ALIGN TECHNOLOGY INC
Form 10-Q
November 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 September 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 October 31, 2006 was 64,072,716.

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Invisalign, Align, ClinCheck and ClinAdvisor, amongst others, are trademarks belonging to Align Technology, Inc. and are pending or registered in the United States and other countries.

PART I FINANCIAL INFORMATION

ITEM 1 FINANCIAL STATEMENTS

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2006	2005	2006	2005
Revenues	$ 49,034	$ 50,866	$ 151,163	$ 155,961
Cost of revenues	16,789 (1)	14,975	47,578 (2)	47,073
Gross profit	32,245	35,891	103,585	108,888
Operating expenses:				
Sales and marketing	19,165 (1)	21,315	59,872 (2)	61,498
General and administrative	19,238 (1)	11,715	49,656 (2)	30,949
Research and development	4,807 (1)	4,400	13,526 (2)	14,658
Total operating expenses	43,210	37,430	123,054	107,105
Profit (loss) from operations	(10,965)	(1,539)	(19,469)	1,783
Interest and other income, net	854	326	2,393	28
Net profit (loss) before provision for income taxes	(10,111)	(1,213)	(17,076)	1,811
Provision for income taxes	(209)	(303)	(618)	(926)
Net profit (loss)	$ (10,320)	$ (1,516)	$ (17,694)	$ 885
Net profit (loss) per share:				
Basic	$ (0.16)	$ (0.02)	$ (0.28)	$ 0.01
Diluted	$ (0.16)	$ (0.02)	$ (0.28)	$ 0.01
Shares used in computing net profit (loss) per share:				
Basic	63,230	61,788	62,907	61,509
Diluted	63,230	61,788	62,907	63,129

(1) Amounts for the three months ended September 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 September 30, 2006, including $0.2 million in cost of revenues, $0.7 million in sales and marketing, $1.0 million in general and administrative and $0.4 million in research and development.

(2) Amounts for the nine months ended September 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 $6.7 million in total stock-based compensation expense in the nine months ended September 30, 2006, including $0.5 million in cost of revenues, $2.1 million in sales and marketing, $3.1 million in general and administrative and $1.0 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)

	September 30, 2006	December 31, 2005
ASSETS		
Current assets:		
Cash and cash equivalents	$ 74,034	$ 74,219
Restricted cash	161	150
Marketable securities, short-term	11,898	
Accounts receivable, net of allowance for doubtful accounts of $930 and $1,626 at September 30, 2006 and December 31, 2005, respectively	32,607	29,305
Inventories, net	2,665	2,930
Prepaid expenses and other current assets	5,299	4,982
Total current assets	126,664	111,586
Property and equipment, net	27,336	26,427
Goodwill	478	478
Intangible assets, net	532	818
Other assets	1,881	2,801
Total assets	$ 156,891	$ 142,110
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Line of credit	$ 15,000	$
Accounts payable	7,137	2,489
Accrued liabilities	31,891	29,372
Deferred revenues	12,143	16,747
Total current liabilities	66,171	48,608
Other long-term liabilities	296	64
Total liabilities	66,467	48,672
Commitments and contingencies (Note 4 and Note 12)		
Stockholders equity:		
Preferred stock: $0.0001 par value; Authorized: 5,000 shares; Issued and outstanding: none at September 30, 2006 and December 31, 2005		
Common stock: $0.0001 par value; Authorized: 200,000 shares; Issued: 63,417 and 62,120 shares at September 30, 2006 and December 31, 2005, respectively; Outstanding: 63,378 and 62,080 shares at September 30, 2006 and December 31, 2005, respectively	6	6
Additional paid-in capital	398,519	383,836
Accumulated other comprehensive income	4	7
Accumulated deficit	(308,105)	(290,411)
Total stockholders equity	90,424	93,438
Total liabilities and stockholders equity	$ 156,891	$ 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)

	Nine Months Ended September 30, 2006	2005
Cash Flows from Operating Activities:		
Net profit (loss)	$ (17,694)	$ 885
Adjustments to reconcile net profit (loss) to net cash provided by (used in) operating activities:		
Depreciation and amortization	6,777	7,543
Amortization of intangibles	286	230
Stock-based compensation expense	6,748	99
(Gain) loss on retirement and disposal of fixed assets	(135)	28
Non-cash accretion on marketable securities	(5)	
Changes in assets and liabilities, net of acquisition effects:		
Accounts receivable	(3,302)	(332)
Inventories	265	(742)
Prepaid expenses and other current assets	(317)	172
Accounts payable	5,281	443
Accrued and other long-term liabilities	2,426	5,872
Deferred revenues	(4,604)	2,813
Net cash provided by (used in) operating activities	(4,274)	17,011
Cash Flows from Investing Activities:		
Purchase of property and equipment	(7,477)	(10,314)
Proceeds from sale of property and equipment	367	
Restricted cash	(11)	38
Purchases of marketable securities	(16,331)	(2,240)
Maturities of marketable securities	4,435	250
Payments for acquisition, net of cash acquired		(856)
Other assets	171	168
Net cash used in investing activities	(18,846)	(12,954)
Cash Flows from Financing Activities:		
Proceeds from line of credit	15,000	
Proceeds from issuance of common stock	7,935	5,070
Payments of debt obligations		(1,432)
Net cash provided by financing activities	22,935	3,638
Net increase (decrease) in cash and cash equivalents	(185)	7,695
Cash and cash equivalents at beginning of period	74,219	69,659
Cash and cash equivalents at end of period	$ 74,034	$ 77,354

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 September 30, 2006 and December 31, 2005, its results of operations for the three and nine months ended September 30, 2006 and 2005, and its cash flows for the nine months ended September 30, 2006 and 2005.

The results of operations for the three and nine months ended September 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 inter-company 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 nine months ended September 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

In July 2006, the FASB issued FASB Interpretation (FIN) No. 48 Accounting for Uncertainty in Income Taxes an interpretation of FASB Statement 109 . FIN 48 prescribes a comprehensive model for recognizing, measuring, presenting and disclosing in the financial statements tax positions taken or expected to be taken on a tax return, including a decision whether to file or not to file in a particular jurisdiction. FIN 48 is effective for fiscal years beginning after December 15, 2006. If there are changes in net assets as a result of application of FIN 48, these will be accounted for as an adjustment to retained earnings. The Company is currently assessing the impact of FIN 48 on its consolidated financial position and results of operations.

In September 2006, the SEC staff issued Staff Accounting Bulletin (SAB) 108 Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements (SAB 108). SAB 108 requires that public companies utilize a dual-approach to assessing the quantitative effects of financial misstatements. This dual approach includes both an income statement focused assessment and a balance sheet focused assessment. The guidance in SAB 108 must be applied to annual financial statements for fiscal years ending after November 15, 2006. The Company is currently assessing the impact of adopting SAB 108 but does not expect that it will have a material effect on our consolidated financial position or results of operations.

In September 2006, the FASB issued FASB Statement No. 157, *Fair Value Measurements*, which defines fair value, establishes a framework for measuring fair value under GAAP, and expands disclosures about fair value measurements. FASB Statement No. 157 applies to other accounting pronouncements that require or permit fair value measurements. The new guidance is effective for financial statements issued for fiscal years beginning after November 15, 2007, and for interim periods within those fiscal years. The Company is currently evaluating the potential impact, if any, of the adoption of FASB Statement No. 157 on its consolidated financial position, results of operations and cash flows.

Note 2. Balance Sheet Components

Inventories comprise of (in thousands):

	September 30, 2006	December 31, 2005
Raw materials	$ 1,545	$ 1,492
Work in process	760	1,060
Finished goods	360	378
	$ 2,665	$ 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):

	September 30 , 2006	December 31, 2005
Accrued payroll and benefits	$ 14,197	$ 12,330
Professional fees	5,003	1,713
Accrued sales rebate	2,629	1,409
Other	10,062	13,920
	$ 31,891	$ 29,372

Note 3. Short-term Investments

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

	Amortized Costs	Gross Unrealized Gains	Gross Unrealized Loss	Fair Value
U.S. Government notes and bonds	$ 4,158	$ 1	$	$ 4,159
Corporate bonds	5,311			5,311
Commercial paper and asset-backed securities	2,427	1		2,428
Total	$ 11,896	$ 2	$	$ 11,898

As of September 30, 2006, all short-term investments have maturity dates less than one year. For the three and nine months ended September 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

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

Years Ending December 31,

2006	$ 858
2007	3,090
2008	2,181
2009	1,225
2010	468
Thereafter	
Total	$ 7,822

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 nine months ended September 30, 2006 and 2005, respectively (in thousands):

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	Nine months ended September 30,	
	2006	2005
Balance at beginning of period	$ 1,998	$ 1,616
Charged to cost of sales	2,093	1,972
Actual warranty expenses	(2,054)	(1,582)
Balance at end of period	$ 2,037	$ 2,006

Equipment purchase commitment

During 2005, the Company agreed to purchase additional capacity sterolithography (SLA) manufacturing equipment from a certain vendor. During the first nine months of 2006, the Company paid $3.2 million of this purchase commitment and will pay the remaining $0.2 million during the fourth quarter of fiscal 2006.

OrthoClear Agreement

On October 13, 2006, the Company entered into a formal agreement with OrthoClear, Inc., OrthoClear Holdings, Inc., and OrthoClear Pakistan Pvt. Ltd. (OrthoClear), together with certain individuals associated with OrthoClear (the Agreement) to end all pending litigation between the parties. In accordance with the terms of the Agreement, the Company made a $20.0 million one-time cash payment to OrthoClear Holdings, Inc. on October 16, 2006. In an attempt to help minimize treatment disruptions for OrthoClear patients and their doctors, the Company has offered to make treatment available to these patients at no additional cost. The Company currently estimates that the cost to service these cases will be in the range of $10 to $13 million. See Note 12 Subsequent Events of the Notes to Condensed Consolidated Financial Statements for more information.

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 alleged 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 alleged that OrthoClear, Chishti and other defendants were 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. Subsequent to the initial filing date, there were extensive proceedings in the case as reported in previous Align filings.

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. .

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 alleged 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 alleged violations by OrthoClear of California s Unfair Practices Act (California Business and Professions Code §17200 et seq.).

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 alleged numerous violations by OrthoClear of the federal Lanham Act and related common law. These violations included 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 alleged violations by OrthoClear of California s Unfair Practices Act.

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 alleged that OrthoClear utilized the Company s trade secrets and infringed 12 of the Company s patents in the production of the OrthoClear aligners at a facility in Lahore, Pakistan. The ITC Complaint requested 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 requested 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.

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.

On October 13, 2006, the Company and OrthoClear, Inc., OrthoClear Holdings, Inc., and OrthoClear Pakistan Pvt. Ltd. (OrthoClear), together with certain individuals associated with OrthoClear, executed a formal agreement (the Agreement). The Agreement includes the following terms:

- OrthoClear is required to immediately discontinue all design, manufacture, marketing and sales of removable dental aligners worldwide

- OrthoClear consented to the entry of an exclusion order by the ITC, enforced by the United States Customs Service, which prevents OrthoClear from importing its dental aligner products into the U.S., either directly or through a third party;

- The parties agreed to dismiss all pending lawsuits against each other, including the State Case, Federal Lanham Action I, Federal Lanham Action II, Patent Infringement Federal Action, with prejudice;

- OrthoClear agreed to stop accepting new patient cases for treatment;

- OrthoClear and Muhammad Ziaullah Chishti its CEO, and Charles Wen, its President, have transferred and assigned to Align all intellectual property rights with application to the treatment of malocclusion;

- OrthoClear principals Muhammad Ziaullah Chishti, Charles Wen, Peter Riepenhausen, and Christopher Kawaja have signed 5-year, global non-compete agreements in the field of removable aligner therapy products and related software market;

- OrthoClear employees Joe Breeland and Jeff Tunnell have signed 5-year U.S. non-compete agreements prohibiting their personal participation in the removable aligner therapy product and related software market;

- The Company will make Invisalign treatment available to OrthoClear patients in the United States, Canada and Hong Kong at no charge from Align.

In accordance with the terms of the Agreement, on October 16, 2006, the Company made a one-time cash payment of $20 million to OrthoClear Holdings, Inc.

Ormco

On January 6, 2003, Ormco Corporation (Ormco) filed suit against the Company in the United States District Court for the Central District, Orange County Division, asserting infringement of U.S. Patent Nos. 5,447,432, 5,683,243 and 6,244,861. Ormco is a division of Sybron Dental Specialties. In May 2006, Danaher Corporation acquired Sybron Dental

Specialties. The complaint sought unspecified monetary damages and injunctive relief. On February 18, 2003, the Company answered the complaint and asserted counterclaims seeking a declaration by the Court of invalidity and non-infringement of the asserted patents. In addition, the Company counterclaimed for infringement of its U.S. Patent No. 6,398,548, seeking unspecified monetary damages and injunctive relief. Ormco filed a reply to the Company s counterclaims on March 10, 2003 and asserted counterclaims against the Company seeking a declaration by the Court of invalidity and non-infringement of U.S. Patent No. 6,398,548. The Company amended its counterclaim to add Allesee Orthodontic Appliances, Inc. (AOA), a wholly-owned subsidiary of Ormco, as a counterdefendant in regard to the Company s counterclaim of infringement of U.S. Patent No. 6,398,548. The Court then permitted Ormco to amend its Complaint and permitted the Company to amend its counterclaim to add an additional patent each. Ormco filed a first amended complaint for infringement of U.S. Patent No. 6,616,444 on October 15, 2003. On October 27, 2003, the Company filed an answer to Ormco s first amended complaint and a counterclaim for invalidity and non-infringement of U.S. Patent No. 6,616,444 and for infringement of U.S. Patent No. 6,554,611.

In connection with these claims, the Court granted five motions for summary judgment that the Company filed. First, on May 14, 2004, the Court granted the Company s motion for summary judgment of non-infringement, finding that 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, the Court ruled 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.

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 s pending appeal of the decisions and orders of the United States District Court relating to Ormco s patents; or (2) the Company s pending 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 the Company $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.

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, the Company has filed its responsive appellate brief and Ormco has filed a response and reply brief. In addition, 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 took place on April 3, 2006. Following oral argument, the U.S. Court of Appeals for the Federal Circuit (CAFC) issued a ruling declaring two out of a total of seventy-one claims in the Company s US Patent No. 6,398,548 and four out of a total of ten claims in US Patent No. 6,544,611 to be invalid as obvious. The CAFC's decision reverses the California District Court summary judgment order of validity.

The 6,398,548 patent consists of seventy-one claims; only claims 10 and 17 were at issue in the appeal and CAFC ruling. These two claims are directed to a system of appliances and method of repositioning teeth from an initial to a final tooth arrangement where at least some of the appliances are marked to show order of use. These claims contain further limitations requiring instructions as to order in which the appliances are to be worn and use of the appliances in intervals of 2-20 days.

The 6,544,611 patent consists of ten claims directed to a system for repositioning teeth that includes one or more intermediate appliances and a final appliance, provided in a single package, as well as instructions which set forth the order in which the appliances are to be worn. The CAFC's ruling pertains only to claims 1, 2, 3 and 7 in the patent.

The majority of the claims in the 6,398,548 patent, including claims that address methods of fabricating aligners, digital data sets or computer-generated models to fabricate appliances, are unaffected by the appeal and the CAFC's ruling. The 6,544,611 patent does not contain claims related to digital data, computer-generated models, or methods of fabrication.

Other matters

USPTO

Ex Parte Requests:

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, requesting Ex Parte re-examination of the Company s patents as follows:

U.S. Patent No.	Request for Reexamination Granted?	Initial Office Actions Received?	Status
5,975,893	Yes	Yes	On January 26, 2006, a first office action was issued rejecting all claims of U.S. Patent No. 5,975,893 (the 893 patent). The Company responded to this initial office action. A Final Office Action was issued by the USPTO on June 23, 2006 rejecting the pending claims of Align s response. On August 23, 2006, the Company filed an amendment in response to this Final Office Action, which included claims discussed in an interview with the Examiners. The Company is awaiting further action by the USPTO.
6,398,548	Yes	No	The Company is awaiting an initial office action.
6,309,215	Yes	Yes	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 respect to U.S. Patent No. 6,309,215 (the 215 patent). 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 in the 215 patent. 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.
6,705,863	Yes	No	The Company is awaiting an initial office action.
6,217,325	Yes	Yes	On July 25, 2006, the Company received an Office Action in U.S. Patent No. 6,217,325 (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. On September 25, 2006, the Company filed an amendment in response to the final Office Action with respect to the claims that were not allowed. The Company is awaiting further action by the USPTO.
6,722,880	No	N/A	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.
6,318,994	Yes	No	The USPTO has granted the requests for reexamination of the U.S. Patent No. 6,318,994. The Company is awaiting an initial Office Action.

Inter Parte Requests made by OrthoClear

As part of the Agreement, OrthoClear agreed to take no further action with respect to the Inter Parte Requests.

Patent No.	Request for Reexamination Granted?	Initial Office Actions Received?	Status
6,629,840	Yes	Yes	In this initial Office Action dated June 13, 2006, the examiners confirmed the validity of eight of the eleven claims of U.S. Patent No. 6,629,840 (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. On September 13, 2006, the Company submitted a response to the initial Office Action. Align is awaiting further action by the USPTO.
6,685,469	No	N/A	The USPTO has neither granted nor denied the requests for reexamination of U.S. Patent No. 6,685,469.

The re-examination proceedings on Patent Nos.6,318,994, 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 two of 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, 215, 325 and 840 patent claims) having a narrower scope of coverage or even to being invalidated, which could have an adverse effect on the Company.

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. On March 16, 2006, 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. On August 18, 2006, the Company filed a motion for summary judgment with respect to Bay s claims for, among other things, breach of implied requirements contract, promissory estoppel and fraud. Also on August 18, 2006, Bay filed a motion for summary judgment with respect to the entirety of the Company s cross-complaint. The Company s motion for summary judgment was heard on November 2, 2006 and the hearing for Bay s motion for summary judgment is set for November 8, 2006. 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 the types discussed in this footnote and in Part II, Item 1 Legal Proceedings of this Quarterly Report on Form 10-Q, 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.

During the third quarter of 2006, the Company borrowed $15.0 million against these credit facilities and elected the interest rate of LIBOR plus two percent, with interest payable monthly at a rate of 7.39% as of September 30, 2006. The outstanding balance on this line of credit as of September 30, 2006 was $15.0 million. There were no outstanding borrowings against the line of credit as of December 31, 2005. The Company anticipates repaying this balance by September 30, 2007, hence this amount was included in the current liabilities as of September 30, 2006. As of September 30, 2006, the Company was in compliance with the restrictive loan covenants of these facilities.

On October 16, 2006, in accordance with the terms of the Agreement with OrthoClear, the Company made a $20.0 million one-time payment to OrthoClear Holdings, Inc. The Company expects to determine the impact of this payment in the fourth quarter of 2006 on our financial statements, at which point it will assess whether the financial impact of this transaction requires the Company to seek any waivers and/or amendments to the restrictive loan covenants contained in its credit agreement. The Company believes it will be able to obtain any such waivers and/or amendments to the extent they are necessary.

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 September 30, 2006, 2,058,146 shares

have been transferred to the 2005 Plan. As of September 30, 2006, 8,182,495 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 September 30, 2006, no 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 September 30,		Nine Months Ended September 30,	
	2006	2005	2006	2005
Expected term (in years)	5.0	3.2	5.0	2.3
Expected volatility	74 %	72 %	77 %	71 %
Risk-free interest rate	4.86 %	4.03 %	4.67 %	3.78 %
Expected dividend				
Weighted average fair value at grant date	$ 4.42	$ 3.57	$ 5.33	$ 3.13

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 nine months ended September 30, 2006 compared to three and nine months ended September 30, 2005, is the result of granting options with shorter vesting in 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 nine months ended September 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	1,549	8.19		
Cancelled or expired	(1,553)	12.37		
Exercised	(835)	6.67		
Outstanding at September 30, 2006	10,465	$ 8.31	7.63	$ 42,559
Ending vested and expected to vest at September 30, 2006	10,234	$ 8.32	7.59	$ 41,686
Exercisable at September 30, 2006	7,621	$ 8.53	7.08	$ 31,594

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 third 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 September 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 September 30, 2006 and 2005 was $0.4 million and $0.7 million, respectively. The total intrinsic value of stock options exercised for the nine months ended September 30, 2006 and 2005 was $1.2 million and $3.1 million, respectively. As of September 30, 2006, there was $9.8 million of total unamortized compensation costs related to stock options. These costs are expected to be recognized over a weighted average period of 1.4 years. For the three and nine months ended September 30, 2006, 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 September 30, 2006, the total fair value of vested restricted stock awards was zero. A summary of the nonvested shares for the nine months ended September 30, 2006 is as follows:

	Shares (in thousands)	Weighted Average Grant Date Fair Value
Nonvested as of December 31, 2005	$	$
Granted	397	8.31
Vested		
Forfeited	(20)	8.27
Nonvested as of September 30, 2006	$ 377	$ 8.31

As of September 30, 2006, there was $2.4 million of total unamortized compensation costs related to restricted stock units. These costs are expected to be recognized over a weighted average period of 1.7 years

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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 nine months ended September 30, 2006, 462,404 shares were issued under the Purchase Plan. As of September 30, 2006, the Company had reserved 8,933,456 shares of common stock for future issuance and 7,272,388 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:

	Nine Months Ended September 30,	
	2006	**2005**
Expected term (in years)	1.26	1.21
Expected volatility	48.2 %	62.0 %
Risk-free interest rate	4.97 %	3.76 %
Expected dividend		
Weighted average fair value at grant date	$ 2.69	$ 3.12

As of September 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 nine months ended September 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 nine months ended September 30, 2006:

(In thousands, except per share amounts)	Three Months Ended September 30, 2006	Nine Months Ended September 30, 2006
Cost of revenues	$ 186	$ 515
Sales and marketing	714	2,125
General and administrative	1,015	3,132
Research and development	362	976
Total share-based compensation	$ 2,277	$ 6,748

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 nine months ended September 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 nine months ended September 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 September 30, 2005**	**Nine Months Ended September 30, 2005**
Net profit (loss), as reported	$ (1,516)	$ 885
Add: Stock-based employee compensation expense included in reported net earnings under APB No. 25, net of related tax effects		70
Deduct: Total stock-based employee compensation determined under the fair value method for all awards, net of related tax effects	(4,556)	(14,382)
Pro forma net loss	$ (6,072)	$ (13,427)
Basic net earning (loss) per share:		
As reported	$ (0.02)	$ 0.01
Pro forma	$ (0.10)	$ (0.22)
Diluted net earning (loss) per share:		
As reported	$ (0.02)	$ 0.01
Pro forma	$ (0.10)	$ (0.22)

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 September 30,		Nine Months Ended September 30,	
	2006	2005	2006	2005
Net profit (loss)	$ (10,320)	$ (1,516)	$ (17,694)	$ 885
Weighted-average common shares outstanding, basic	63,230	61,788	62,907	61,509
Effect of potential dilutive common shares				1,620
Total shares, diluted	63,230	61,788	62,907	63,129
Basic net profit (loss) per share	$ (0.16)	$ (0.02)	$ (0.28)	$ 0.01
Diluted net profit (loss) per share	$ (0.16)	$ (0.02)	$ (0.28)	$ 0.01

For the three and nine months ended September 30, 2006, stock options and restricted stock units totaling 9.6 million and 7.5 million, respectively, were excluded from diluted net loss per share because of their anti-dilutive effect. For the three and nine months ended September 30, 2005, stock options totaling 8.5 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 intangible assets as of September 30, 2006 (in thousands):

	September 30, 2006			December 31, 2005	
	Gross Carrying Value	Accumulated Amortization	Net Carrying Value	Accumulated Amortization	Net Carrying Value
Consultant relationships	$ 980	$ 544	$ 436	$ 299	$ 681
Patent	180	108	72	81	99
Other	55	31	24	17	38
Total	$ 1,215	$ 683	$ 532	$ 397	$ 818

During 2003, the Company obtained a patent for $180,000 and is amortizing it over the expected useful life of five years. Estimated future amortization expense for the patent as of September 30, 2006 is $9,000, $36,000 and $27,000 in 2006, 2007 and 2008, respectively.

Other 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 September 30, 2006 is $86,000, $345,000 and $29,000 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 September 30,		Nine Months Ended September 30,	
	2006	2005	2006	2005
Revenues:				
Domestic	$ 41,058	$ 45,253	$ 127,545	$ 138,743
Europe	6,472	4,676	19,628	14,817
Other International	1,504	937	3,990	2,401
Total revenues	$ 49,034	$ 50,866	$ 151,163	$ 155,961

	As of September 30, 2006	As of December 31, 2005
Long-lived assets:		
Domestic	$ 27,642	$ 27,281
Europe	713	990
Other International	1,872	2,253
Total long-lived assets	$ 30,227	$ 30,524

Note 12. Subsequent Events

On October 13, 2006, the Company entered into a formal agreement with OrthoClear, Inc., OrthoClear Holdings, Inc., and OrthoClear Pakistan Pvt. Ltd. (OrthoClear), together with certain individuals associated with OrthoClear (the Agreement) to end all pending litigation between the

parties. In addition, OrthoClear agreed, among other things, to stop accepting new patient cases for treatment, consent to the entry of an exclusion order by the ITC prohibiting the importation of OrthoClear aligners into the United States, assign and transfer to Align all intellectual property rights with application to the correction of malocclusion and discontinue all design, manufacture, marketing and sales of removable dental aligners worldwide. In an attempt to help minimize treatment disruptions for these patients and their doctors, the Company has

offered to make treatment available to OrthoClear patients at no additional cost. The Company currently estimates that the cost to service these cases will be in the range of $10 to $13 million.

In accordance with the terms of the Agreement, the Company made a $20.0 million one-time cash payment to OrthoClear Holdings, Inc. on October 16, 2006. During the fourth quarter of 2006, the Company engaged a third-party firm to assess the value of the assets received in conjunction with this agreement. Based on this valuation, the Company expects to determine the impact of this transaction on its balance sheet and statement of operations and if it would be necessary to seek any waivers and/or amendments to the restrictive loan covenants contained in its credit agreement. See Note 5 Legal Proceedings of the Notes to Condensed Consolidated Financial Statements for more information.

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 determine the impact of the $20 million payment to OrthoClear in the fourth quarter of 2006 on our financial statements, our belief we will obtain any necessary waiver and /or amendment to our credit facilities, our expectation on the cost to transition current OrthoClear patients to Invisalign treatment through our Patients First Program, 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 expectation regarding rate of growth internationally and domestically, 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 we will introduce product enhancements and new products and that such enhancement and products will increase our market share, our expectation that our general and administrative expenses will increase significantly in 2006 and decrease in 2007, and our sales and marketing and our research and development expenses will be comparable to 2005, 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, and 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 nine 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.

- *Settlement with OrthoClear.* On October 13, 2006, we entered into a formal agreement with OrthoClear, Inc., OrthoClear Holdings, Inc., and OrthoClear Pakistan Pvt. Ltd. (OrthoClear), together with certain individuals associated with OrthoClear (the Agreement) to end all pending litigation between the parties. In addition, OrthoClear agreed, among other things, to stop accepting new patient cases for treatment, consent to the entry of an exclusion order by the ITC prohibiting the importation of OrthoClear aligners into the United States, assign and transfer to Align all intellectual property rights with application to the correction of malocclusion and to discontinue all design, manufacture, marketing and sales of removable dental aligners worldwide. In accordance with the terms of the Agreement, we made a one-time cash payment of $20 million to OrthoClear Holdings, Inc. *See Part II, Item 1 Legal Proceedings of this Quarterly Report on Form 10-Q for a more complete summary of the Agreement.* During the fourth quarter of 2006, we engaged a third-party firm to assess the value of the assets received in conjunction with the Agreement. Based on this valuation, we expect to determine the impact of this transaction on our balance sheet and statement of operations and if it is necessary to seek any waivers and/or amendments to the restrictive loan covenants contained in our credit agreement. We believe we will be able to obtain any such waivers and/or amendments to the extent they are necessary. Through the Agreement we will achieve our primary objectives in the litigation as well as eliminate the costs and risks of protracted litigation. As a result of the Agreement, we expect our legal expenses will be reduced significantly in fiscal 2007 and our management and technical personnel can focus their energy and resources on our customers and product development.

- *Patients First Program* . As part of the Agreement, OrthoClear agreed to stop the importation of aligners into the United States and discontinue all aligner business operations worldwide. As a result, current OrthoClear patients may not be able to complete their orthodontic treatment with OrthoClear. In an attempt to help minimize treatment disruptions for these patients and their doctors, we have offered to make Invisalign treatment available to OrthoClear patients at no additional charge from Align. Therefore, we will receive no revenue for any additional cases we start under this program while incurring significant expenses. We currently estimate that the cost to service these cases will be in the range of $10 to $13 million. Additionally this program will generate increased demands on our sales and customer service representatives and on our manufacturing processes, including increased headcount. Our success will depend in part on management s ability to effectively integrate the OrthoClear patients into our infrastructure with minimal impact on our existing and new customers. We may have difficulty managing the deployment of this program, including the internal allocation of personnel and resources potentially resulting in production delays. Any such difficulty could cause us to lose existing customers, face potential customer disputes or limit the number of new customers who purchase our products or services. This could cause a decline in our revenues, gross margins and net profits and could adversely affect our operating results.

- *Changing Product Mix and Lower Unit Prices.* In the third quarter of 2005, we launched Invisalign Express, a low-cost solution for less complex orthodontic cases. We have recently experienced and expect to continue to experience increased sales volumes of the lower-priced Invisalign Express and this shifting product mix has had and will continue to have an adverse effect on our revenue, gross margin and net profits. In addition, in the fourth quarter of 2005 we announced that all Invisalign cases (other than Invisalign Express) in our domestic market would 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. We expect these programs, and any other similar programs we may launch in the future, including our program offering doctors who became part of our exclusivity program one free case in the fourth quarter of 2006, may have a negative impact on our revenues, gross margins and net profits.

- *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 nine months of 2006, our domestic GP channel generated 46% of our total revenue, while the orthodontist channel represented 34%. In the first nine months of 2006, we experienced a slower rate of growth in the GP channel as compared to the first nine months of 2005, and we expect the slower rate of growth to continue in the GP channel during the fourth quarter of 2006. This is due in part to OrthoClear s recent focus on this channel and our expectation that working through the Patients First Program with these GPs will continue to adversely impact the growth rate of this channel. 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 September 30, 2006, we have integrated the Invisalign technique into the curriculums of 36 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 recently announced a phased rollout of ClinAdvisor, a new suite of software tools designed to make Invisalign case selection, submission and review processes more efficient for doctors. We expect to launch further software enhancements directed at our more experienced doctors that will make our Invisalign system easier to use. We are also planning to introduce 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. 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 nine months of 2006, our international channel represented approximately 16% of our total revenue primarily as a result of growth in Europe. Although we expect our international revenue to continue to increase in absolute dollars, international revenue as a percentage of total revenue will be consistent or slightly lower in the foreseeable future due in part to an expected increase in our domestic revenue.

- *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 decline or 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 nine months ended September 30, 2006, stock-based compensation expense recognized in accordance with FAS 123R is as follows (in thousands):

	Three Months Ended September 30, 2006 Stock-based Compensation	Percent of Revenues	Nine Months Ended September 30, 2006 Stock-based Compensation	Percent of Revenues
Cost of revenues	$ 186	0.4 %	$ 515	0.3 %
Sales and marketing	714	1.5 %	2,125	1.4 %
General and Administrative	1,015	2.1 %	3,132	2.1 %
Research and development	362	0.7 %	976	0.6 %
Total stock-based compensation expense	$ 2,277	4.6 %	$ 6,748	4.5 %

Results of Operations

Revenues:

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

	Three Months Ended				Nine Months Ended			
(in million)	September 30, 2006	September 30, 2005	Net Change	% Change	September 30, 2006	September 30, 2005	Net Change	% Change
Domestic:								
Orthodontic	$ 16.2	$ 20.3	$ (4.1)	(20.0)%	$ 51.2	$ 66.7	$ (15.5)	(23.3)%
GP	22.7	22.9	(0.2)	(0.7)%	69.4	65.9	3.5	5.2 %
International	7.3	5.7	1.6	27.3 %	22.5	16.6	5.9	36.1 %
Total Invisalign	46.2	48.9	(2.7)	(5.4)%	143.1	149.2	(6.1)	(4.1)%
Other revenues	2.8	2.0	0.8	40.7 %	8.1	6.7	1.4	20.1 %
Total Revenues	$ 49.0	$ 50.9	$ (1.9)	(3.6)%	$ 151.2	$ 155.9	$ (4.7)	(3.1)%

Case volume data which represents Invisalign case shipment by channel, for the three and nine months ended September 30, 2006 and 2005 are as follows:

	Three Months Ended				Nine Months Ended			
	September 30, 2006	September 30, 2005	Net Change	% Change	September 30, 2006	September 30, 2005	Net Change	% Change
Case Volume (in thousands)								
Domestic:								
Orthodontic	13.0	11.5	1.5	12.9 %	41.1	38.0	3.1	8.1 %
GP	18.3	14.5	3.8	26.2 %	56.2	41.4	14.8	35.8 %
International	4.4	3.2	1.2	39.4 %	13.7	9.4	4.3	45.5 %
Total Invisalign	35.7	29.2	6.5	22.4 %	111.0	88.8	22.2	25.0 %

For the three months and nine months ended September 30, 2006, total revenues decreased by $1.9 million or 3.6% and $4.7 million or 3.1% compared to the three and nine months ended September 30, 2005, respectively. These decreases were 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 our volume based discount program, all of which were launched in the second half of 2005. These factors impacted both the Orthodontic and GP channels.

For the three and nine months ended September 30, 2006 our domestic Orthodontic channel revenue decreased $4.1 million or 20.0% and $15.5 million or 23.3%, respectively, compared to the same periods in 2005. These decreases were primarily due to decreased volumes of full Invisalign cases partially offset by increased sale of Invisalign Express, as well as a lower average selling price for full Invisalign due to the other factors noted above.

For the three months ended September 30, 2006, revenues from our domestic GP channel decreased by $0.2 million or 0.7% compared to the three months ended September 30, 2005 due to lower average selling prices partially offset by a significant increase in case volume. For the nine months ended September 30, 2006, revenues from our GP channel increased $3.5 million or 5.2% compared to the same period in 2005 primarily due to the significant increase in case volume partially offset by decreases in average selling prices. The increases in case volume for the three and nine months ended September 30, 2006 compared to the same periods in 2005 were driven by sales of Invisalign Express.

International revenue increased $1.6 million or 27.3% and $5.9 million or 36.1% for the three and nine months ended September 30, 2006 compared to the three and nine months ended September 30, 2005. These increases were primarily due to a significant increase in our international full Invisalign case volumes partially offset by a lower average selling price as a result of 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 the launch of Invisalign Express in the second half of 2005. Additionally in Europe, we introduced new pricing initiatives in the first quarter of 2006 which have resulted in a lower average selling price.

Cost of revenues:

	Three months ended September 30,			Nine months ended September 30,		
(In millions)	**2006**	**2005**	**Change**	**2006**	**2005**	**Change**
Cost of revenues	$ 16.8	$ 15.0	$ 1.8	$ 47.6	$ 47.1	$ 0.5
% of Revenues	34.2 %	29.4 %		31.5 %	30.2 %	
Gross profit	$ 32.2	$ 35.9	$ (3.7)	$ 103.6	$ 108.9	$ (5.3)
% of Revenues	65.8 %	70.6 %		68.5 %	69.8 %	

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 to 65.8% of revenues for the three months ended September 30, 2006, compared to 70.6% of revenues for the three months ended September 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.

Gross margin decreased to 68.5% of revenues for the nine months ended September 30, 2006, compared to 69.8% of revenues for the nine months ended September 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 this decrease is a $2.2 million reduction in the provision for estimated losses on case refinement sales.

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.

Sales and marketing:

(In millions)	Three months ended September 30, 2006	2005	Change	Nine months ended September 30, 2006	2005	Change
Sales and marketing	$ 19.2	$ 21.3	$ (2.1)	$ 59.9	$ 61.5	$ (1.6)
% of Revenues	39.1 %	41.9 %		39.6 %	39.4 %	

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 $2.1million in the three months ended September 30, 2006 compared to the three months ended September 30, 2005 primarily as a result of a $3.4 million decrease in media, advertising and other marketing expenses due to the consumer marketing campaign in the third quarter of 2005, a $0.4 million decrease in payroll expense due to the retention incentives for our sales force in the third quarter of 2005 and a $0.4 million decrease in outside services. Partially offsetting these decreases were a $1.3 million increase in training expense due to the timing of the 2006 GP Summit and a $0.7 million increase in stock-based compensation expense.

Sales and marketing expense decreased $1.6 million in the nine months ended September 30, 2006 compared to the nine months ended September 30, 2005 primarily due to a $5.9 million decrease in media, advertising and other marketing expenses due to the consumer marketing campaign launched in the second quarter of 2005 and a $0.9 million decrease in outside services. Partially offsetting these decreases were a $2.1 million increase in stock-based compensation expense, a $1.4 million increase in training expense attributable to an increase in sales and marketing collateral and clinical education costs, a $0.9 million increase in payroll related expenses due to the replacement of orthodontic sales representatives who left Align in the first half of 2005 and a $0.6 million an increase in commission expense due to increase in international revenues.

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:

(In millions)	Three months ended September 30, 2006	2005	Change	Nine months ended September 30, 2006	2005	Change
General and administrative	$ 19.2	$ 11.7	$ 7.5	$ 49.7	$ 30.9	$ 18.8
% of Revenues	39.2 %	23.0 %		32.8 %	19.8 %	

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 September 30, 2006 increased by $7.5 million compared to the three months ended September 30, 2005 due to a $6.7 million increase in external legal fees primarily related to the OrthoClear litigation and a $1.0 million increase in stock-based compensation expense.

General and administrative expense for the nine months ended September 30, 2006 increased by $18.8 million compared to the nine months ended September 30, 2005 primarily due to a $15.2 million increase in external legal fees primarily related to the OrthoClear litigation, a $2.4 million increase in payroll related expenses primarily resulting from the hiring of additional legal and administrative staff, and a $3.1 million increase in stock-based compensation expense. Partially offsetting these increases was a $0.8 million decrease in bad debt expense.

For fiscal year 2006, we expect that general and administrative expense will increase significantly from fiscal 2005 primarily as a result of higher OrthoClear litigation related expenses and stock-based compensation expense. As a result of the Agreement we entered into with OrthoClear in October 2006, we expect our legal expenses will be reduced significantly in fiscal 2007.

Research and development:

(In millions)	Three months ended September 30, 2006	2005	Change	Nine months ended September 30, 2006	2005	Change
Research and development	$ 4.8	$ 4.4	$ 0.4	$ 13.5	$ 14.7	$ (1.2)
% of Revenues	9.8 %	8.7 %		8.9 %	9.4 %	

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 September 30, 2006 increased by $0.4 million compared to the three months ended September 30, 2005, primarily due to a $0.3 million increase in payroll related expenses and a $0.4 million increase in stock-based compensation, partially offset by a $0.2 million decrease in temporary services and outside consulting.

Research and development expense for the nine months ended September 30, 2006 decreased by $1.2 million compared to the nine months ended September 30, 2005, primarily due to a $1.5 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 partially offset by $1.0 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.

Interest and other, net:

(In millions)	Three months ended September 30, 2006	2005	Change	Nine months ended September 30, 2006	2005	Change
Interest income, net	$ 0.8	$ 0.5	$ 0.3	$ 2.3	$ 1.2	$ 1.1
Other income (expense), net	0.1	(0.2)	0.3	0.1	(1.2)	1.3
Total interest and other, net	$ 0.9	$ 0.3	$ 0.6	$ 2.4	$	$ 2.4

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 nine months ended September 30, 2006 increased $0.3 million and $1.1 million, respectively, compared to the three and nine months ended September 30, 2005. These increases were primarily due to increased interest income as a result of higher effective interest rates.

Other income (expense) increased $0.3 million and $1.3 million in the three and nine months ended September 30, 2006, respectively, compared to the same period in 2005, primarily due to the changes in foreign currency translation gains (losses).

Income tax provision:

(In millions)	Three months ended September 30, 2006	2005	Change	Nine months ended September 30, 2006	2005	Change
Provision for income taxes	$ 0.2	$ 0.3	$ (0.1)	$ 0.6	$ 0.9	(0.3)

We recorded an income tax provision of $0.2 million and $0.3 million for the three months ended September 30, 2006 and 2005, respectively, representing effective tax rates of (2.1)% and (25.0)%, respectively. For the nine months ended September 30, 2006 and 2005, we recorded income tax provision of $0.6 million and $0.9 million, respectively, representing

effective tax rates of (3.6)% and 51.1%, 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 September 30, 2006 we had $ 74.0 million in cash and cash equivalents and $11.9 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 September 30, 2006 and December 31, 2005.

Net cash used in operating activities for the nine months ended September 30, 2006 was $4.3 million, resulting primarily from our operating loss of $17.7 million adjusted for non-cash items reflected in our net loss amount such as depreciation and amortization of $7.1 million and stock-based compensation of $6.7 million, a $3.3 million increase in accounts receivable as a higher percentage of revenues were shipped during the latter part of the third quarter and a $4.6 million reduction in deferred revenue, which were partially offset by a $5.2 million increase in accounts payable and a $2.4 million increase in accrued liabilities. For the nine months ended September 30, 2005, net cash provided by operating activities was $17.0 million, primarily from operating profit of $0.9 million adjusted for $7.9 million of non-cash items reflected in our net income and increases in accrued liabilities and deferred revenue.

For the nine months ended September 30, 2006, we used $18.8 million of cash in our investing activities primarily due to an $11.9 million net purchase of short-term marketable securities and $7.5 million for the purchase of capital assets. For the nine months ended September 30, 2005, net cash used in investing activities was $13.0 million primarily from the purchase of property and equipment for capacity expansion, manufacturing improvements, purchases of short-term marketable securities and the purchase of General Orthodontics, LLC.

Net cash provided by financing activities was $22.9 million and $3.6 million for the nine months ended September 30, 2006 and 2005, respectively. For the nine months ended September 30, 2006, net cash provided by financing activities consisted of $15.0 million in proceeds from the line of credit and $7.9 million in proceeds from the issuance of common stock, primarily from exercises of employee stock options. For the nine months ended September 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 have 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. During the third quarter of 2006, we borrowed $15.0 million against these credit facilities and elected LIBOR plus two percent as our interest rate being 7.39% as of September 30, 2006. The outstanding balance as of September 30, 2006 was $15.0 million. We anticipate repaying this balance by September 30, 2007, hence this amount was included in the current liabilities as of September 30, 2006. On October 16, 2006, in accordance with the terms of the Agreement with OrhtoClear, we made a $20.0 million one-time payment to OrthoClear Holdings, Inc. During the fourth quarter of 2006, we engaged a third-party firm to assess the value of the assets received in conjunction with the Agreement. Based on this valuation, we expect to determine the impact of this transaction on our balance sheet and statement of operations and if it is necessary to seek any waivers and/or

amendments to the restrictive loan covenants contained in our credit agreement. We believe we will be able to obtain any such waivers and/or amendments to the extent they are necessary.

Our expense levels for the first nine months of 2006 were higher than the first nine months of 2005, and as a result we expect our expense levels for fiscal 2006 to be higher than fiscal 2005. 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 $23.0 million to $25.0 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

In accordance with the terms of the Agreement we entered into with OrthoClear, we made a $20 million one-time cash payment to OrthoClear Holdings, Inc. on October 16, 2006. We also offered to make treatment available to OrthoClear patients at no additional cost. We currently estimate that the cost to service these cases will be in the range of $10 to $13 million. See Note 12 Subsequent Events of the Notes to Condensed Consolidated Financial Statements for additional information.

As of September 30, 2006, there were no other 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 nine months ended September 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, we 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 nine months ended September 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 nine months ended September 30, 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.

Recent Accounting Pronouncements

See Note 1 Summary of Significant Accounting Policies of the Notes to Condensed Consolidated Financial Statements for a discussion of recent accounting pronouncements.

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 September 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 alleged 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 alleged that OrthoClear, Chishti and other defendants were 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. Subsequent to the initial filing date, there were extensive proceedings in the case as reported in previous Align filings.

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.

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 alleged 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 alleged violations by OrthoClear of California s Unfair Practices Act (California Business and Professions Code §17200 et seq.).

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 alleged 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 alleged violations by OrthoClear of California s Unfair Practices Act.

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 alleged that OrthoClear utilized our trade secrets and infringed 12 of our patents in the production of the OrthoClear aligners at a facility in Lahore, Pakistan. The ITC Complaint requested the ITC institute an immediate investigation and ultimately issues an exclusionary order, enforced by U.S. Customs and Border Protection, excluding OrthoClear aligners from importation into the United States. The ITC Complaint also requested 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.

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 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.

On October 13, 2006, the Company and OrthoClear, Inc., OrthoClear Holdings, Inc., and OrthoClear Pakistan Pvt. Ltd. (OrthoClear), together with certain individuals associated with OrthoClear executed a formal agreement (the Agreement). The Agreement includes the following terms:

- OrthoClear is required to immediately discontinue all design, manufacture, marketing and sales of removable dental aligners worldwide

- OrthoClear consented to the entry of an exclusion order by the ITC, enforced by the United States Customs Service, which prevents OrthoClear from importing its dental aligner products into the U.S., either directly or through a third party;

- The parties agreed to dismiss all pending lawsuits against each other, including the State Case, Federal Lanham Action I, Federal Lanham Action II, Patent Infringement Federal Action, with prejudice;

- OrthoClear agreed to stop accepting new patient cases for treatment;

- OrthoClear and Zia Chishti, its CEO, and Charlie Wen, its President, have transferred and assigned to Align all intellectual property rights with application to the treatment of malocclusion;

- OrthoClear principals Zia Chishti, Charlie Wen, Peter Riepenhausen, and Christopher Kawaja have signed 5-year, global non-compete agreements in the field of removable aligner therapy products and related software market;

- OrthoClear employees Joe Breeland and Jeff Tunnell have signed 5-year U.S. non-compete agreements prohibiting their personal participation in the removable aligner therapy product and related software market;

- We will make Invisalign treatment available to OrthoClear patients in the United States, Canada and Hong Kong at no charge from Align.

In accordance with the terms of the Agreement, on October 16, 2006, the Company made a one-time cash payment of $20 million to OrthoClear Holdings, Inc.

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. Ormco is a division of Sybron Dental Specialties. In May 2006, Danaher Corporation acquired Sybron Dental Specialties. 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, the Court ruled 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.

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 s pending appeal of the decisions and orders of the United States District Court relating to Ormco s patents; or (2) our pending 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.

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, we have filed our responsive appellate brief and Ormco has filed a response and reply brief. In addition, 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 took place on April 3, 2006. Following oral argument, the U.S. Court of Appeals for the Federal Circuit (CAFC) issued a ruling declaring two out of a total of seventy-one claims in our US Patent No. 6,398,548 and four out of a total of ten claims in US Patent No. 6,544,611 to be invalid as obvious. The CAFC s decision reverses the California District Court summary judgment order of validity.

The 6,398,548 patent consists of seventy-one claims; only claims 10 and 17 were at issue in the appeal and CAFC ruling. These two claims are directed to a system of appliances and method of repositioning teeth from an initial to a final tooth arrangement where at least some of the appliances are marked to show order of use. These claims contain further limitations requiring instructions as to order in which the appliances are to be worn and use of the appliances in intervals of 2-20 days.

The 6,544,611 patent consists of ten claims directed to a system for repositioning teeth that includes one or more intermediate appliances and a final appliance, provided in a single package, as well as instructions which set forth the order in which the appliances are to be worn. The CAFC s ruling pertains only to claims 1, 2, 3 and 7 in the patent.

The majority of the claims in the 6,398,548 patent, including claims that address methods of fabricating aligners, digital data sets or computer-generated models to fabricate appliances, are unaffected by the appeal and the CAFC s ruling. The 6,544,611 patent does not contain claims related to digital data, computer-generated models, or methods of fabrication.

Other matters

USPTO

Ex Parte Requests:

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, requesting Ex Parte re-examination of our patents as follows:

U.S. Patent No.	Request for Reexamination Granted?	Initial Office Actions Received?	Status
5,975,893	Yes	Yes	On January 26, 2006, a first office action was issued rejecting all claims of U.S. Patent No. 5,975,893 (the 893 patent). We responded to this initial office action. A Final Office Action was issued by the USPTO on June 23, 2006 rejecting the pending claims of our response. On August 23, 2006, we filed an amendment in response to this Final Office Action, which included claims discussed in an interview with the Examiners. We are awaiting further action by the USPTO.
6,398,548	Yes	No	We are awaiting an initial office action.
6,309,215	Yes	Yes	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 respect to U.S. Patent No. 6,309,215 (the 215 patent). 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 in the 215 patent. 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 proceedings as a valid and enforceable patent with 42 claims.
6,705,863	Yes	No	We are awaiting an initial office action.
6,217,325	Yes	Yes	On July 25, 2006, we received an Office Action in U.S. Patent No. 6,217,325 (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. On September 25, 2006, we filed an amendment in response to the final Office Action with respect to the claims that were not allowed. We are awaiting further action by the USPTO
6,722,880	No	N/A	On December 23, 2005, in a non-appealable, final Order, the USPTO denied the request for re-examination with respect to all 21 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.
6,318,994	Yes	No	The USPTO has granted the requests for reexamination of the U.S. Patent No. 6,318,994. We are awaiting an initial Office Action

Inter Parte Requests made by OrthoClear

As part of the Agreement, OrthoClear agreed to take no further action with respect to the Inter Parte Requests.

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Patent No.	Request for Reexamination Granted?	Initial Office Actions Received?	Status
6,629,840	Yes	Yes	In this initial Office Action dated June 13, 2006, the examiners confirmed the validity of eight of the eleven claims of U.S. Patent No. 6,629,840 (the 840 patent) without amendment and preliminarily rejected the remaining claims of the patents. The non-final initial Office Action presented us with our first opportunity to respond to the USPTO s review and interpretation of the prior art. On September 13, 2006, we submitted a response to the initial Office Action. We are awaiting further action by the USPTO.
6,685,469	No	N/A	The USPTO has neither granted nor denied the requests for reexamination of U.S. Patent No. 6,685,469.

The re-examination proceedings on Patent Nos. 6,318,994, 6,398,548 and 6,705,863 (collectively, the Remaining Patents) are currently pending but no Office Action has been received by us. However, we filed Preliminary Amendments adding additional claims regarding two of the Remaining Patents. 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, 215, 325 and 840 patent claims) having a narrower scope of coverage or even to being invalidated, which could have an adverse effect on us.

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. On August 18, 2006, we filed a motion for summary judgment with respect to Bay s claims for, among other things, breach of implied requirements contract, promissory estoppel and fraud. Also on August 18, 2006, Bay filed a motion for summary judgment with respect to the entirety of our cross-complaint. Our motion for summary judgment was heard on November 2, 2006 and the hearing for Bay s motion for summary judgment is set for November 8, 2006. A trial date has been scheduled for December 4, 2006. We intend to vigorously defend ourselves.

Litigating claims of the types discussed in Note 5 Legal Proceedings of the Notes to Condensed Consolidated Financial Statements and in Part II, Item 1 Legal Proceedings of this Quarterly Report on Form 10-Q, 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.

PART II OTHER INFORMATION

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 match prospective patients with 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.

In addition, in an attempt to help minimize treatment disruptions for former OrthoClear patients and their doctors, we have offered to make Invisalign treatment available to existing OrthoClear patients at no charge from Align through our Patients First Program . As a result, we will receive no revenue for any additional cases we start under this program while incurring significant expenses as well as increased demands on our sales and customer service representatives and on our manufacturing processes. Our success will depend in part on management s ability to effectively integrate the OrthoClear patients into our infrastructure with minimal impact on our existing and new customers. We may have difficulty managing the deployment of this program, including the internal allocation of personnel and resources potentially resulting in production delays. Any such difficulty could cause us to lose existing customers, face potential customer disputes or limit the number of new customers who purchase our products or services. This could cause a decline in our revenues, gross margins and net profits, and could adversely affect our operating results.

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 three 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 the first nine months 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

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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;
- aggressive price competition from competitors;
- changes in the timing of receipt of case product orders during a given quarter;
- changes in product mix due to the introduction of Invisalign Express, a lower-cost alternative for treating less complex cases;
- costs and expenditures in connection with ongoing litigation;
- 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. For instance, we experienced increased pricing pressure when OrthoClear announced the commercial launch of the OrthoClear System, a product that was intended to compete directly with our Invisalign system. However, 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 would 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 nine months of 2006, and had a negative impact on our revenues, gross margins and net profits. We believed that OrthoClear s product infringed on our intellectual property and we filed several lawsuits. In October 2006, we entered into a definitive agreement whereby, among other things, OrthoClear agreed to discontinue all design, manufacture, marketing and sales of removable dental aligners worldwide. 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.

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. Litigating claims of this type is costly and could distract our management and cause a decline in our results of operations and stock price.

Our success will depend in part on our ability to maintain existing intellectual property and to obtain and maintain further intellectual property protection for our products, both in the U.S. and in other countries. Our inability to do so could harm our competitive position. As of September 30, 2006, we had 76 issued U.S. patents, 89 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 on behalf of OrthoClear, requesting re-examination of a number of our patents. *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.

In addition, in an effort to protect our intellectual property we have in the past been and may in the future be involved in litigation. For example, we entered into the Agreement with OrthoClear amongst other things, to dismiss all pending lawsuits against each other, including the Patents Infringement Federal Action. In addition, we are currently involved in a patent infringement lawsuit with Ormco. The potential effects on our business operations resulting from similar litigation that we may participate in the future, 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. In the first nine months of 2006, we experienced a slower rate of growth in the GP Channel as compared to the first nine months of 2005, and we expect the slower rate of growth to continue in the GP Channel during the fourth quarter of 2006. This is due in part to OrthoClear s recent focus on this channel and our expectation that working through the Patients First Program with these GPs will continue to adversely impact the growth rate of this channel. In addition, unanticipated poor clinical performance of Invisalign could result in significant adverse publicity and, consequently, reduced acceptance by dental professionals. Also 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.

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

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. These programs have adversely affected, and other similar programs that we may introduce in the future may, adversely affected 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. Prior to OrthoClear agreeing, pursuant to the terms of a agreement entered into in October 2006, to discontinue all design, manufacture, marketing and sales of removable dental aligners worldwide our Invisalign system competed directly with an aligner product manufactured by them. 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. Increased competition from OrthoClear and other competitors 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. 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 focused on adding additional functionality into our business enterprise systems and intend to continue this effort for the foreseeable future, 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. We recently announced a phased rollout of ClinAdvisor, a new suite of software tools designed to make Invisalign case selection, submission and review processes more efficient for doctors. We expect to launch further software

enhancements directed at our more experienced doctors that will make our Invisalign systems easier to use. In addition, we are planning to introduce 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. 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, as well as staffing in numbers sufficient to implement the Patients First Program;
- 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.

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.

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 1,114 employees as of September 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 September 30, 2006 our North America sales organization consisted of 126 people of which 105 were direct sales representatives and 21 were sales administration and management. Internationally, we have approximately 30 people engaged in sales and sales support as September 30, 2006. 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. If we are unable retain our direct sales force personnel or replace them 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 nine months 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

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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 the 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

Not applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

(a) Exhibits:

Exhibit Number	Description	Incorporated by reference herein			Filed herewith
		Filing	Date	Exhibit Number	
10.1	Employment Agreement with Sonia Clark, Vice President Human Resources	Form 8-K	09/26	10.1	
10.2	Binding Settlement Term Sheet	Form 8-K	09/28	10.2	
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: November 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

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