results and may even retroactively affect previously reported transactions. Our accounting policies that recently have been or may be affected by changes in the accounting rules are as follows:

- revenue recognition;
- accounting for share-based payments; and

- accounting for income taxes.

In particular, the FASB recently enacted SFAS No. 123 (revised 2004), "Share-Based Payment" ("SFAS 123R") which we will adopt effective in the first quarter of fiscal 2006. As a result, we expect that SFAS 123R will have a significant adverse effect on our reported financial results and may impact the way in which we conduct our business, which may affect our stock price.

We have made use of a device to limit the possibility that we are acquired, which may mean that a transaction that shareholders are in favor of or are benefited by may be prevented.

Our board of directors has the authority to issue up to 5,000,000 shares of preferred stock and to determine the rights, preferences, privileges and restrictions of such shares without any further vote or action by our shareholders. To date, our board of directors has designated 200,000 shares as Series A participating preferred stock in connection with our shareholder rights' plan. The issuance of preferred stock under certain circumstances could have the effect of delaying or preventing an acquisition of our company or otherwise adversely affecting the rights of the holders of our stock. The shareholder rights' plan may have the effect of rendering more difficult or discouraging an acquisition of our company which is deemed undesirable by our board of directors. The shareholder rights' plan may cause substantial dilution to a person or group attempting to acquire us on terms or in a manner not approved by our board of directors, except pursuant to an offer conditioned on the negation, purchase or redemption of the rights issued under the shareholder rights' plan.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Quantitative Disclosures

For quantitative and qualitative disclosures about market risk affecting us, see Item 7A, "Quantitative and Qualitative Disclosures About Market Risk," of our Annual Report on Form 10-K for the fiscal year ended December 31, 2004, which is incorporated herein by reference. Our exposure to market risk has not changed materially since December 31, 2004.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of disclosure controls and procedures.

Our management evaluated, under the supervision and with the participation of our Chief Executive Officer and our Chief Financial Officer, the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of the end of the period covered by this Quarterly Report on Form 10-Q. Based upon that evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that our disclosure controls and procedures are effective as of September 30, 2005 to provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our Chief Executive Officer and our Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure, and that such information is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission rules and forms.

Changes in internal control over financial reporting.

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

PART II—OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

OrthoClear

On February 2, 2005, we filed a multi-claim lawsuit in San Francisco County Superior Court against defendants OrthoClear, Inc., OrthoClear Holdings, Inc., Muhammad Ziaullah Chishti, Bao Tran, Peter Riepenhausen, Joe Breeland, Jeff Tunnell, Christopher Kawaja, and Charles Wen. Among other things, the complaint alleges tort, contract, statutory and common law causes of action arising from OrthoClear and the individual defendants' alleged plan to unlawfully utilize our intellectual property, confidential information and employees. The complaint also alleges that OrthoClear, Chishti and other defendants are in breach of contractual obligations, statutory law and common law for attempting to intentionally interfere and disrupt our ongoing business operations and improperly gain access to our customer relationships and trade secrets. The complaint seeks injunctive relief and monetary damages in an amount to be determined.

On February 15, 2005, OrthoClear, Chishti, Riepenhausen, Breeland, Tunnell, Kawaja and Wen filed a multi-claim cross-complaint against Align, Thomas Prescott, Roger George, Eldon Bullington, David Thrower, Patricia Wadors, Gil Laks and Kelsey Wirth (collectively, the "Align Parties") alleging conspiracy, breach of contract, libel, slander, unjust enrichment, intentional interference with prospective economic advantage, and unfair competition. The cross-complaint seeks injunctive relief and monetary damages in an amount to be determined.

On February 18, 2005, the Court granted our request for and issued a Temporary Restraining Order ("TRO") prohibiting OrthoClear and the individual OrthoClear defendants from engaging, assisting, or participating, directly or indirectly, in soliciting, inducing to leave, recruiting, or encouraging any current Align employee or consultant to terminate or alter his or her employment or business relationship with Align or attempting to do the same. The Court also granted our request and issued a TRO prohibiting OrthoClear and the individual OrthoClear defendants from disclosing, using, lecturing upon or publishing any of our proprietary information without our express prior written permission. In addition, in response to a cross-application for TRO filed by certain

OrthoClear defendants, the Court enjoined Chishti and the Align Parties from disparaging each other in such a manner as to violate the mutual non-disparagement clause contained in the Separation

Agreement between Align and Chishti dated as of March 27, 2002. The Court also enjoined the Align Parties from advising any Align employee or consultant that he or she will be subject to criminal charges or a civil lawsuit if that person elects to change his or her employment status with Align, unless we have good cause to believe criminal conduct has been or will be committed or that a civil cause of action will lie against the employee or consultant. The Court also required the Align Parties to refrain from taking any actions inconsistent with Federal or State securities laws relating to the issuance or redemption of Align stock. On March 1, 2005, the Court signed a Stipulated Preliminary Injunction Order, whereby the Court ordered that the express terms of the TRO remain in place until the earlier of (i) trial, (ii) written agreement of the parties or further Court order setting an earlier termination, or (iii) as to the preliminary injunction regarding non-solicitation or recruiting of Align employees or consultants only, October 27, 2005.

The defendants and the Align Parties filed demurrers to the complaint and the cross-complaint, respectively. On June 6, the Court ruled on demurrers on the complaint filed by OrthoClear and denied OrthoClear's challenges to the core of our complaint—Align's claims of Misappropriation of Trade Secrets and Breach of Contract—by overruling the OrthoClear demurrers to these causes of action. In addition, the Court granted our request for permission to amend our original complaint to consolidate several duplicative causes of action and to add specific evidence not available to us when the original complaint was filed. OrthoClear did not oppose the demurrer filed by us and amended its original pleading by filing a first supplemental and amended cross-complaint.

On July 6, 2005, OrthoClear filed a demurrer to our first amended complaint. On August 23, 2005, the Court issued an order overruling all of OrthoClear's demurrers. As a result, on September 9, 2005, OrthoClear filed answers to eleven causes of action brought by us. In September 2005, we presented demurrers to OrthoClear's first supplemental and amended cross-complaint. As of the date of this Form 10-Q, the Court has not ruled on our demurrers. We deny the allegations in the amended cross-complaint, and will vigorously defend against such claims that survive our demurrers. A trial date has been scheduled for October 30, 2006.

On July 19, 2005, we filed a multi-claim lawsuit in the United States District Court for the Northern District of California against OrthoClear. The complaint alleges numerous violations of the federal Lanham Act (15 U.S.C. §1051 et seq.) by OrthoClear and its officers and employees. These violations include unfair competition, trademark infringement and false advertising. The complaint also alleges violations by OrthoClear of California's Unfair Practices Act (California Business and Professions Code §17200 et seq.).

The complaint seeks monetary damages according to proof at trial and an injunction preventing OrthoClear from further false advertising and unfair competition including any use of our trademarks or any advertising which deceives consumers into incorrectly believing that OrthoClear has a program for training and certifying dentists and orthodontists or that dentists or orthodontists have used OrthoClear to successfully treated patients. No trial date has been set in the case.

Ormco

On January 6, 2003, Ormco Corporation ("Ormco") filed suit against us in the United States District Court for the Central District, Orange County Division, asserting infringement of U.S. Patent Nos. 5,447,432, 5,683,243 and 6,244,861. The complaint sought unspecified monetary damages and injunctive relief. On February 18, 2003, we answered the complaint and asserted counterclaims seeking a declaration by the Court of invalidity and non-infringement of the asserted patents. In addition, we counterclaimed for infringement of our U.S. Patent No. 6,398,548, seeking unspecified monetary damages and injunctive relief. Ormco filed a reply to our counterclaims on March 10, 2003 and asserted counterclaims against us seeking a declaration by the Court of invalidity and non-infringement of U.S. Patent No. 6,398,548. We amended our counterclaim to add Allesee Orthodontic Appliances, Inc. ("AOA"), a wholly-owned subsidiary of Ormco, as a counterdefendant in regard to our counterclaim of infringement of U.S. Patent No. 6,398,548. The Court then permitted Ormco to amend its Complaint and permitted us to amend our counterclaim to add an additional patent each. Ormco filed a first amended complaint for infringement of U.S. Patent No. 6,616,444 on October 15, 2003. On October 27, 2003, we filed an answer to Ormco's first amended complaint and a counterclaim for invalidity and non-infringement of U.S. Patent No. 6,616,444 and for infringement of U.S. Patent No. 6,554,611.

In connection with these claims, the Court granted five motions for summary judgment that we filed. First, on May 14, 2004, the Court granted our motion for summary judgment of non-infringement, finding that our Invisalign system does not infringe any of the asserted Ormco patents (5,477,432, 5,683,243, 6,244,861 and 6,616,644). Second, on July 2, 2004, the Court granted in part our motion for summary judgment of infringement, finding that Ormco and AOA infringe certain, but not all, claims of our patents Nos. 6,398,548 and 6,554,611 through the manufacture and sale of Red, White & Blue appliances. Third, on August 26, 2004, the Court granted our motion for summary judgment of invalidity of Ormco's asserted patents claims (5,477,432, 5,683,243, 6,244,861 and 6,616,644). As noted above, the Court earlier found that we do not infringe these patents. In addition, the Court also denied Ormco's and AOA's motion for summary judgment seeking a finding of invalidity of our asserted patent claims (6,398,548 and 6,554,611). Fourth, the Court granted our summary judgment motion that our asserted patent claims are not invalid based on the evidence currently before the Court. Although the Court granted that motion, it reopened discovery on two additional invalidity arguments Ormco and AOA asserted. Fifth, the Court also granted our summary judgment motion that our patents are not unenforceable and granted Ormco's and AOA's summary judgment motion that Ormco and AOA did not willfully infringe our patents.

On December 20, 2004, we filed a further summary judgment motion that our asserted claims are not invalid based on Ormco's and AOA's new evidence. Ormco and AOA filed a counter-summary judgment motion that our asserted claims are invalid based on this new evidence. The motions were heard by the Court on February 7, 2005. On February 24, 2005, the Court granted our motion in part, confirming the validity of all of the asserted claims of our 6,554,611 patent and two of the asserted claims of our 6,398,548 patent. The Court also granted Ormco's and AOA's motion in part, finding certain claims of our 6,398,548 patent to be invalid in view of prior use evidence. On March 10, 2005, Ormco and AOA moved for reconsideration of the Court's ruling that Claims 10 and 17 of our U.S. Patent No. 6,398,548 are not invalid. On April 8, 2005, upon a motion for reconsideration made by Ormco and AOA, the Court advised that it would adhere to its previous ruling that Claims 10 and 17 of our 6,398,548 patent are not invalid.

On March 28, 2005, we filed a motion for permanent injunction to prevent Ormco and AOA from selling the infringing Red, White & Blue system. On May 26, 2005, the Court issued a permanent injunction (the "Permanent Injunction") to enjoin Ormco and AOA from further infringement of Claims 10 and 17 of our 6,398,548 patent and Claims 1-3 and 7 of our 6,554,611 patent. On May 31, 2005, Ormco and AOA noticed an appeal to the Federal Circuit from the Permanent Injunction. As of the date of this Form 10-Q, the Permanent Injunction remains in full force and effect.

As of the date of this Form 10-Q, only our remedies for Ormco's and AOA's adjudged infringement remain at issue A trial date has been scheduled for February 28, 2006.

Other matters

In the second quarter and third quarter of 2005, requests were filed with the United States Patent and Trademark Office ("USPTO") by a San Francisco, California, law firm, acting on behalf of an unnamed party, requesting reexamination of five of our patents (U.S. Patent Nos. 5,975,893, 6,398,548, 6,309,215, 6,705,863 and 6,217,325, (collectively, the "Reexam Patents")). The USPTO granted the request to reexamine the Reexam Patents. The reexamination proceedings on these patents are currently pending. While the pending reexaminations are in a preliminary stage and we are still evaluating all issues, we believe that the Reexam Patents are valid. However, there can be no assurance that we will prevail, and an adverse outcome of the reexamination proceedings could cause some or all of the Reexam Patent claims to have a narrower scope of coverage or even to be invalidated.

On July 25, 2005, Bay Materials, LLC ("Bay") filed suit against us in the Superior Court of the State of California for the County of San Mateo. The complaint, as amended, asserts, among other things, breach of contract, promissory estoppel, fraud and negligent misrepresentation by us. Bay alleges that we breached the terms of a purchase order by failing to pay for unshipped goods manufactured by Bay pursuant to such order. Bay further alleges that we promised to purchase from Bay an alternative polyurethane product and Bay relied on this representation to develop such an alternative product which we determined not to use. The complaint seeks monetary damages of $1.1 million related to breach of contract and research and development costs incurred plus unspecified damages related to lost profit, punitive and exemplary damages, and legal expenses. We intend to vigorously defend ourselves.

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

Not applicable.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

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

Not applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

(a) Exhibits:

Exhibit Number	Description	Incorporated by reference herein			Filed herewith
		Filing	Date	Exhibit Number	
10.1	Standard compensation arrangement for lead director	Form 8-K	07/28/2005	None	
10.2	Commitment to purchase sterolithography equipment from 3D Systems	Form 8-K	08/01/2005	None	
10.3†	Employment Agreement dated September 12, 2005 with Gil Laks	Form 8-K	09/14/2005	10.1	
31.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				*
31.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				*
32.1	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				*

† Management contract or compensatory plan or arrangement

SIGNATURES

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

Date: November 4, 2005

ALIGN TECHNOLOGY, INC.

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

By: /s/ ELDON M. BULLINGTON
Eldon M. Bullington
Vice President of Finance and Chief Financial Officer

EXHIBIT INDEX

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† Management contract or compensatory plan or arrangement

Exhibit 31.1

CERTIFICATION

I, Thomas M. Prescott, certify that:

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

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and we have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

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

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 4, 2005

/s/ THOMAS M. PRESCOTT
Thomas M. Prescott
President and Chief Executive Officer

Exhibit 31.2

CERTIFICATION

I, Eldon M. Bullington, certify that:

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

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and we have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

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

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 4, 2005

/s/ ELDON M. BULLINGTON
Eldon M. Bullington
Vice President of Finance and Chief Financial Officer

Exhibit 32.1

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

I, Thomas M. Prescott, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Quarterly Report of Align Technology, Inc. on Form 10-Q for the quarter ended September 30, 2005 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in such Quarterly Report on Form 10-Q fairly presents in all material respects the financial condition and results of operations of Align Technology, Inc.

Date: November 4, 2005

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

I, Eldon M. Bullington, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Quarterly Report of Align Technology, Inc. on Form 10-Q for the quarter ended September 30, 2005 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in such Quarterly Report on Form 10-Q fairly presents in all material respects the financial condition and results of operations of Align Technology, Inc.

Date: November 4, 2005

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