ALIGN TECHNOLOGY INC
Form 10-Q
August 07, 2006

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2006

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 x No o

Indicate by check mark whether the Registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act.

Large accelerated filer o Accelerated filer x Non-accelerated filer 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 x

The number of shares outstanding of the registrant s Common Stock, $0.0001 par value, as of July 31, 2006 was 63,256,273.

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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 June 30,				Six Months Ended June 30,			
	2006		2005		2006		2005	
Revenues	$ 53,221		$ 53,940		$ 102,129		$ 105,095	
Cost of revenues	16,492	(1)	16,620		30,789	(2)	32,098	
Gross profit	36,729		37,320		71,340		72,997	
Operating expenses:								
Sales and marketing	20,641	(1)	21,049		40,707	(2)	40,183	
General and administrative	15,354	(1)	9,723		30,418	(2)	19,234	
Research and development	4,025	(1)	5,355		8,719	(2)	10,258	
Total operating expenses	40,020		36,127		79,844		69,675	
Profit (loss) from operations	(3,291)		1,193		(8,504)		3,322	
Interest and other income (expense), net	841		(238)		1,539		(298)	
Net profit (loss) before provision for income taxes	(2,450)		955		(6,965)		3,024	
Provision for income taxes	(160)		(417)		(409)		(623)	
Net profit (loss)	$ (2,610)		$ 538		$ (7,374)		$ 2,401	
Net profit (loss) per share:								
Basic	$ (0.04)		$ 0.01		$ (0.12)		$ 0.04	
Diluted	$ (0.04)		$ 0.01		$ (0.12)		$ 0.04	
Shares used in computing net profit (loss) per share:								
Basic	62,966		61,484		62,743		61,367	
Diluted	62,966		62,953		62,743		62,939	

(1) Amounts for the three months ended June 30, 2006 include stock-based compensation expense recognized under FAS 123R for stock options, restricted stock units and employee stock purchases (see Note 7 Stock-based Compensation of the Notes to Condensed Consolidated Financial Statements). The Company recognized $2.3 million in total stock-based compensation expense in the three months ended June 30, 2006, including $0.2 million in cost of revenues, $0.8 million in sales and marketing, $1.0 million in general and administrative and $0.3 million in research and development.

(2) Amounts for the six months ended June 30, 2006 include stock-based compensation expense recognized under FAS 123R for stock options, restricted stock units and employee stock purchases (see Note 7 Stock-based Compensation of the Notes to Condensed Consolidated Financial Statements). The Company recognized $4.5 million in total stock-based compensation expense in the six months ended June 30, 2006, including

$0.3 million in cost of revenues, $1.5 million in sales and marketing, $2.1 million in general and administrative and $0.6 million in research and development.

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)

	June 30, 2006	December 31, 2005
ASSETS		
Current assets:		
Cash and cash equivalents	$ 57,486	$ 74,219
Restricted cash	159	150
Marketable securities, short-term	12,268	
Accounts receivable, net of allowance for doubtful accounts of $927 and $1,626 at June 30, 2006 and December 31, 2005, respectively	32,790	29,305
Inventories, net	2,733	2,930
Prepaid expenses and other current assets	6,487	4,982
Total current assets	111,923	111,586
Property and equipment, net	26,610	26,427
Goodwill	478	478
Intangible assets, net	546	719
Other assets	2,200	2,900
Total assets	$ 141,757	$ 142,110
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 4,813	$ 2,489
Accrued liabilities	26,600	29,372
Deferred revenues	13,250	16,747
Total current liabilities	44,663	48,608
Other long-term liabilities	379	64
Total liabilities	45,042	48,672
Commitments and contingencies (Note 4)		
Stockholders equity:		
Preferred stock: $0.0001 par value; Authorized: 5,000 shares; Issued and outstanding: none at June 30, 2006 and December 31, 2005		
Common stock: $0.0001 par value; Authorized: 200,000 shares; Issued: 63,044 and 62,120 shares at June 30, 2006 and December 31, 2005, respectively; Outstanding: 63,004 and 62,080 shares at June 30, 2006 and December 31, 2005, respectively	6	6
Additional paid-in capital	394,500	383,836
Accumulated other comprehensive income (loss)	(6)	7
Accumulated deficit	(297,785)	(290,411)
Total stockholders equity	96,715	93,438
Total liabilities and stockholders equity	$ 141,757	$ 142,110

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)

	Six Months Ended June 30, 2006	2005
Cash Flows from Operating Activities:		
Net profit (loss)	$ (7,374)	$ 2,401
Adjustments to reconcile net profit (loss) to net cash provided by (used in) operating activities:		
Depreciation and amortization	4,601	5,367
Amortization of intangibles	191	162
Stock-based compensation expense	4,471	90
(Gain) loss on retirement and disposal of fixed assets	(257)	19
Non-cash accretion on marketable securities	(152)	
Changes in assets and liabilities, net of acquisition effects:		
Accounts receivable	(3,485)	(6,384)
Inventories	197	(273)
Prepaid expenses and other current assets	(1,505)	(2,646)
Accounts payable	2,368	1,009
Accrued and other long-term liabilities	(2,092)	4,996
Deferred revenue	(3,497)	3,304
Net cash provided by (used in) operating activities	(6,534)	8,045
Cash Flows from Investing Activities:		
Purchase of property and equipment	(4,768)	(5,939)
Proceeds from sale of property and equipment	367	
Restricted cash	(9)	(99)
Purchases of marketable securities	(12,130)	(250)
Maturities of marketable securities		250
Payments for acquisition, net of cash acquired		(856)
Other assets	147	47
Net cash used in investing activities	(16,393)	(6,847)
Cash Flows from Financing Activities:		
Proceeds from issuance of common stock	6,194	3,141
Payments on line of credit		(984)
Net cash provided by financing activities	6,194	2,157
Net increase (decrease) in cash and cash equivalents	(16,733)	3,355
Cash and cash equivalents at beginning of period	74,219	69,659
Cash and cash equivalents at end of period	$ 57,486	$ 73,014

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

ALIGN TECHNOLOGY, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(unaudited)

Note 1. Summary of Significant Accounting Policies

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. The December 31, 2005 balance sheet was derived from audited financial statements, but does not include all disclosures required by accounting principles generally accepted in the United States. However, the Company believes that the disclosures are adequate to make the information presented not misleading. In the opinion of management, the accompanying unaudited Condensed Consolidated Financial Statements reflect all adjustments necessary to present fairly the financial position of the Company as of June 30, 2006 and December 31, 2005, its results of operations for the three and six months ended June 30, 2006 and 2005, and its cash flows for the six months ended June 30, 2006 and 2005.

The results of operations for the three and six months ended June 30, 2006 are not necessarily indicative of the results that may be expected for the year ending December 31, 2006, 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, 2005.

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.

Stock-based compensation

Effective January 1, 2006, the Company adopted Statement of Financial Accounting Standards (FAS) No. 123 (Revised 2004), Share-Based Payment (FAS 123R), which requires the measurement and recognition of compensation expense for all stock-based payment awards made to employees and directors, including stock options, restricted stock units and employee stock purchases related to the Employee Stock Purchase Plan based on estimated fair values of these awards over the requisite employee service period. FAS 123R supersedes Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees (APB 25), which the Company previously followed in accounting for stock-based awards. In March 2005, the SEC issued Staff Accounting Bulletin No. 107 (SAB 107) to provide guidance on FAS 123R. The Company has applied SAB 107 in its adoption of FAS 123R.

Under the provisions of FAS 123R, the Company adopted the modified prospective transition method which requires stock-based compensation cost to be recognized for share-based payments awards granted to, but not yet vested as of, December 31, 2005 based on the grant date fair value estimated in accordance with the pro forma provisions of FASB Statement 123, Accounting for Stock-Based Compensation (FAS 123) and stock-based payment awards granted subsequent to December 31, 2005 based on the grant date fair value estimated in accordance with the provisions of FAS 123R. In accordance with the modified prospective transition method, the Company s Condensed Consolidated Financial Statements as of and for the three and six months ended June 30, 2006 reflect the impact of FAS 123R, and prior periods have not been restated to reflect, and do not include the impact of FAS 123R. In conjunction with the adoption of FAS 123R, the Company elected to use the straight-line single option approach as its method of attributing the value of stock-based compensation expense. See Note 7 Stock-based Compensation of the Notes to Condensed Consolidated Financial Statements for more information.

In November 2005, the Financial Accounting Standard Board (FASB) issued FASB Staff Position No. FAS 123R-3, Transition Election Related to Accounting for Tax Effects of Share-Based Payment Awards (FSP 123R-3). It provides an elective alternative transition method that includes simplified methods to establish the beginning balance of the additional

paid-in capital pool related to the tax effect of stock-based compensation and to determine the subsequent impact on the additional paid-in capital pool and the Consolidated Statement of Cash Flows for stock-based compensation awards that are outstanding upon the adoption of FAS No. 123R. Align is currently evaluating this transition method and will make a determination by December 31, 2006. See Note 7 Stock-based Compensation of the Notes to Condensed Consolidated Financial Statements for more detailed stock-based compensation information.

Reclassification

Certain prior period amounts have been reclassified to conform with current period presentation. These reclassifications had no impact on previously reported net earnings and financial position.

Recent Accounting Pronouncements

There have been no material changes to the recent pronouncements as previously reported in Align s Annual Report on Form 10-K for the fiscal year ended December 31, 2005.

Note 2. Balance Sheet Components

Inventories comprise (in thousands):

	June 30, 2006	December 31, 2005
Raw materials	$ 1,475	$ 1,492
Work in process	956	1,060
Finished goods	302	378
	$ 2,733	$ 2,930

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

Accrued liabilities consist of the following (in thousands):

	June 30 , 2006	December 31, 2005
Accrued payroll and benefits	$ 11,351	$ 12,330
Professional fees	2,669	1,713
Accrued sales rebate	2,682	1,409
Other	9,898	13,920
	$ 26,600	$ 29,372

Note 3. Short-term Investments

The Company has the following short-term investments as of June 30, 2006 (in thousands):

	Amortized Costs	Gross Unrealized Gains	Gross Unrealized Loss	Fair Value
U.S. Government notes and bonds	$ 6,062	$	$ (4)	$ 6,058
Corporate bonds and asset-backed securities	6,216		(6)	6,210
Total	$ 12,278	$	$ (10)	$ 12,268

As of June 30, 2006, all short-term investments have less than one year maturity dates. For the three and six months ended June 30, 2006 and 2005, no gains were realized on the sale of short-term investments. The Company had no short-term investments as of December 31, 2005.

Note 4. **Commitments and Contingencies**

Operating leases

Minimum future lease payments for non-cancelable leases as of June 30, 2006, are as follow (in thousands):

Years Ending December 31,	
2006	$ 1,762
2007	3,049
2008	2,181
2009	1,233
2010	467
Thereafter	
Total	$ 8,692

Product Warranty

The Company warrants its products against defects in materials and workmanship until the Invisalign case is completed. Align accrues for estimated warranty in costs of goods sold upon the shipment of products. The amount of accrued estimated warranty costs are primarily based on historical experience as to product failures as well as current information on repair costs. Actual warranty costs could differ from the estimated amounts. The Company regularly reviews the accrued balances and updates these balances based on historical warranty cost trends. Actual warranty costs incurred have not materially differed from those accrued. If the Company was to experience higher rates of warranty events, the Company would be required to accrue additional warranty costs, which would negatively affect its operating results.

The following table reflects the change in the Company s warranty accrual during the six months ended June 30, 2006 and 2005, respectively (in thousands):

	Six months ended June 30, 2006	**2005**
Balance at beginning of period	$ 1,998	$ 1,616
Charged to cost and expenses	1,287	1,293
Actual warranty expenses	(1,443)	(991)
Balance at end of period	$ 1,842	$ 1,918

Equipment purchase commitment

The Company agreed to purchase additional capacity sterolithography (SLA) manufacturing equipment from a certain vendor. During the first six months of 2006, the Company paid $2.2 million of this purchase commitment and will pay an additional $1.2 million during the remainder of fiscal 2006, based on the delivery dates for each machine. In the event the Company does not accept delivery of any of the systems on or before December 31, 2006, the Company has agreed to pay approximately 60% of the purchase price for each such system that is not shipped, and the order for that system will be deemed cancelled.

Note 5. **Legal Proceedings**

OrthoClear

State Action. 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 (the State Action). Among other things, the State Action alleges tort, contract, statutory and common law causes of action arising from OrthoClear and

the individual defendants alleged plan to unlawfully utilize the Company s intellectual property, confidential information and employees. The State Action 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 its customer relationships and trade secrets. The State Action 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 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 the Company s proprietary information without its 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 the Company 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. This TRO remained in place until October 27, 2005.

The defendants and the Align Parties filed demurrers to the complaint and the cross-complaint, respectively. On June 6, 2005 the Court ruled on demurrers on the complaint filed by OrthoClear and denied OrthoClear s challenges to the core of the Company 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 the Company s request for permission to amend its original complaint to consolidate several duplicative causes of action and to add specific evidence not available to the Company when the original complaint was filed. OrthoClear did not oppose the demurrer filed by the Company and amended its original pleading by filing a first supplemental and amended cross-complaint.

On July 6, 2005, OrthoClear filed a demurrer to the Company 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 the Company. On September 6, 2005, defendant Bao Tran filed answers to the Company s causes of action and also filed a cross-complaint against the Align Parties. In September 2005, the Company presented demurrers to OrthoClear s first supplemental and amended cross-complaint. In November 2005, the Court agreed with the Align Parties challenges to 18 of the 19 causes of action. Of the 18 causes of action successfully challenged by Align, the Court ordered that 6 be dismissed entirely. As to the remaining 12 challenged causes of action, OrthoClear is required to either dismiss them or attempt to state a valid claim against the Align Parties. On December 5, 2005, OrthoClear filed a second amended cross-complaint alleging unfair competition, intentional interference with prospective economic advantage, intentional interference with contract, libel, slander, breach of contract, wrongful withholding of wages, and abuse of process. The second amended cross-complaint eliminates David Thrower as a cross-defendant and attempts to add a new cross-defendant. On December 9, 2005, defendant Bao Tran filed a first amended cross-complaint alleging wrongful termination, intentional interference with contract, wrongful withholding of wages, breach of contract, libel, slander, false light, abuse of process, and unfair competition.

On January 4, 2006, the Align Parties filed a demurrer to OrthoClear s second amended cross-complaint, and a motion to strike the portions of the second amended cross-complaint that refer to the new cross-defendant. On January 12, 2006, the Align Parties filed a demurrer to Bao Tran s first amended cross-complaint and also filed special motions to strike certain causes of action in both OrthoClear s and Bao Tran s cross-complaints. Bao Tran subsequently agreed to dismiss his cause of action for abuse of process, and in response Align has agreed to withdraw its special motion to strike Bao Tran s cross-complaint. The demurrers against OrthoClear s second amended cross-complaint and against Bao Tran s first amended cross-complaint, the motion to strike the portions of OrthoClear s second amended cross-complaint that refer to the new cross-defendant, and the special motion to strike certain causes of action in OrthoClear s second amended cross-complaint was heard on February 27, 2006. The Court issued an order granting in part and denying in part the Company s demurrers and

also issued an order granting in part and denying in part the Company s special order to strike and later ordered OrthoClear to pay certain of the Company s attorneys fees related to the special motion to strike. A trial date has been scheduled for June 25, 2007.

Federal Lanham Action. On July 19, 2005, the Company filed a multi-claim lawsuit in the United States District Court for the Northern District of California against OrthoClear (the Federal Lanham Action I). The Federal Lanham Action I 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 Federal Lanham Action I also alleges violations by OrthoClear of California s Unfair Practices Act (California Business and Professions Code §17200 et seq.).

The Federal Lanham Action I seeks monetary damages according to proof at trial and an injunction preventing OrthoClear from further false advertising and unfair competition including any use of the Company 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 dentists or orthodontists have used OrthoClear to successfully treat patients. The Company also seeks an order requiring OrthoClear to conduct corrective advertising to counteract its misleading advertising. OrthoClear recently filed two motions for summary judgment, to be heard by the Court on August 18, 2006. A trial date has been scheduled for October 30, 2006.

On June 19, 2006, the Company filed a multi-claim lawsuit in the United States District Court for the Northern District of California against OrthoClear, Inc. and OrthoClear Holdings, Inc. (Federal Lanham Action II). The Federal Lanham Action II alleges numerous violations by OrthoClear of the federal Lanham Act and related common law. These violations include unfair competition, false advertising, trade libel and defamation based on OrthoClear s public statements touting the alleged quality and effectiveness of its products and falsely disparaging those of Align. The Federal Lanham Action II also alleges violations by OrthoClear of California s Unfair Practices Act.

The Federal Lanham Action II seeks monetary damages according to proof at trial and an injunction preventing OrthoClear from further false advertising and unfair competition. A trial date has not yet been set in this matter.

Patent Infringement ITC Complaint. On January 11, 2006, the Company filed a formal complaint with the United States International Trade Commission (ITC) against OrthoClear, seeking to halt the importation into the United States of infringing aligners manufactured by OrthoClear in Pakistan in violation of its patents and other intellectual property rights (the ITC Complaint). The ITC Complaint alleges that OrthoClear utilizes the Company s trade secrets and infringes 12 of the Company s patents in the production of the OrthoClear aligners at a facility in Lahore, Pakistan. The ITC Complaint requests the ITC institute an immediate investigation and ultimately issue an exclusionary order, enforced by U.S. Customs and Border Protection, excluding OrthoClear aligners from importation into the United States. The ITC Complaint also requests the ITC issue two cease and desist orders specifically preventing OrthoClear from importing infringing aligners and from selling in the United States imported OrthoClear aligners.

The ITC instituted a formal investigation on February 7, 2006. Pursuant to a scheduling order issued by the administrative law judge, the hearing on the ITC Complaint is set to take place from November 6-16, 2006 in Washington, D.C. The scheduling order sets February 15, 2007 as the target date for the initial determination and May 15, 2007 as the target date for completion of the ITC investigation. On Friday, July 28, 2006, the Company filed a motion entitled Complainant s Motion to Modify the Target Date and Revised the Procedural Schedule requesting the hearing on the ITC Complaint be rescheduled for December 5-15, 2006 and proposing a new target date for the initial determination as March 30, 2007 and proposing a new target date for completion of the ITC investigation of July 30, 2007. As of the date of this Quarterly Report on Form 10-Q, the administrative law judge has not ruled on the Company s motion.

On July 12, 2006, the administrative law judge granted the Company s unopposed motion to terminate the investigation as to U.S. Patent No. 6,450,807.

Patent Infringement Federal Action. On January 11, 2006, the Company filed a federal court patent infringement action against OrthoClear in the Western District of Wisconsin (Madison) (the Patent Infringement Federal Action) asserting infringement of the Company s U.S. Patents Nos. 6,685,469; 6,450,807; 6,394,801; 6,398,548; 6,722,880; 6,629,840; 6,669,037; 6,318,994; 6,729,876; 6,602,070; 6,471,511 and 6,227,850. The Patent Infringement Federal Action seeks

monetary damages and an injunction to augment the exclusionary relief available from the ITC.

On February 6, 2006, OrthoClear filed a motion to transfer venue of the Patent Infringement Federal Action from the Western District of Wisconsin to the Northern District of California. OrthoClear also filed a motion to stay the Patent Infringement Federal Action, pursuant to the mandatory stay provisions of the ITC, pending the outcome of the litigation of the same patents in the ITC Complaint. The Company opposed OrthoClear s motion to transfer, but did not oppose the

motion to stay. On March 10, 2006, the Court granted OrthoClear s unopposed motion to stay, thereby staying the matter pending resolution of the ITC proceedings. The Court made no ruling on OrthoClear s motion to transfer.

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, 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 us 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 us to amend the Company s 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 its 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 its 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 its 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 its patents are not unenforceable and granted Ormco s and AOA s summary judgment motion that Ormco and AOA did not willfully infringe its 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 its 6,554,611 patent and two of the asserted claims of its 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 its 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 Quarterly Report on Form 10-Q, the Permanent Injunction remains in full force and effect.

On February 1, 2006, the Company entered into a settlement agreement (the Settlement Agreement) with Ormco and AOA. Pursuant to the Settlement Agreement, the issues of past damages, willfulness and attorneys fees for Ormco s and AOA s adjudged infringement of its U.S. patent Nos. 6,398,548 and 6,554,611 (the Align Patents) through the manufacture and sale by Ormco and AOA of its Red, White & Blue appliances have been settled. The Settlement Agreement does not affect (1) Ormco and AOA s currently pending appeal of the permanent injunction preventing Ormco and AOA from selling

the infringing Red, White & Blue system; (2) Ormco s pending appeal of the decisions and orders of the United States District Court relating to Ormco s patents; or (3) the Company s cross-appeal of the orders of the United States District Court relating to its patents.

In accordance with the terms of the Settlement Agreement, Ormco and AOA will pay us $884,000 (the Settlement Amount) to resolve the issues of past damages, willfulness and attorneys fees for the adjudged infringement of the Align Patents through the manufacture and sale of Ormco s and AOA s Red, White & Blue appliances. The Settlement Amount will be paid into escrow pending the completion of the appeals process. The Company s receipt of the payments out of escrow is contingent upon the Court, in a final, non-appealable judgment, finding that Ormco or AOA infringes at least one of the claims in the Align Patents. If, however, the Court issues a final, non-appealable judgment of non-infringement, invalidity or unenforceability with respect to each asserted claim of the Align Patents, all funds in the escrow account will be returned to Ormco and AOA.

After the Permanent Injunction was entered, Ormco and AOA appealed that injunction and the orders of the District Court on summary judgment on which that order was based. Oral argument on that appeal took place on April 3, 2006. No ruling from the appellate court has yet been received. In addition, once final judgment was entered, Ormco filed a Notice of Appeal from the final judgment, and the Company filed a notice of cross-appeal. Ormco has filed its opening appellate brief.

Other matters

USPTO

During fiscal 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 re-examination of six of the Company s patents (U.S. Patent Nos. 5,975,893, 6,398,548, 6,309,215, 6,705,863, 6,217,325 and 6,722,880). In 2006, requests were filed with the USPTO on behalf of OrthoClear requesting reexamination of US Patent No. 6,629,840 (the 840 patent) and US Patent No. 6,685,469 (the 469 patent). In addition, the same San Francisco law firm filed a request for reexamination of US Patent No. 6,318,994 (the 994 patent). The USPTO has granted the request to reexamine six of the nine patents, specifically, Patent No. 5,975,893, Patent No. 6,398,548, Patent No. 6,309,215, Patent No. 6,705,863, Patent No. 6,217,325 and Patent No. 6,629,840. As of the date of this Quarterly Report on Form 10-Q, the USPTO issued initial Office Actions with regard to US Patent Nos. 6,217,325 (the 325 patent), 6,309,215 (the 215 patent), 5,975,893 (the 893 patent) and 6,629,840 (the 840 patent). On July 27, 2006, after submitting amendments, affidavits, declarations or other documents as evidence of patentability, the Company received an action entitled Notice of Intent to Issue Ex Parte Reexamination Certificate . With this Notice, the USPTO has closed prosecution on the merits in reexamination and affirmed the patentability of all of the Company s claims pending in reexamination. While the 215 patent entered the reexamination proceedings with 16 claims, 26 additional claims were added in the reexamination by the Company and the 215 patent leaves the proceedings as a valid and enforceable patent with 42 claims. On July 25, 2006, the Company also received an Office Action in the 325 patent confirming the patentability of 32 claims. While the 325 patent entered the reexamination proceedings with 26 claims, 15 additional claims were added by the Company in the reexamination. The Company intends to pursue, in continuing proceedings, the allowance of the rejected claims. In the remaining initial Office Actions, the examiners confirmed the validity of eight of the eleven claims of the 840 patent without amendment and preliminarily rejected the remaining claims of the patents. The non-final initial Office Action presented the Company with its first opportunity to respond to the USPTO s review and interpretation of the prior art. The Company may and intends to submit amendments, affidavits or declarations, or other documents as evidence of patentability in response to its actions on the 840 patent. On January 26, 2006, a first office action was issued rejecting all claims of the 893 patent. The Company responded to this initial office action. However a final office action was issued by the USPTO on June 23, 2006 rejecting the pending claims of the Company s response. The Company is currently preparing its response to the current office action. The re-examination proceedings on Patent Nos. 6,398,548 and 6,705,863 (collectively, the Remaining Patents) are currently pending but no Office Action has been received by the Company. The Company, however filed Preliminary Amendments adding additional claims regarding the Remaining Patents. While the pending re-examinations are in a preliminary stage, the Company believes that claims of the patents in re-examination will be determined to be patentable as currently written or as may be amended during the re-examination proceeding. However, there can be no assurance that the Company will prevail, and re-examination proceedings could result in some or all of the Remaining Patent claims (as well as the 893 and 840 patent claims) having a narrower scope of coverage or even to being invalidated, which could have an adverse effect on the Company. On December 23, 2005, in a non-appealable, final Order, the USPTO denied the request for re-examination with respect to all twenty-one claims of U.S. Patent No. 6,722,880 (the 880 patent). Accordingly, the validity of all twenty-one claims of the 880 patent stand reaffirmed by the USPTO. On January 23, 2006, a Petition Seeking Review of Denial of Request for Re-examination of the 880 patent was filed by the same San Francisco, California law firm. As of the date of this Form 10-Q, the Company has not received a response from the USPTO. As of the date of this Quarterly Report on Form 10-Q, the USPTO has neither granted nor denied the requests for reexamination of the US Patent No. 6,318,994 and US Patent No. 6,685,469.

Bay Materials

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 Align 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 exceeding $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 costs. Pursuant to the Company s demurrer to Bay s first amended complaint, the Court dismissed Bay s negligent misrepresentation claim.

On March 27, 2006, the Company filed its answer to Bay s amended complaint, and also filed a cross-complaint against Bay for breach of contract, breach of implied warranty of fitness, intentional misrepresentation, concealment, specific performance, unjust enrichment and unfair business practices. The cross-complaint seeks monetary damages against Bay exceeding $1.0 million. Both Align and Bay intend to file motions for summary judgment by August 18, 2006 with hearing date to be determined. A trial date has been scheduled for December 4, 2006.

The Company cannot predict the ultimate outcome of this matter at this time although the Company intends to vigorously defend itself. As a result, in accordance with Statement of Financial Accounting Standard No. 5 Accounting for Contingencies , the Company has disclosed the existence of this lawsuit; however, no accrual for potential losses, if any, has been recorded.

Litigating claims of these types, whether or not ultimately determined in the Company s favor or settled by the Company, is costly and diverts the efforts and attention of the Company s management and technical personnel from normal business operations. Any of these results from litigation could adversely affect the Company s results of operations and stock price. From time to time, the Company has received, and may again receive, letters from third parties drawing the Company s attention to their patent rights. While the Company does not believe that it infringes any such rights that have been brought to the Company s attention, there may be other more pertinent proprietary rights of which the Company is presently unaware.

Note 6. Credit Facilities

In December 2005, the Company renegotiated and amended its existing revolving line of credit, which was originally obtained in December 2002. The amended credit agreement increases the available borrowings under the then existing revolving line of credit from $15 million to $20 million. Included in the new revolving line of credit is a letter of credit facility of up to $5 million, a foreign exchange facility of up to $5 million and an equipment facility of up to $10 million. The Company may elect interest rates on its borrowing calculated by reference to the bank s prime rate less one-half of one percent or LIBOR plus two percent. The new credit facility matures on December 16, 2007, at which time all outstanding borrowings must be repaid. The new credit facility contains certain restrictive loan covenants, including, among others, financial covenants requiring a minimum quick ratio and minimum tangible net worth, and covenants limiting the Company s ability to dispose of assets, make acquisitions, be acquired, incur indebtedness, grant liens, make investments, pay dividends and repurchase stock.

As of June 30, 2006, there are no outstanding borrowings, and the Company is in compliance with the restrictive loan covenants of these facilities.

Note 7. Stock-based Compensation

2005 Incentive Plan

In May 2005, stockholder approval was obtained for the 2005 Incentive Plan (2005 Plan), which replaced the 2001 Stock Incentive Plan (the 2001 Plan). The 2005 Plan, which expires December 31, 2010, provides for the granting of incentive stock options, non-statutory stock options, restricted stock units, stock appreciation rights, performance units and performance shares. Employees, non-employee directors and consultants are eligible to receive grants under the 2005 Plan. The options are granted for periods not exceeding ten years and generally vest over 4 years with 25% vesting one year from the date of grant and 1/48th each month thereafter. The Plan Administrator may, however, grant options with different vesting schedules at its option. In the first quarter of 2005, the Company granted options under the 2001 Plan (prior to the approval of the 2005 Plan), that vest over 3 years, with 25% vested at the date of grant, and 1/36th each month thereafter. Options are to be granted at an exercise price not less than the fair market value of the underlying shares at the date of grant.

Starting in the first quarter of 2006, the Compensation Committee granted awards of restricted stock units (contracts that give the recipients the right to receive shares as the units vest) to its employees and director(s) in addition to stock options. Each restricted stock unit award generally vests over 4 years with 25% on the one year anniversary of the date of grant and 6.25% vesting quarterly thereafter. Any grants of restricted stock units will reduce shares available for grant at a 2:1 ratio.

The 2005 Plan has 9,983,379 shares of the Company s common stock reserved for issuance, plus up to an aggregate of 5,000,000 shares that are or would have been returned to the 2001 Plan as a result of termination of outstanding options or repurchase of shares granted under the 2001 Plan on or after March 28, 2005. As of June 30, 2006, 1,732,989 shares have been transferred to the 2005 Plan. As of June 30, 2006, 8,012,218 shares remain available for issuance under the 2005 Plan.

Executive Grants

In January 2001, the stockholders approved two option grants to purchase 1,000,000 shares of the Company s common stock at an exercise price of $15.00 per share to each of the Company s then Chief Executive Officer and President. The options were granted outside of the 1997 Equity Incentive Plan and prior to the adoption of the 2001 Plan or the 2005 Plan. As of June 30, 2006, an aggregate of 500,000 options to purchase shares of common stock remained outstanding under these grants.

Stock Options

The fair value of stock options granted were estimated at the grant date using the Black-Scholes option pricing model with the following weighted average assumptions:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2006	2005	2006	2005
Expected term (in years)	5.0	3.0	5.0	2.0
Expected volatility	75%	76%	77%	71%
Risk-free interest rate	4.91%	3.65%	4.64%	3.74%
Expected dividend				
Weighted average fair value at grant date	$ 5.28	$ 3.24	$ 5.45	$ 3.06

The expected term of stock options represents the weighted-average period the stock options are expected to remain outstanding. Upon the adoption of FAS 123R, the Company used a midpoint model to determine the expected term of stock options based on the Company s historical exercise and post vesting cancellation experience, and the remaining contractual life of its outstanding options.

The increase to expected life assumption used in the Black-Scholes option pricing for the three and six months ended June 30, 2006 compared to three and six months ended June 30, 2005, is the result of granting options with shorter vesting in the first quarter of 2005.

The Company used a combination of historical volatility and peer group volatility in deriving its expected volatility assumption as allowed under FAS 123R and SAB 107. The Company s historical volatility from 2002 to 2006 was used in determining expected volatility. The Company used peer group volatility instead of its own historical data for 2001, as the Company had unusually high volatility in its stock price as the result of its Initial Public Offering in 2001. The peer group volatility was derived based on historical volatility of a comparable peer group consisting of companies of similar size and operating in a similar industry.

The risk free interest rate is based on the implied yield on a U.S. Treasury zero-coupon issue with a remaining term equal to the expected term of the option.

The dividend yield reflects that the Company has not paid any cash dividends since inception and does not anticipate paying cash dividends in the foreseeable future.

A summary of stock option activity under the 2001 and 2005 Plans for the six months ended June 30, 2006 is as follows (in thousands, except per share data):

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding at December 31, 2005	11,304	$ 8.76		
Granted	1,371	8.35		
Cancelled or expired	(672)	11.63		
Exercised	(678)	7.15		
Outstanding at June 30, 2006	11,325	$ 8.64	7.68	$ 10,530
Ending vested and expected to vest at June 30, 2006	11,069	$ 8.66	7.64	$ 10,436
Exercisable at June 30, 2006	8,408	$ 8.98	7.16	$ 9,058

The aggregate intrinsic value in the table above represents the total pretax intrinsic value (the difference between Align s closing stock price on the last trading day of the second quarter of fiscal 2006 and the exercise price, multiplied by the number of in-the-money options) that would have been received by the option holders had all option holders exercised their options on June 30, 2006. This amount changes based on the fair market value of Align s stock. The total intrinsic value of stock options exercised for the three months ended June 30, 2006 and 2005 was $0.2 million and $0.5 million, respectively. The total intrinsic value of stock options exercised for the six months ended June 30, 2006 and 2005 was $0.8 million and $2.4 million, respectively. As of June 30, 2006, there was a $10.7 million of total unamortized compensation costs related to stock options. These costs are expected to be recognized over a weighted average period of 1.5 years. For the three and six months ended June 30, 2006, the total recognized tax benefit from exercised options was immaterial.

Option Acceleration

On October 6, 2005, the Compensation Committee of the Board of Directors approved the acceleration of the vesting for all unvested stock options with exercise prices greater than $7.10. The fair market value of Align s common stock on the date of acceleration was $6.41 as quoted on the NASDAQ National Market. Options held by non-employee directors were excluded from the vesting acceleration. As a result of the acceleration, approximately 3.8 million options or 35% of the then total outstanding options became immediately exercisable as of October 6, 2005. The primary purpose of the acceleration was to eliminate future compensation expense the Company would otherwise recognize in its statement of operations with respect to these accelerated options upon the adoption of FAS 123R.

Restricted Stock Units

Starting in the first quarter of 2006, the Company began granting restricted stock units that generally vest over 4 years with 25% vesting on the one year anniversary of the date of grant and 6.25% vesting quarterly thereafter. The fair value of each award is based on the Company s closing stock price on the date of grant. As of June 30, 2006, the total fair value of vested restricted stock awards was zero. A summary of the nonvested shares for the six months ended June 30, 2006 is as follows:

	Shares (in thousands)	Weighted Average Grant Date Fair Value
Nonvested as of December 31, 2005		$
Granted	370	8.42
Vested		
Forfeited	(9)	8.41
Nonvested as of June 30, 2006	361	$ 8.42

As of June 30, 2006, there was $2.5 million of total unamortized compensation costs related to restricted stock units. These costs are expected to be recognized over a weighted average period of 1.9 years.

Employee Stock Purchase Plan

Align s Employee Stock Purchase Plan (the Purchase Plan) consists of overlapping twenty-four month offering periods with four six-month purchase periods in each offering period. Employees purchase shares at 85% of the fair market value of the common stock at either the beginning of the purchase period or the end of the purchase period, whichever price is lower. The Purchase Plan provides that the number of shares of the Company s common stock reserved for issuance thereunder will automatically increase on the first trading day of January in each calendar year by an amount equal to three percent (3%) of the total number of shares of common stock outstanding on the last trading day in December of the immediately preceding calendar year, with this annual increase not to exceed 1,500,000 shares.

During the six months ended June 30, 2006, 245,774 shares were issued under the Purchase Plan. As of June 30, 2006, the Company had reserved 8,933,456 shares of common stock for future issuance and 7,489,018 shares remain available for future issuance.

The Company accounts for the Purchase Plan as a compensatory plan and has valued the shares in accordance with FAS 123R. The fair value of the option component of the Purchase Plan shares was estimated at the date of grant using the Black-Scholes option pricing model with the following weighted average assumptions:

	Six Months Ended June 30,	
	2006	2005
Expected term (in years)	1.27	1.25
Expected volatility	54.9 %	66.0 %
Risk-free interest rate	4.72 %	3.55 %
Expected dividend		
Weighted average fair value at grant date	$ 3.18	$ 3.75

As of June 30, 2006, there was $0.8 million of total unamortized compensation costs related to employee stock purchases. These costs are expected to be recognized over a weighted average period of 0.5 years.

Summary of Stock-based Compensation Expense

Stock-based compensation expense recognized in the Condensed Consolidated Statements of Operations for the three and six months ended June 30, 2006 is based on awards ultimately expected to vest and has been reduced for estimated forfeitures. FAS 123R requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Forfeitures were estimated based on historical experience. In the Company s pro forma information required under FAS 123 for periods prior to fiscal 2006, the Company accounted for forfeitures as they occurred. The following table summarizes stock-based compensation expense related to all of the Company s stock-based awards and employee stock purchases under FAS 123R for the three and six months ended June 30, 2006:

(In thousands, except per share amounts)	Three Months Ended June 30, 2006	Six Months Ended June 30, 2006
Cost of revenues	$ 181	$ 329
Sales and marketing	732	1,411
General and administrative	1,029	2,117
Research and development	324	614
Total share-based compensation	$ 2,266	$ 4,471

Pro Forma Information Under FAS 123 for Periods Prior to Fiscal 2006

Prior to January 1, 2006, the Company accounted 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 complied with the disclosure requirements of SFAS 148, Accounting for Stock-Based Compensation-Transition and Disclosure-an amendment of FASB Statement No. 123. Under the intrinsic method, the

difference between the market price on the date of grant and the exercise price is charged to the results of operations over the vesting period. Accordingly, the Company was not required to recognize compensation cost for stock options issued to its employees or shares issued under the Purchase Plan because options were issued at market price on the date of grant.

Historically, the Company has accelerated the vesting of options to several employees in connection with severance packages. These accelerations were accounted for as a charge to the Condensed Consolidated Statements of Operations. This charge is equal to the intrinsic value of the options which was calculated as a difference between the exercise price of the accelerated options and the fair value of the common stock on the date of the acceleration. For the three months ended June 30, 2005, the Company recorded $0.1 million resulting from accelerated vesting of options in connection with severance packages.

FAS 123R requires the Company to present pro forma information for the comparative period prior to the adoption as if it had accounted for all of its stock options under the fair value method of FAS 123. The following table illustrates the pro forma information regarding the effect on net earnings and net earnings per share for the three and six months ended June 30, 2005 as if the Company had accounted for the stock-based employee compensation under the fair value method of accounting:

(In thousands, except per share amounts)	**Three Months Ended June 30, 2005**	**Six Months Ended June 30, 2005**
Net earnings, as reported	$ 538	$ 2,401
Add: Stock-based employee compensation expense included in reported net earnings under APB No. 25, net of related tax effects	70	70
Deduct: Total stock-based employee compensation determined under the fair value method for all awards, net of related tax effects	(4,630)	(9,827)
Pro forma net loss	$ (4,022)	$ (7,356)
Basic net earning (loss) per share:		
As reported	$ 0.01	$ 0.04
Pro forma	$ (0.07)	$ (0.12)
Diluted net earning (loss) per share:		
As reported	$ 0.01	$ 0.04
Pro forma	$ (0.06)	$ (0.12)

Note 8. 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 period. 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 restricted stock units.

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 June 30,		Six Months Ended June 30,	
	2006	2005	2006	2005
Net profit (loss)	$ (2,610)	$ 538	$ (7,374)	$ 2,401
Weighted-average common shares outstanding, basic	62,966	61,484	62,743	61,367
Effect of potential dilutive common shares		1,469		1,572
Total shares, diluted	62,966	62,953	62,743	62,939
Basic net profit (loss) per share	$ (0.04)	$ 0.01	$ (0.12)	$ 0.04
Diluted net profit (loss) per share	$ (0.04)	$ 0.01	$ (0.12)	$ 0.04

For the three and six months ended June 30, 2006, stock options and restricted stock units totaling 6.8 million and 6.6 million, respectively, were excluded from diluted net loss per share because of their anti-dilutive effect. For the three and six months ended June 30, 2005, stock options totaling 4.4 million and 4.7 million, respectively, were excluded from diluted net profit per share because of their anti-dilutive effect.

Note 9. 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 were 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, and the remaining $0.5 million in April 2006.

Note 10. Goodwill and Other Intangible Assets

In January 2005, the Company completed the acquisition of GO (See Note 9) 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 2006, or sooner if events or changes in circumstances indicate the assets may be impaired.

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The following is a summary of the Company s purchased intangible assets as of June 30, 2006 (in thousands):

	June 30, 2006			December 31, 2005	
	Gross Carrying Value	Accumulated Amortization	Net Carrying Value	Accumulated Amortization	Net Carrying Value
Consultant relationships	$ 980	$ 463	$ 517	$ 299	$ 681
Other	55	26	29	17	38
Total	$ 1,035	$ 489	$ 546	$ 316	$ 719

Intangible assets are being amortized on a straight-line basis over the estimated useful life of three years. Estimated future amortization expense for purchased intangible assets as of June 30, 2006 is $172,000, $345,000 and $29,000 in 2006, 2007 and 2008, respectively.

During 2003, the Company obtained a patent for $180,000 and is amortizing it over the expected useful life of five years. The Company recorded amortization expense of $9,000 and $18,000 for the three and six months ended June 30, 2006 and 2005, respectively. The accumulated amortization as of June 30, 2006 and December 31, 2005 was $99,000 and $81,000, respectively. Estimated future amortization expense for the patent as of June 30, 2006 is $18,000, $36,000 and $27,000 in 2006, 2007 and 2008, respectively.

Note 11. Segments and Geographical Information

Segment

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 periods presented, the Company operated as a single business segment.

Geographical Information

Revenues and long-lived assets are presented below by geographic area (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2006	2005	2006	2005
Revenues:				
Domestic	$ 44,691	$ 47,738	$ 86,487	$ 93,491
Europe	7,085	5,393	13,156	10,141
Other International	1,445	809	2,486	1,463
Total revenues	$ 53,221	$ 53,940	$ 102,129	$ 105,095

	As of June 30, 2006	As of December 31, 2005
Long-lived assets:		
Domestic	$ 27,057	$ 27,281
Europe	786	990
Other International	1,991	2,253
Total long-lived assets	$ 29,834	$ 30,524

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

In addition to historical information, this Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. These statements include, among other things, statements concerning our expectations regarding the impact that Invisalign Express will have on our product mix and results of operations, our expectations that the percentage of revenue generated by general practitioner dentists will represent an increasingly larger percentage of our revenue, our expectation that we will experience a slower rate of growth in our GP channel during the last six months of 2006 as compared to the first six months of 2006, our expectation that the overall market for Invisalign will continue to increase, our expectation that additional dental schools will integrate the Invisalign technique into their curriculum, resulting in an increasing number of GPs who will use our products in their practice, *our expectations regarding further expansion into North American and international markets, our anticipated volume growth in fiscal 2006, our expectations regarding lower revenues and gross margin in fiscal 2006, our expectation regarding costs, our expectation regarding the impact that pricing initiatives and other similar programs may have on our results of operations, our expectations that product enhancements and new products will increase our market share, our expectation that our general and administrative expenses will increase significantly in 2006 and our sales and marketing and our research and development expenses will be comparable to 2005, our expectation regarding estimated incremental costs, including legal fees that we may incur as a result of the OrthoClear litigation, 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 any revision to these forward-looking statements. Given these risks and uncertainties, readers are cautioned not to place undue reliance on such forward-looking statements.*

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

Overview

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

Our traditional, full Invisalign treatment plan is unique to the individual patients, and the treatment plan will consist of as many Aligners as necessary to achieve the doctors treatment goals. In the third quarter of 2005, we launched Invisalign Express, a low-cost solution for less complex orthodontic cases. Invisalign Express is a dual arch orthodontic treatment consisting of up to ten Aligners. Invisalign Express is intended to assist our customers treat a broader range of patients by providing a lower cost option for adult relapse cases, for minor crowding and spacing and as a pre-cursor to restorative or cosmetic treatment such as veneers.

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 made available to the prescribing dental professional via our proprietary customer interfacing software, VIP. The prescribing orthodontist or general practitioner dentist (GP) then reviews the ClinCheck simulation. 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, then use 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, our third party shelter services provider ships the finished products to our customers.

We generate the vast majority of our revenues from the sales of the Invisalign system (which includes full Invisalign treatment and Invisalign Express as discussed above) to orthodontists and GPs in the United States and Canada, our domestic market. Sales of the Invisalign system in our domestic GP channel and our domestic orthodontist channel represented approximately 46% and 34% of our total revenues during the first six months of 2006, respectively.

A number of factors, the most important of which are set forth below, may affect our success during the remainder of 2006 and beyond.

- *Increased Pricing Pressure.* 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 we have filed several lawsuits alleging, among other things, OrthoClear s unlawful use of our intellectual property, including our trade secrets. *See Part II, Item 1 Legal Proceedings of this Quarterly Report on Form 10-Q for a more complete summary of the OrthoClear litigation.* In response to OrthoClear s launch and in an effort to simplify our pricing structure, in the fourth quarter of 2005 we announced that all Invisalign cases (other than Invisalign Express) in our domestic market will have a list price of $1,495 per case. Previously, list prices ranged from $1,195 to $1,895 per case depending on the treatment option selected. In addition, in the fourth quarter of 2005, we expanded our volume based discount program to all doctors. These programs were in effect in the first half of 2006, and we expect these and other similar programs that we may launch in the future to continue to impact our revenues, gross margins and net profits. We have also experienced increased sales volumes of the lower priced Invisalign Express and this shifting product mix has had and will continue to have an affect on our revenue, gross margin and net profits. Additionally in Europe, we introduced new pricing initiatives, similar to those introduced domestically, in the first quarter of 2006 which has resulted in a lower average selling price.

- *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 shipment volumes in our orthodontic channel were slightly lower in the last two quarters of 2005 compared to the first two quarters of 2005 due in part to the disruption in our sales force and the resulting disruption to many of our customer relationships. However, in the first half of 2006, with the deployment of our new sales team, we began to see a slight increase in case shipments in our orthodontic channel as compared to the fourth quarter of 2005. *See Part II, Item 1A Risk Factors We rely on our direct sales force to sell our products, and any failure to maintain our direct sales force could harm our business.*

- *Penetration into our Domestic Market.* 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. Largely due to the fact that there are significantly more GPs than orthodontists, we expect that an increasingly larger percentage of our revenues will be generated by GPs. In fact, in the first half of 2006, our domestic GP channel generated 46% of our total revenue, while the orthodontist channel represented 34%. We believe that, in the second half of 2006, the GP channel will experience a slower rate of growth in case submissions compared to the first half of 2006 due in part to OrthoClear s recent focus on this channel. However, we continue to believe that by focusing on increasing utilization rates among our existing GP customers, the overall market for Invisalign will increase, as patients who would not have otherwise sought orthodontic treatment are introduced to Invisalign by their GPs. In addition, by educating dental students and orthodontic residents on the benefits of the Invisalign technique, we believe they will be more likely to use this technology in their future practices and offer Invisalign as a treatment option. As of June 30, 2006, we have integrated the Invisalign technique into the curriculums of 27 university programs, including Harvard

University, Columbia University, Temple University and the University of Texas at San Antonio. We expect additional dental schools to integrate the Invisalign technique into their curriculums in the future. Furthermore, we have teamed with The Pankey Institute to develop Invisalign certification and clinical curriculum at The Pankey Institute.

- *Continued Product Leadership*. We are committed to investing in delivering new products, enhancing the user experience and introducing new product features to our existing products. In the second half of 2005, we launched Invisalign Express, a lower-cost Aligner system to be used for less complex cases. Invisalign Express is intended to assist our customers to treat a broader range of patients by providing a lower cost option for less complex orthodontic cases, thereby increasing the market for our products. In addition, we are planning the introduction of a compliance indicator which will help doctors and patients understand if the patients have worn their Aligners for enough time to effectively move their teeth, as well as a next generation Aligner material. We have recently announced that

commencing August 1, 2006, we will laser-etch the Invisalign logo on the Aligners to allow doctors and patients to easily distinguish between Invisalign aligners and similar-look or substitute products. By investing in developing these new products and continually enhancing our existing products, we expect to increase market share.

- *Expansion of International Markets.* We will focus our efforts towards increasing adoption of Invisalign by dental professionals in key international markets, including Europe and Japan. We will consider expanding into additional countries on a case by case basis. In the first half of 2006, our international channel represented approximately 15% of our total revenue primarily as a result of growth in Europe.

- *Increasing Reliance on International Manufacturing Operations.* Our manufacturing efficiency has been and will be an important factor in our future profitability. We use a third party based in Juarez, Mexico, International Manufacturing Solutions Operaciones, S.R.L. (IMS), for the fabrication and packaging of Aligners. In the first quarter of 2006, we completed the relocation of our SLA mold fabrication operations from our Santa Clara, California facility to IMS. As a result of this relocation, our reliance on our international manufacturing operations will continue to increase. Our success will depend in part on the efforts and abilities of management to effectively manage this international operation, including our relationship with IMS. In addition, we currently are and will become increasingly dependant on IMS s ability to hire and retain employees generally, as well as hire and retain employees with the necessary skills to perform the more technical aspects of our operations. If our management and/or IMS fail in any of these respects, we could experience production delays and lost or delayed revenue. In addition, even if we have case submissions in the manufacturing backlog, if IMS is unable for any of these or other reasons to ship our product to our customers on a timely basis, our revenue will be delayed which will cause our operating results to fluctuate. *See Part II, Item 1A Risk Factors for risks related to our international operations*.

Stock-based compensation. Effective January 1, 2006, we adopted Statement of Financial Accounting Standards No. 123 (Revised 2004), Share-based Payment (FAS 123R) using the modified prospective transition method, which requires the measurement and recognition of compensation expense for all share-based payment awards made to our employees and directors and employee stock purchases related to the Employee Stock Purchase Plan based on estimated fair values over the requisite service period. In accordance with the modified prospective method, our financial statements for the prior periods have not been restated to reflect and do not include the impact of FAS 123R. For the three and six months ended June 30, 2006, stock based compensation expense recognized in accordance with FAS 123R is as follows (in thousands):

	Three Months Ended June 30, 2006		Six Months Ended June 30, 2006	
	Stock-based Compensation	Percent of Revenues	Stock-based Compensation	Percent of Revenues
Cost of revenues	$ 181	0.3 %	$ 329	0.3 %
Sales and marketing	732	1.4 %	1,411	1.4 %
General and Administrative	1,029	2.0 %	2,117	2.1 %
Research and development	324	0.6 %	614	0.6 %
Total stock-based compensation expense	$ 2,266	4.3 %	$ 4,471	4.4 %

Results of Operations

Revenues.

Invisalign product revenues by channel and other revenues, which represented training and sales of ancillary products, for the three and six months ended June 30, 2006 and 2005 are as follows:

	Three Months Ended				Six Months Ended			
(in million)	June 30, 2006	June 30, 2005	Net Change	% Change	June 30, 2006	June 30, 2005	Net Change	% Change
Domestic:								
Orthodontic	$ 17.7	$ 23.2	$ (5.5)	(23.7)%	$ 35.0	$ 46.5	$ (11.5)	(24.7)%
GP	24.1	22.3	1.8	7.9 %	46.6	43.0	3.6	8.3 %
International	8.3	5.7	2.6	45.7 %	15.3	10.9	4.4	40.7 %
Total Invisalign	50.1	51.2	(1.1)	(2.2)%	96.9	100.4	(3.5)	(3.5)%
Other revenues	3.1	2.7	0.4	15.5 %	5.2	4.7	0.5	11.3 %
Total Revenues	$ 53.2	$ 53.9	$ (0.7)	(1.3)%	$ 102.1	$ 105.1	$ (3.0)	(2.8)%

For the three months and six months ended June 30, 2006, total revenues decreased by $0.7 million or 1.3% and $3.0 million or 2.8% compared to the three and six months ended June 30, 2005, respectively, primarily due to lower average selling prices as a result of a reduced list price for full Invisalign, sales of the lower priced Invisalign Express product, and the volume based discount program, all of which were launched in the second half of 2005. These factors impacted both the Orthodontic and GP channels. In the domestic GP channel, however, we experienced significant increase in case volumes driven by the sales of Invisalign Express which more than offset the adverse effects of these factors and resulted in an increase of $1.8 million and $3.6 million for the three and six month periods ended June 30, 2006, respectively, compared to the same periods in 2005. The decreases in the domestic Orthodontic channel revenue for the three and six month periods ended June 30, 2006 compared to the same periods in 2005 were due to decreased volumes of full Invisalign cases offset by sales of Invisalign Express, as well as a lower average selling price for full Invisalign due to the other factors noted above. International revenue increased $2.6 million and $4.4 million for the three and six months ended June 30, 2006 compared to the three and six months ended June 30, 2005 primarily due to a significant increase in full Invisalign case volumes partially offset by a lower average selling price as a result pricing initiatives introduced in the first quarter of 2006.

For fiscal year 2006, although we expect our case shipment volume to increase year over year, we anticipate that our revenues will be slightly lower than fiscal year 2005 primarily as a result of lower average selling prices resulting from both the introduction of pricing initiatives and volume-based discount programs discussed above, and Invisalign Express launched in the second half of 2005. Additionally in Europe, we introduced new pricing initiatives in the first quarter of 2006 which has resulted in a lower average selling price.

Cost of revenues:

	Three months ended June 30,			Six months ended June 30,		
(In millions)	2006	2005	Change	2006	2005	Change
Cost of revenues	$ 16.5	$ 16.6	$ (0.1)	$ 30.8	$ 32.1	$ (1.3)
% of Revenues	31.0 %	30.8 %		30.1 %	30.5 %	
Gross profit	$ 36.7	$ 37.3	$ (0.6)	$ 71.3	73.0	$ (1.7)
% of Revenues	69.0 %	69.2 %		69.9 %	69.5 %	

Cost of revenues includes salaries for staff involved in the production process, the cost of materials, packaging, shipping costs, depreciation on capital equipment used in the production process, training costs and the cost of facilities.

Gross margin decreased slightly to 69.0% of revenues for the three months ended June 30, 2006, compared to 69.2% of revenues for the three months ended June 30, 2005. This decrease in gross margin is primarily due to lower average selling

prices as a result of the reduction in the list price of full Invisalign and increased sales of the lower priced Invisalign Express. Partially offsetting the impact of lower average selling prices are the reductions in product costs driven by increased volumes and manufacturing efficiencies as a result of the relocation of the SLA mold operations to Juarez, Mexico, and a $0.7 million reduction in the provision for estimated losses on case refinement sales.

Gross margin increased to 69.9% of revenues for the six months ended June 30, 2006, compared to 69.5% of revenues for the six months ended June 30, 2005. This improvement in gross margin is primarily due to lower product costs driven by increased volumes and manufacturing efficiencies as a result of the relocation of the SLA mold operations to Juarez, Mexico, and a $2.2 million reduction in the provision for estimated losses on case refinement sales. Excluding the $2.2 million reduction in the provision for estimated losses, gross margin would have decreased for the six months ended June 30, 2006 compared to the six months ended June 30, 2005 primarily due to lower average selling prices as a result of the reduction in the list price of full Invisalign and increased sales of the lower priced Invisalign Express.

For fiscal 2006, we anticipate that our gross margin, including stock-based compensation will be slightly lower compared to fiscal 2005 primarily due to the lower average selling prices discussed above.

S*ales and marketing*:

	Three months ended June 30,			Six months ended June 30,		
(In millions)	**2006**	**2005**	**Change**	**2006**	**2005**	**Change**
Sales and marketing	$ 20.6	$ 21.0	$ (0.4)	$ 40.7	$ 40.2	$ 0.5
% of Revenues	38.8 %	39.0 %		39.9 %	38.2 %	

Sales and marketing expense includes sales force compensation (combined with travel related costs and expenses for professional marketing programs), conducting workshops and market surveys, advertising and dental professional trade show attendance.

Sales and marketing expense decreased $0.4 million to $20.6 million in the three months ended June 30, 2006 compared to the three months ended June 30, 2005 primarily due to a $1.7 million decrease in media, advertising and other marketing expenses primarily due to the launch of consumer marketing campaign in the second quarter of 2005. Partially offsetting this decrease was a $0.7 million increase in stock-based compensation expense recognized in accordance with FAS 123R and a $0.3 million increase in commission expense.

Sales and marketing expense increased $0.5 million to $40.7 million in the six months ended June 30, 2006 compared to the six months ended June 30, 2005 primarily due to a $1.4 million increase in stock-based compensation expense and a $1.3 million increase in payroll related expenses due to the replacement of orthodontic sales representatives who left Align in the first half of 2005. These increases were offset by a $2.5 million decrease in media, advertising and other marketing expenses primarily due to the launch of a consumer marketing campaign in the second quarter of 2005.

For fiscal 2006, we expect sales and marketing expense, including stock-based compensation, to be comparable to 2005, as we continue to develop and expand our domestic and international markets, develop new media programs, enhance our website and provide clinical education.

General and administrative:

	Three months ended June 30,			Six months ended June 30,		
(In millions)	**2006**	**2005**	**Change**	**2006**	**2005**	**Change**
General and administrative	$ 15.4	$ 9.7	$ 5.7	$ 30.4	$ 19.2	$ 11.2
% of Revenues	28.8 %	18.0 %		29.8 %	18.3 %	

General and administrative expense includes salaries for administrative personnel, outside consulting services, legal expenses and general corporate expenses.

General and administrative expense for the three months ended June 30, 2006 increased by $5.7 million compared to

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the three months ended June 30, 2005 due to a $4.8 million increase in external legal fees primarily related to the OrthoClear litigation and a $1.0 million increase in stock-based compensation expense, partially offset by a $0.4 million decrease in bad debt expense.

General and administrative expense for the six months ended June 30, 2006 increased by $11.2 million compared to the six months ended June 30, 2005 primarily due to a $7.6 million increase in external legal fees related to the OrthoClear litigation, a $1.8 million increase in payroll related expenses primarily resulting from the hiring of additional legal and administrative staff, and a $2.0 million increase in stock-based compensation expense, partially offset by a $0.8 reduction in bad debt expense.

For fiscal year 2006, we expect that general and administrative expense will increase significantly from fiscal 2005. This increase will be primarily attributable to higher OrthoClear litigation related expenses and stock-based compensation expense.

Research and development:

	Three months ended June 30,			Six months ended June 30,		
(In millions)	**2006**	**2005**	**Change**	**2006**	**2005**	**Change**
Research and development	$ 4.0	$ 5.4	$ (1.4)	$ 8.7	$ 10.3	$ (1.6)
% of Revenues	7.6 %	9.9 %		8.5 %	9.8 %	

Research and development expense includes the costs associated with software engineering, 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 expense for the three months ended June 30, 2006 decreased by $1.4 million compared to the three months ended June 30, 2005, primarily due to a $1.1 million decrease in temporary services and outside consulting, attributable to efficiencies in the product development process and higher consulting prior to the launch of Invisalign Express and Clincheck 2.0 in the second half of 2005, and a $0.3 million decrease in payroll related requirements expenses partially offset by $0.3 million increase in stock-based compensation.

Research and development expense for the six months ended June 30, 2006 decreased by $1.6 million compared to the six months ended June 30, 2005, primarily due to a $1.3 million decrease in temporary services and outside consulting attributable to efficiencies in the product development process and higher consulting prior to the launch of Invisalign Express and Clincheck 2.0 in the second half of 2005, and a $0.4 million decrease in payroll related requirements expenses partially offset by $0.6 million increase in stock-based compensation.

For fiscal 2006, we expect research and development spending, including stock based compensation, to be comparable to fiscal 2005 as we continue to invest in research and development efforts to bring new products to market, conduct clinical research and focus on product improvement initiatives. Additionally in 2006, we will benefit from efficiencies in our product development process.

Interest and other, net:

	Three months ended June 30,			Six months ended June 30,		
(In millions)	**2006**	**2005**	**Change**	**2006**	**2005**	**Change**
Interest income, net	$ 0.8	$ 0.4	$ 0.4	$ 1.5	$ 0.6	$ 0.9
Other income (expense), net		(0.6)	0.6		(0.9)	0.9
Total interest and other, net	$ 0.8	$ (0.2)	$ 1.0	$ 1.5	$ (0.3)	$ 1.8

Interest and other, net includes interest income earned on cash balances, interest expense on debt, foreign currency translation gains and losses for the dollar against other currencies related to international businesses and other miscellaneous charges.

Interest income, net for the three and six months ended June 30, 2006 increased $0.4 million and $0.9 million, respectively, compared to the three and six months ended June 30, 2005. These increases were primarily due to increased interest income as a result of higher effective interest rates.

Other income (expense) increased $0.6 million and $0.9 million in the three and six months ended June 30, 2006, respectively, compared to the same periods in 2005, primarily due to a decrease in foreign currency translation loss.

Income tax provision:

	Three months ended June 30,			Six months ended June 30,		
(In millions)	**2006**	**2005**	**Change**	**2006**	**2005**	**Change**
Provision for income taxes	$ 0.2	$ 0.4	$ (0.2)	$ 0.4	$ 0.6	(0.2)

We recorded an income tax provision of $0.2 million and $0.4 million for the three months ended June 30, 2006 and 2005, respectively, representing effective tax rates of (6.5)% and 43.7%, respectively. For the six months ended June 30, 2006 and 2005, we recorded income tax provision of $0.4 million and $0.6 million, respectively, representing effective tax rates of (5.9)% and 20.6%, respectively. Our effective tax rate for the remainder of 2006 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.

Liquidity and Capital Resources

We fund our operations from the proceeds of the sale of our common stock and from cash generated from sales of our product. As of June 30, 2006 we had $57.5 million in cash and cash equivalents and $12.3 million in short-term marketable securities. As of December 31, 2005, our cash and cash equivalents balance was $74.2 million. Restricted cash was $0.2 million as of June 30, 2006 and December 31, 2005.

Net cash used by operating activities for the six months ended June 30, 2006 was $6.5 million, resulting primarily from operating losses adjusted for non cash items and a $3.5 million increase in accounts receivable as a higher percentage of revenues were shipped during the latter part of the second quarter, a $1.5 million increase in prepaid and other current assets and a $3.5 million reduction in deferred revenue. For the six months ended June 30, 2005, net cash provided by operating activities was $8.0 million, primarily from operating profits adjusted for non cash items and increases in accrued liabilities and deferred revenue, which was partially offset by increases in accounts receivable and prepaid and other current assets.

For the six months ended June 30, 2006, we used $16.4 million of cash in our investing activities primarily due to a $12.1 million purchase of short-term marketable securities and $4.8 million for the purchase of capital assets. For the six months ended June 30, 2005, net cash used in investing activities was $6.8 million primarily from the purchase of property and equipment for capacity expansion, manufacturing improvements and the purchase of General Orthodontics, LLC.

Net cash provided by financing activities was $6.2 million and $2.2 million for the six months ended June 30, 2006 and 2005, respectively. For the six months ended June 30, 2006, net cash provided by financing activities consisted entirely of proceeds from the issuance of common stock, primarily from exercises of employee stock options. For the six months ended June 30, 2005, 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.

Net proceeds from the issuance of common stock related to the exercise of employee stock options has historically been a significant component of our liquidity. However, in the first quarter of 2006, we began granting RSUs which, unlike stock options, do not generate cash from exercise. In addition, because RSUs are taxable to the individuals when they vest, the number of shares we issued to each of our executive officers and members of our board of directors will be net of applicable payroll withholding taxes which taxes will be paid on their behalf. As a result, we will likely generate less cash from the proceeds of the sale of our common stock in future periods.

In December 2005, we renegotiated and amended our existing revolving line of credit, which was originally obtained in December 2002. The amended credit agreement increases the available borrowings under the then existing revolving line of credit from $15 million to $20 million. Included in the new revolving line of credit is a letter of credit facility of up to $5 million, a foreign exchange facility of up to $5 million and an equipment facility of up to $10 million. We may elect interest rates on our borrowing calculated by reference to bank s prime rate less one-half of one percent or LIBOR plus two percent. The new credit facility matures on December 16, 2007, at which time all outstanding borrowings must be repaid. The new

credit facility contains certain restrictive loan covenants, including, among others, financial covenants requiring a minimum quick ratio and minimum tangible net worth, and covenants limiting our ability to dispose of assets, make acquisitions, be acquired, incur indebtedness, grant liens, make investments, pay dividends and repurchase stock. As of June 30, 2006, there were no outstanding borrowings and we are in compliance with the restrictive loan covenants of these credit facilities.

We expect that our expense levels for 2006, which includes stock based compensation, will increase from 2005, depending on our level of business activity. We expect that any increases will be focused on continuing efforts to automate our manufacturing processes, including increasing our capacity, continued international sales and marketing efforts, legal expenses including $18.0 million to $20.0 million related to OrthoClear litigation, 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 and short-term marketable securities 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 implementing our business strategy 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.

Contractual Obligations

As of June 30, 2006, 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, 2005.

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, 2005.

- Recognition of revenues
- Warranty expense
- Legal contingencies
- Deferred tax valuation allowance

Except as set forth below, there have been no significant changes in our critical accounting policies during the six months ended June 30, 2006 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, 2005.

Stock-based Compensation Expense

Effective January 1, 2006, the Company adopted the modified prospective transition method of Statement of Financial Accounting Standards No. 123 (Revised 2004), *Share-Based Payment*, or FAS 123R, which requires the measurement and recognition of compensation expense for all share-based payment awards made to employees and directors, including stock options and restricted stock units related to our 2001 Plan and our 2005 Plan and employee stock purchases related to our Employee Stock Purchase Plan based on estimated fair values over requisite employee service period. In accordance with the modified prospective transition method, our financial statements for prior periods have not been restated to reflect, and do not include, the impact of FAS 123R. Our Condensed Consolidated Financial Statements as of and for the three and six months ended June 30, 2006 reflect the impact of FAS 123R related to share-based payment awards granted prior to, but not yet vested as of, December 31, 2005 based on the grant date fair value estimated in accordance with the pro forma provisions of FASB Statement 123, Accounting for Stock-Based Compensation (FAS 123) and stock-based payment awards granted subsequent to December 31, 2005 based on the grant date fair value estimated in accordance with the provisions of FAS 123R. In conjunction with the adoption of FAS 123R, we changed our method of attributing the value of stock-based compensation to expense from the accelerated multiple-option approach to the straight-line single option method.

We estimate the fair value of stock options using a Black-Scholes valuation model, consistent with the provisions of FAS 123R and Staff Accounting Bulletin (SAB) No. 107. Option-pricing models require the input of highly subjective assumptions, including the option s expected term and stock price volatility. Judgment is also required in estimating the number of stock-based awards that are expected to be forfeited. As stock based compensation expense recognized in our financial statements for the three and six months of fiscal 2006 is based on awards ultimately expected to vest, it has been reduced for estimated forfeitures. FAS 123R requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Forfeitures were estimated based on historical experience. If our estimates change or if we employ different assumptions in the application of FAS 123R in future periods, the compensation expense that we record under FAS 123R may differ significantly from what we have recorded in the current period and could materially impact our results of operations. See Note 7 Stock-based Compensation of the Notes to Condensed Consolidated Financial Statements for additional information.

On October 6, 2005, the Compensation Committee of the Board of Directors approved the acceleration of the vesting for all unvested stock options with exercise prices greater than $7.10. Options held by non-employee directors were excluded from the vesting acceleration. The fair market value of our common stock on the date of acceleration was $6.41 as quoted on the NASDAQ National Market. As a result of the acceleration, approximately 3.8 million options or 35% of the then total outstanding options became immediately exercisable as of October 6, 2005. The primary purpose of the acceleration was 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.

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, 2005, which is incorporated herein by reference. Our exposure to market risk has not changed materially since December 31, 2005.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of disclosure controls and procedures.

Under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, we have evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of the end of the period covered by this Quarterly Report on Form10-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 June 30, 2006 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

State Action. 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 (the State Action). Among other things, the State Action 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 State Action 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 State Action 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, 2005 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. On September 6, 2005, defendant Bao Tran filed answers to our causes of action and also filed a cross-complaint against us. In September 2005, we presented demurrers to OrthoClear s first supplemental and amended cross-complaint. In November 2005, the Court agreed with the Align Parties challenges to 18 of the 19 causes of action. Of the 18 causes of action successfully challenged by Align, the Court ordered that 6 be dismissed entirely. As to the remaining 12 challenged causes of action, OrthoClear is required to either dismiss them or attempt to state a valid claim against the Align Parties. On December 5, 2005, OrthoClear filed a second amended cross-complaint alleging unfair competition, intentional interference with prospective economic advantage, intentional interference with contract, libel, slander, breach of contract, wrongful withholding of wages, and abuse of process. The second amended cross-complaint eliminates David Thrower as a cross-defendant and attempts to add a new cross-defendant. On December 9, 2005, defendant Bao Tran filed a first amended cross-complaint alleging wrongful termination, intentional interference with contract, wrongful withholding of wages, breach of contract, libel, slander, false light, abuse of process, and unfair competition.

On January 4, 2006, the Align Parties filed a demurrer to OrthoClear s second amended cross-complaint, and a motion to strike the portions of the second amended cross-complaint that refer to the new cross-defendant. On January 12, 2006, the Align Parties filed a demurrer to Bao Tran s first amended cross-complaint and also filed special motions to strike certain causes of action in both OrthoClear s and Bao Tran s cross-complaints. Bao Tran subsequently agreed to dismiss his cause of action for abuse of process, and in response Align has agreed to withdraw its special motion to strike Bao Tran s cross-complaint. The demurrers against OrthoClear s second amended cross-complaint and against Bao Tran s first amended cross-complaint, the motion to strike the portions of OrthoClear s second amended cross-complaint that refer to the new cross-defendant, and the special motion to strike certain causes of action in OrthoClear s second amended cross-complaint was heard on February 27, 2006. The Court issued an order granting in part and denying in part our demurrers and issued an order granting in part and denying in part our special order to strike and later ordered OrthoClear to pay certain of our legal fees related to the special motion to strike. A trial date has been schedule for June 25, 2007.

Federal Lanham Action. 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 Federal Lanham Action I). The Federal Lanham Action I 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 Federal Lanham Action I also alleges violations by OrthoClear of California s Unfair Practices Act (California Business and Professions Code §17200 et seq.).

The Federal Lanham Action I 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 treat patients. We also seek an order requiring OrthoClear to conduct corrective advertising to counteract its misleading advertising. OrthoClear recently filed two motions for summary judgment, to be heard by the Court on August 18, 2006. A trial date has been scheduled for October 30, 2006.

On June 19, 2006, we filed a multi-claim lawsuit in the United States District Court for the Northern District of California against OrthoClear, Inc. and OrthoClear Holdings, Inc. (Federal Lanham Action II). The Federal Lanham Action II alleges numerous violations by OrthoClear of

the federal Lanham Act and related common law. These violations include unfair competition, false advertising, trade libel and defamation based on OrthoClear s public statements touting the

alleged quality and effectiveness of its products and falsely disparaging those of Align. The Federal Lanham Action II also alleges violations by OrthoClear of California s Unfair Practices Act.

The Federal Lanham Action II seeks monetary damages according to proof at trial and an injunction preventing OrthoClear from further false advertising and unfair competition. A trial date has not yet been set in this matter.

Patent Infringement ITC Complaint. On January 11, 2006, we filed a formal complaint with the United States International Trade Commission (ITC) against OrthoClear, seeking to halt the importation into the United States of infringing aligners manufactured by OrthoClear in Pakistan in violation of our patents and other intellectual property rights (the ITC Complaint). The ITC Complaint alleges that OrthoClear utilizes our trade secrets and infringes 12 of our patents in the production of the OrthoClear aligners at a facility in Lahore, Pakistan. The ITC Complaint requests the ITC institute an immediate investigation and ultimately issue an exclusionary order, enforced by U.S. Customs and Border Protection, excluding OrthoClear aligners from importation into the United States. The ITC Complaint also requests the ITC issue two cease and desist orders specifically preventing OrthoClear from importing infringing aligners and from selling in the United States imported OrthoClear aligners.

The ITC instituted a formal investigation on February 7, 2006. Pursuant to a scheduling order issued by the administrative law judge, the hearing on the ITC Complaint is set to take place from November 6-16, 2006 in Washington D.C. The scheduling order sets February 15, 2007 as the target date for initial determination and May 15, 2007 as the target date for completion of the ITC investigation. On Friday, July 28, 2006 we filed a motion entitled Complainant s Motion to Modify the Target Date and Revise the Procedural Schedule requesting the hearing on the ITC Complaint to be rescheduled for December 5-15, 2006 and proposing a new target date for the initial determination as March 30, 2007 and proposing a new target date for completion of ITC investigation of July 30, 2007. As of the date of this Quarterly Report on Form 10-Q, the administrative law judge has not ruled on our motion.

On July 12, 2006, the administrative law judge granted our unopposed motion to terminate the investigation as to US Patent No. 6,450,807.

Patent Infringement Federal Action. On January 11, 2006, we filed a federal court patent infringement action against OrthoClear in the Western District of Wisconsin (Madison) (the Patent Infringement Federal Action) asserting infringement of our U.S. Patents Nos. 6,685,469; 6,450,807; 6,394,801; 6,398,548; 6,722,880; 6,629,840; 6,669,037; 6,318,994; 6,729,876; 6,602,070; 6,471,511 and 6,227,850. The Patent Infringement Federal Action seeks monetary damages and an injunction to augment the exclusionary relief available from the ITC.

On February 6, 2006, OrthoClear filed a motion to transfer venue of the Patent Infringement Federal Action from the Western District of Wisconsin to the Northern District of California. OrthoClear also filed a motion to stay the Patent Infringement Federal Action, pursuant to the mandatory stay provisions of the ITC, pending the outcome of the litigation of the same patents in the ITC Complaint. We opposed OrthoClear s motion to transfer, but did not oppose OrthClear s motion for stay. On March 10, 2006, the Court granted OrthoClear s unopposed motion to stay, thereby staying the matter pending resolution of the ITC proceedings. The Court made no ruling on OrthoClear s motion to transfer.

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 Quarterly Report on Form 10-Q, the Permanent Injunction remains in full force and effect.

On February 1, 2006, we entered into a settlement agreement (the Settlement Agreement) with Ormco and AOA. Pursuant to the Settlement Agreement, the issues of past damages, willfulness and attorneys fees for Ormco s and AOA s adjudged infringement of our U.S. patent Nos. 6,398,548 and 6,554,611 (the Align Patents) through the manufacture and sale by Ormco and AOA of its Red, White & Blue appliances have been settled. The Settlement Agreement does not affect (1) Ormco and AOA s currently pending appeal of the permanent injunction preventing Ormco and AOA from selling the infringing Red, White & Blue system; (2) Ormco s pending appeal of the decisions and orders of the United States District Court relating to Ormco s patents; or (3) our cross-appeal of the orders of the United States District Court relating to our patents.

In accordance with the terms of the Settlement Agreement, Ormco and AOA will pay us $884,000 (the Settlement Amount) to resolve the issues of past damages, willfulness and attorneys fees for the adjudged infringement of the Align Patents through the manufacture and sale of Ormco s and AOA s Red, White & Blue appliances. The Settlement Amount will be paid into escrow pending the completion of the appeals process. Our receipt of the payments out of escrow is contingent upon the Court, in a final, non-appealable judgment, finding that Ormco or AOA infringes at least one of the claims in the Align Patents. If, however, the Court issues a final, non-appealable judgment of non-infringement, invalidity or unenforceability with respect to each asserted claim of the Align Patents, all funds in the escrow account will be returned to Ormco and AOA.

After the Permanent Injunction was entered, Ormco and AOA appealed that injunction and the orders of the District Court on summary judgment on which that order was based. Oral argument on that appeal took place on April 3, 2006. No ruling from the appellate court has yet been received. In addition, once final judgment was entered, Ormco filed a Notice of Appeal from the final judgment, and we filed a notice of cross-appeal. Ormco has filed its opening appellate brief.

Other matters

USPTO

During fiscal 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 re-examination of six of our patents (U.S. Patent Nos. 5,975,893, 6,398,548, 6,309,215, 6,705,863, 6,217,325 and 6,722,880). In 2006, requests were filed with the USPTO on behalf of OrthoClear requesting reexamination of US Patent No. 6,629,840 (the 840 patent) and US Patent No. 6,685,469 (the 469 patent). In addition, the same San Francisco law firm filed a request for reexamination of US Patent No. 6,318,994 (the 994 patent). The USPTO has granted the request to reexamine six of the nine patents, specifically, Patent

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No. 5,975,893, Patent No. 6,398,548, Patent No. 6,309,215, Patent No. 6,705,863 and Patent No. 6,217,325 and Patent No. 6,629,840. As of the date of this Quarterly Report on Form 10-Q, the USPTO issued initial Office Actions with regard to US Patent Nos. 6,217,325 (the 325 patent), 6,309,215 (the 215 patent), 5,975,893 (the 893 patent) and 6,629,840 (the 840 patent). On July 27, 2006, after submitting amendments, affidavits, declarations or other documents as evidence of patentability, we received an action entitled Notice of Intent to Issue Ex Parte Reexamination Certificate . With this Notice, the USPTO has closed prosecution on the merits in reexamination and affirmed the patentability of all of our claims pending in reexamination. While the 215 patent entered the reexamination proceedings with 16 claims, 26 additional claims were added in the reexamination by us and the 215 patent leaves the proceeding as a valid and enforceable patent with 42 claims. On July 25, 2006, we also received an Office Action in the 325 patent confirming the patentability of 32 claims. While the 325 patent entered the reexamination proceedings with 26 claims, 15 additional claims were added by us in the reexamination. We intend to pursue, in continuing proceedings, the allowance of the rejected claims. In the remaining initial Office Action, the examiners confirmed the validity of eight of the eleven claims of the 840 patent without amendment and preliminarily rejected the remaining claims of the patent. The non-final initial Office Action present us with our first opportunity to respond to the USPTO s review and interpretation of the prior art. We may and intend to submit amendments, affidavits or declarations, or other documents as evidence of patentability in response to its actions on the 840 patent. On January 26, 2006, a first office action was issued rejecting all claims of the 893 patent. We responded to this initial office action. However a final office action was issued by the USPTO on June 23, 2006 rejecting the pending claims of our response. We are currently preparing our response to the current office actions. The re-examination proceedings on Patent Nos. 6,398,548 and 6,705,863 (collectively, the Remaining Patents) are currently pending but no Office Action has been received by us. While the pending re-examinations are in a preliminary stage, we believe that claims of the patents in re-examination will be determined to be patentable as currently written or as may be amended during the re-examination proceeding. However, there can be no assurance that we will prevail, and re-examination proceedings could result in some or all of the Remaining Patent claims (as well as the 893 and 840 patent claims) having a narrower scope of coverage or even to being invalidated, which could have an adverse effect on us. On December 23, 2005, in a non-appealable, final Order, the USPTO denied the request for re-examination with respect to all twenty-one claims of our U.S. Patent No. 6,722,880 (the 880 patent). Accordingly, the validity of all twenty-one claims of our 880 patent stand reaffirmed by the USPTO. On January 23, 2006, a Petition Seeking Review of Denial of Request for Re-examination of the 880 Patent was filed by the same San Francisco, California law firm. As of the date of this Quarterly Report on Form 10-Q, the USPTO has neither granted nor denied the requests for reexamination of the US Patent No. 6,318,994 and US Patent No. 6,685,469.

Bay Materials

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 exceeding $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 costs. Pursuant to our demurrer to Bay s first amended complaint, the Court dismissed Bay s negligent misrepresentation claim, and that claim is removed from the case.

On March 27, 2006, we filed our answer to Bay s amended complaint, and also filed our cross-complaint against Bay for breach of contract, breach of implied warranty of fitness, intentional misrepresentation, concealment, specific performance, unjust enrichment and unfair business practices. The cross-complaint seeks monetary damages against Bay exceeding $1.0 million. Both Align and Bay intend to file motions for summary judgment by August 18, 2006, with hearing dates to be determined. A trial date has been scheduled for December 4, 2006. We intend to vigorously defend ourselves.

Litigating claims of these types, 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 litigation could adversely affect our results of operations and stock price. From time to time, we have received, and may again receive, letters from third parties drawing our attention to their patent rights. While we do not believe that we infringe any such rights that have been brought to our attention, there may be other more pertinent proprietary rights of which we are presently unaware.

ITEM 1A. RISK FACTORS

If we fail to grow our revenue while controlling our expenses, 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. Consistent with a company in an early stage of operations, 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;
- execute clinical research and education plans;
- develop technological improvements to our products and new product development;
- continue our international sales and marketing efforts;
- protect our intellectual property, including trade secrets; and
- undertake quality assurance and improvement initiatives.

For instance, in an effort to raise the profile of Invisalign and drive prospective patients to our most experienced dental professionals, in the second quarter of 2005, we launched a consumer marketing campaign involving television, radio and print media. Marketing programs of this nature are expensive and may have limited success, if any, and may not result in revenue generation commensurate with their costs.

While we achieved profitability beginning in the fourth quarter of fiscal 2003, we experienced a net loss in the third quarter of 2005 as well as in each of the first and second quarters of 2006. In addition, we expect lower revenue in fiscal 2006 compared to fiscal 2005. If we are to achieve profitability in future periods, we will need to continue to increase our revenues, while controlling our expenses. While we generated positive operating cash flow for the first time in fiscal year 2003 and continued to generate positive operating cash flow in fiscal years 2004 and 2005, we experienced negative cash flows in each of the first and second quarters of 2006. We cannot be certain that we will be able to achieve positive cash flow from operations, from period to period, in the future. Because our business is evolving, it is difficult to predict our future operating results or levels of growth, and we have in the past not been and may in the future not be able to sustain our historical growth rates. 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 existing and new competitors, such as OrthoClear, Inc.;
- aggressive price competition from competitors, including OrthoClear;
- changes in the timing of receipt of case product orders during a given quarter;
- costs and expenditures in connection with ongoing litigation, in particular the litigation related to OrthoClear;
- changes in product mix due to the introduction of Invisalign Express, a lower-cost alternative for treating less complex cases;
- unanticipated delays in production caused by insufficient capacity, any disruptions in the manufacturing process, including as a result of unexpected turnover in the labor force or the introduction of new production processes;
- inaccurate forecasting of revenues, production and other operating costs; 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. Therefore, our operating results for a given period may be adversely affected. 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 is 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 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.). On January 11, 2006, we filed a complaint with the International Trade Commission (ITC) against OrthoClear, seeking to halt the importation into the United States of infringing aligners manufactured by OrthoClear in Pakistan in violation of our patents and other intellectual property rights. The ITC Complaint requests the ITC institute an immediate investigation and ultimately issue an exclusionary order, enforced by U.S. Customs and Border Protection, excluding OrthoClear aligners from importation into the United States. The ITC Complaint also requests the ITC issue two cease and desist orders specifically preventing OrthoClear from importing infringing aligners and from selling in the United States imported OrthoClear aligners. The ITC has determined to institute a formal investigation and such investigation is ongoing. In addition, on January 11, 2006, we filed a federal court patent infringement action in the Western District of Wisconsin (Madison). This federal action seeks monetary damages and an injunction to augment the exclusionary relief available from the ITC.

Although each of these lawsuits 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.

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 Quarterly Report on Form 10-Q for a summary of our material pending legal proceedings.

We depend on the sale of Invisalign for the vast majority of our revenues, and any decline in sales of Invisalign or average selling prices would adversely affect revenue, gross margin and net profits.

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, if consumers prove unwilling to adopt Invisalign as rapidly as we anticipate or in the volume that we anticipate, if orthodontists and GPs do not collaborate as we expect, if orthodontists or GPs choose to use a competitive product rather than Invisalign or if the average selling price of our product declines as it has in the past, our operating results would be harmed. Factors that could cause Invisalign not to achieve market acceptance at the rate at which we expect, as well as the risk related to declining average selling prices 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. For instance, in the second half of 2006, we believe that the GP channel will experience a slower rate of growth in case submissions compared to the first half of 2006 due to OrthoClear s recent focus on

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this channel. In addition, 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 dental professionals 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 affected 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.

Declines in average selling prices of our products.

In response to challenges in our business, including increased competition, in the second half of 2005, we reduced the list price of full Invisalign cases and introduced Invisalign Express, a lower-cost solution for less complex cases. In addition, in the fourth quarter of 2005, we expanded our volume based discount program to all doctors. As a result of these programs, the blended average selling price for our products has declined. Additionally in Europe, we introduced new pricing initiatives in the first quarter of 2006 which have resulted in a lower average selling price. We expect each of these programs, and other similar programs that we may introduce in the future, to adversely affect our revenue, gross margin and net profits.

We experience competition from manufacturers of traditional braces and expect aggressive competition from these and other companies that 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 Quarterly Report on Form 10-Q for a more complete summary of the OrthoClear litigation.* Increased competition from OrthoClear and other

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competitors has recently resulted in and may in the future result in volume discounting and 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 fourth quarter of 2005, in order to encourage continued use of our products, we extended our volume based discount program directed to all of our doctors. In addition, in the second half of 2005, we introduced Invisalign Express, a lower-cost solution for less complex cases as well as a new pricing initiative which had the effect of reducing our average selling price per case. These programs have adversely affected our revenues, gross margin and net profit. OrthoClear has recently begun to focus on the GP channel which may reduce the number of case submissions by GPs which would adversely affect our revenues. 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 business 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.

Throughout 2006 we intend to add additional functionality into our business enterprise systems, which will more efficiently integrate these systems 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 ClinCheck and VIP. Software applications frequently contain errors or defects, especially when they are first introduced or when new versions are released. In addition, we currently do not have adequate resiliency in our information technology systems. The discovery of a defect or error in a new upgraded version or the failure of our primary information systems 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.

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

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 lower-cost Aligner system to be used for less complex cases. In addition, we are planning the introduction of a compliance indicator which will help doctors and patients understand if the patients have worn their Aligners for enough time to effectively move their teeth, as well as a next generation Aligner material. We have recently announced that commencing August 1, 2006, we will laser-etch the Invisalign logo on the Aligners to allow doctors and patients to easily distinguish between Invisalign Aligners and similar-look or substitute products. There can be no assurance that we will be able to successfully develop, 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 shelter services provider in Juarez, Mexico, IMS, fabricates Aligners and ships the completed products to our customers. In the first quarter of 2006, we completed the process of relocating our SLA mold fabrication operations from our Santa Clara, California facility to IMS. As a result of this relocation, our reliance on our international manufacturing operations will continue to increase. Our costs associated with these operations are denominated in Costa Rican colons, Mexican pesos and U.S. dollars. Our increasing reliance on international operations exposes us to risks and uncertainties that may affect our business or results of operation, including:

- difficulties in hiring and retaining employees generally, as well as difficulties in hiring and retaining employees with the necessary skills to perform the more technical aspects of our operations;
- difficulties in managing international operations, including our relationship with our third party shelter services provider;
- import and export license requirements and restrictions;
- controlling production volume and quality of the manufacturing process;
- political, social and economic instability;
- acts of terrorism and acts of war;
- 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, we could experience production delays and lost or delayed revenue.

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 June 30, 2006, we had 71 issued U.S. patents, 93 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. During fiscal 2005 and 2006, 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 and in some instances acting in behalf of OrthoClear, requesting re-examination of a number of our patents. The USPTO has granted the request to reexamine U.S. Patent Nos. 5,975,893, 6,398,548, 6,309,215, 6,705,863, 6,217,325 and 6,629,840. As of the date of this Quarterly Report on Form 10-Q, the USPTO issued initial Office Actions with regard to U.S. Patent Nos. 6,217,325 (the 325 patent), 6,309,215 (the 215 patent), 6,629,840 (the 840 patent) and 5,975,893 (the 893 patent) and a final office action regarding to the 893 patent, the 215 patent and the 325 patent. On May 26, 2006 and July 18, 2006 additional requests were filed with the USPTO on behalf of an anonymous party and OrthoClear requesting re-examination of U.S. Patents No. 6,318,994 (ex-parte) and 6, 685,469 (inter-partes), respectively. The USPTO has neither granted nor denied these requests for re-examination. While the pending re-examinations are in a preliminary stage and we are still evaluating all issues, we believe that the claims of the patents in re-examination will be determined to be patentable as currently written or as may be amended during the re-examination proceedings. However, there can be no assurance that we will prevail, and the re-examination proceedings could cause some or all of these patent claims to have a narrower scope of coverage or even to be invalidated, which would have an adverse affect on us. *See Part II Item 1 of this Quarterly Report on Form 10-Q for a summary of the USPTO proceedings.* 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 Quarterly Report on 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 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. If we are unable to attract and retain key personnel, our business could be materially harmed.

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 Quarterly Report on 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 shelter services provider located in Juarez, Mexico, Manufacturing Solutions Operaciones, S.R.L. (IMS), to fabricate Aligners and to ship the completed product to customers. In addition, in the first quarter of 2006, we completed the relocation of our SLA mold fabrication process to IMS. As a result, if IMS 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 IMS with respect to hiring and retaining qualified 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 1,143 employees as of June 30, 2006. 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, 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 growth could harm our business.

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 June 30, 2006 our sales organization consisted of 124 people of which 102 were direct sales representatives and 22 were sales administration and management. 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 and our third party shelter services provider have not yet been subject to an FDA inspection, and we cannot assure you we or our third party shelter services provider will successfully pass such an inspection in the future. Our failure or the failure of our third party shelter services provider to take satisfactory corrective action in response to an adverse inspection or the 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 their 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 enforced regulations on our business is difficult to predict, and there can be no assurance that we will adequately address the business risks created by HIPAA and its implementation or that we will be able to take advantage of any resulting business opportunities.

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

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

- storage, transmission and disclosure of medical information and healthcare records;
- prohibitions against the offer, payment or receipt of remuneration to induce referrals to entities providing healthcare services or goods or to induce the order, purchase or recommendation of our products; 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, Hong Kong and Japan and may expand into other countries from time to time. 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 2005 and during the first half of fiscal 2006, 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, 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 (FAS 123R) which we adopted effective in the first quarter of fiscal 2006. *See Note 7 Stock-based Compensation of the Notes to Condensed Consolidated Financial Statements for further information on the impact of FAS 123R on our reported financial results.*

We have made use of a shareholders rights plan 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 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

On May 24, 2006, we held our Annual Meeting of Stockholders (the Annual Meeting).

At the Annual Meeting, our stockholders elected the following individuals to the Board of Directors to serve until the next Annual Meeting of Stockholders or until their respective successors have been duly qualified and elected:

NOMINEE	VOTES IN FAVOR	VOTES WITHHELD
H. Kent Bowen	55,066,863	2,276,542
David E. Collins	55,108,160	2,235,245
Joseph Lacob	55,919,715	1,423,690
C. Raymond Larkin, Jr.	55,917,228	1,426,177
George J. Morrow	55,112,266	2,231,139
Thomas M. Prescott	55,911,631	1,431,774
Greg J. Santora	55,952,944	1,390,461
Warren S. Thaler	55,958,556	1,384,849

At the Annual Meeting, our stockholders voted on the following proposals:

1. To ratify the appointment of PricewaterhouseCoopers LLP as our independent registered public accountants for the fiscal year ending December 31, 2006.

FOR	AGAINST	ABSTAIN	BROKER NON-VOTE
57,066,397	222,294	57,714	0

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

(a) Exhibits:

Exhibit Number	Description	Incorporated by reference herein			Filed herewith
		Filing	Date	Exhibit Number	
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.				*

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: August 7, 2006

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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