ALIGN TECHNOLOGY INC
Form 10-Q
November 05, 2009
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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, 2009

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)

(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 has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes o No o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definitions of large accelerated filer, accelerated filer, and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer x	Accelerated filer o
Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company 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 30, 2009 was 74,461,321.

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PART I FINANCIAL INFORMATION

ITEM 1 FINANCIAL STATEMENTS

ALIGN TECHNOLOGY, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per share data)

(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
Net revenues	$ 79,269	$ 75,173	$ 225,717	$ 229,851
Cost of revenues	20,268	18,766	56,031	58,617
Gross profit	59,001	56,407	169,686	171,234
Operating expenses:				
Sales and marketing	27,687	28,214	84,649	88,737
General and administrative	16,224	14,395	46,231	45,905
Research and development	5,611	5,918	16,471	20,214
Restructurings		2,189	1,319	2,189
Litigation settlement	69,673		69,673	
Total operating expenses	119,195	50,716	218,343	157,045
Profit (loss) from operations	(60,194)	5,691	(48,657)	14,189
Interest and other income (expense), net	(271)	264	434	1,673
Net profit (loss) before provision for income taxes	(60,465)	5,955	(48,223)	15,862
Provision for (benefit from) income taxes	(10,523)	798	(5,462)	1,371
Net profit (loss)	$ (49,942)	$ 5,157	$ (42,761)	$ 14,491
Net profit (loss) per share:				
Basic	$ (0.72)	$ 0.08	$ (0.64)	$ 0.21
Diluted	$ (0.72)	$ 0.08	$ (0.64)	$ 0.21
Shares used in computing net profit (loss) per share:				
Basic	69,528	67,367	67,278	68,330
Diluted	69,528	68,704	67,278	69,906

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

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ALIGN TECHNOLOGY, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands, except per share data)

(unaudited)

	September 30, 2009	December 31, 2008
ASSETS		
Current assets:		
Cash and cash equivalents	$ 135,961	$ 87,100
Marketable securities, short-term	18,979	23,066
Accounts receivable, net of allowance for doubtful accounts of $1,446 and $612, respectively	55,035	52,362
Inventories, net	1,892	1,965
Prepaid expenses and other current assets	25,671	13,414
Total current assets	237,538	177,907
Property and equipment, net	24,429	26,979
Goodwill	478	478
Intangible assets, net	5,688	7,788
Deferred tax asset	61,048	61,696
Other assets	1,603	4,493
Total assets	$ 330,784	$ 279,341
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 7,498	$ 5,580
Accrued liabilities	37,484	38,282
Deferred revenues	27,920	16,710
Total current liabilities	72,902	60,572
Other long-term liabilities	202	229
Total liabilities	73,104	60,801
Commitments and contingencies (Notes 5 and 8)		
Stockholders equity:		
Preferred stock, $0.0001 par value (5,000 shares authorized; none issued)		
Common stock, $0.0001 par value (200,000 shares authorized; 74,329 and 65,633 shares issued and outstanding, respectively.)	7	7
Additional paid-in capital	521,133	439,494
Accumulated other comprehensive income, net	531	269
Accumulated deficit	(263,991)	(221,230)
Total stockholders equity	257,680	218,540
Total liabilities and stockholders equity	$ 330,784	$ 279,341

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

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ALIGN TECHNOLOGY, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

(unaudited)

	Nine Months Ended September 30,	
	2009	**2008**
Cash Flows from Operating Activities:		
Net profit (loss)	$ (42,761)	$ 14,491
Adjustments to reconcile net profit (loss) to net cash provided by operating activities:		
Deferred taxes	740	
Depreciation and amortization	7,582	7,365
Amortization of intangibles	2,100	2,127
Stock-based compensation	12,011	13,176
Litigation settlement costs and amortization of prepaid royalties	58,430	
Provision from doubtful accounts	958	
Loss on retirement and disposal of fixed assets	20	206
Excess tax benefit from share-based payment arrangements		(188)
Non-cash restructuring charges		411
Changes in assets and liabilities:		
Accounts receivable	(3,167)	(4,093)
Inventories	74	(109)
Prepaid expenses and other current assets	(7,036)	1,491
Accounts payable	816	(733)
Accrued and other long-term liabilities	(912)	(6,269)
Deferred revenues	11,051	3,116
Net cash provided by operating activities	39,906	30,991
Cash Flows from Investing Activities:		
Purchase of property and equipment	(4,084)	(12,361)
Proceeds from sale of equipment		189
Purchases of marketable securities	(33,940)	(65,094)
Maturities of marketable securities	40,910	66,463
Other assets	35	272
Net cash provided by (used in) investing activities	2,921	(10,531)
Cash Flows from Financing Activities:		
Proceeds from issuance of common stock	6,376	10,222
Payments on short-term obligations	(136)	(271)
Repurchased shares of common stock		(39,432)
Excess tax benefit from share-based payment arrangements		188
Employees taxes paid upon the vesting of restricted stock units	(264)	(347)
Net cash provided by (used in) financing activities	5,976	(29,640)
Effect of foreign exchange rate changes on cash and cash equivalents	58	(204)
Net increase (decrease) in cash and cash equivalents	48,861	(9,384)
Cash and cash equivalents at beginning of period	87,100	89,140
Cash and cash equivalents at end of period	$ 135,961	$ 79,756

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

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ALIGN TECHNOLOGY, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(unaudited)

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 (SEC) and contain all adjustments, including normal recurring adjustments, necessary to present fairly Align s financial position as of September 30, 2009, its results of operations for the three and nine months ended September 30, 2009 and 2008, and its cash flows for the nine months ended September 30, 2009 and 2008. The Condensed Consolidated Balance Sheet as of December 31, 2008 was derived from the December 31, 2008 audited financial statements. Certain prior period amounts have been reclassified to conform with the current period presentation. These reclassifications had no impact on previously reported net earnings or financial position.

The results of operations for the three and nine months ended September 30, 2009 are not necessarily indicative of the results that may be expected for the year ending December 31, 2009 or any other future period, 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 year ended December 31, 2008.

In connection with the preparation of the condensed consolidated financial statements, the Company evaluated events subsequent to the balance sheet date of September 30, 2009 through the financial statement issuance date of November 5, 2009.

The preparation of financial statements in accordance with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the amounts reported in Align s Condensed Consolidated Financial Statements and accompanying notes. Actual results could differ materially from those estimates.

Recent Accounting Pronouncements

In September 2006, the Financial Accounting Standards Board (FASB) issued Financial Accounting Standard No. 157 (FAS 157) or Accounting Standard Codification (ASC) 820 which provides guidance for using fair value to measure assets and liabilities. It also responds to investors requests for expanded information about the extent to which companies measure assets and liabilities at fair value, the information used to measure fair value, and the effect of fair value measurements on earnings. FAS 157 (ASC 820) applies whenever other standards require (or permit) assets or liabilities to be measured at fair value, and does not expand the use of fair value in any new circumstances. FAS 157 (ASC 820), as originally issued, was effective for fiscal years beginning after November 15, 2007, except that under FASB Staff Position, or, Effective Date of FASB Statement 157 (FSP 157-2) or ASC 820 companies are allowed to delay the effective date of FAS 157(ASC 820) for non-financial assets and non-financial liabilities that are not recognized or disclosed at fair value on a recurring basis until fiscal years beginning after November 15, 2008. In October 2008, FASB Staff Position 157-3 Determining the Fair Value of a Financial Asset When the Market for that Asset is not Active, (FASP 157-3 or ASC 820), was issued and effective upon issuance, including prior periods for which financial statements have not been issued FSP 157-3(ASC 820), clarified the application of FAS 157 (ASC 820) in a market that is not active. Effective January 1, 2008, the Company adopted the provisions of FAS 157(ASC 820) for all financial assets and liabilities. Effective January 1, 2009, the Company adopted FSP 157-2 (ASC 820) and 157-3(ASC 820). The adoption of these Topics did not have a material impact on the Company s consolidated financial statements.

In April 2009, the FASB issued FSP No. 157-4 FSP 157-4 ASC 820 *Determining Fair Value When the Volume and Level of Activity for the Asset or Liability Have Significantly Decreased and Identifying Transactions That Are Not Orderly* , which provides guidance on determining fair value when there is no active market or where the price inputs being used represent distressed sales. FSP 157-4 (ASC 820) is effective for interim and annual periods ending after June 15, 2009 and was adopted by the Company in the second quarter of 2009. The adoption did not have a material impact on the Company s consolidated financial statements.

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In April 2009, the FASB issued FSP No. 115-2 FSP 115-2 and ASC 320, *Recognition and Presentation of Other-Than-Temporary Impairments* , which is effective for the Company for the quarterly period beginning April 1, 2009. FSP 115-2 (ASC 320) amends existing guidance for determining whether an other than temporary impairment of debt securities has occurred. Among other changes, the FASB replaced the existing requirement that an entity s management assert it has both the intent and ability to hold an impaired security until recovery with a requirement that management assert (a) it does not have the intent to sell the security, and (b) it is more likely than not it will not have to sell the security before recovery of its cost basis. The adoption of this pronouncement did not have a material effect on the Company s consolidated financial statements.

In April 2009, the FASB issued FSP 107-1 and ABP 28-1 or ASC 825*, Interim Disclosures about Fair Value of Financial Instruments.* This pronouncement require disclosures about fair value of financial instruments for interim reporting periods of publicly traded companies as well as in annual financial statements and also requires those disclosures in summarized financial information at interim reporting periods. FSP 107-1 and ABP 28 (ASC 825) are effective for interim and annual reporting periods ending after June 15, 2009. The Company adopted this pronouncement and provided the required disclosures in Note 2.

In April 2009, the FASB issued FSP 141(R)-1 or ASC 805, *Accounting for Assets Acquired and Liabilities Assumed in a Business Combination That Arise from Contingencies*. FSP 141(R)-1 (ASC 805) requires that assets acquired and liabilities assumed in a business combination that arise from contingencies be recognized at fair value if fair value can be reasonably estimated. If fair value of such an asset or liability cannot be reasonably estimated, the asset or liability would generally be recognized in accordance with FASB Statement No. 5 or ASC 450*, Accounting for Contingencies* , and FASB Interpretation No. 14, *Reasonable Estimation of the Amount of a Loss.* This pronouncement is effective for assets or liabilities arising from contingencies in business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008. The adoption of FSP 141(R)-1 (ASC 805) did not have a material effect on the Company s consolidated financial statements.

In May 2009, the FASB issued FAS 165, Subsequent Events (FAS 165) or ASC 855. FAS 165 (ASC 855) establishes general standards of accounting for and disclosure of events that occur after the balance sheet date but before financial statements are issued or are available to be issued. FAS 165 (ASC 855), which includes a new required disclosure of the date through which an entity has evaluated subsequent events, is effective for interim or annual periods ending after June 15, 2009. The Company has adopted this standard as of June 30, 2009; however, the adoption of FAS 165 (ASC 855) had no impact to the Company s consolidated financial statements.

In June 2009, the FASB issued FAS No. 166, Accounting for Transfers of Financial Assets an amendment of FASB 140 (FAS 166). FAS 166 eliminates the concept of a qualifying special-purpose entity, creates more stringent conditions for reporting a transfer of a portion of a financial asset as a sale, clarifies other sale-accounting criteria, and changes the initial measurement of a transferor s interest in transferred financial assets. FAS 166 will be effective for transfers of financial assets in annual reporting periods beginning after November 15, 2009 and in interim periods within those first annual reporting periods with earlier adoption prohibited. The Company is currently assessing the potential impact, if any, on the adoption of FAS 166 on its consolidated financial statements.

In June 2009, the FASB issued FAS No. 167, Amendments to FASB Interpretation No. 46(R) (FAS 167). FAS 167 amends FIN 46(R), Consolidation of Variable Interest Entities (revised December 2003) an interpretation of ARB No. 51 (FIN 46(R)) to require an enterprise to perform an analysis to determine whether the enterprise s variable interest or interests give it a controlling financial interest in a variable interest entity. This analysis identifies the primary beneficiary of a variable interest entity as one with the power to direct the activities of a variable interest entity that most significantly impact the entity s economic performance and the obligation to absorb losses of the entity that could potentially be significant to the variable interest. FAS 167 will be effective as of the beginning of the annual reporting period commencing after November 15, 2009. The Company is assessing the potential impact, if any, of the adoption of FAS 167 on its consolidated financial statements.

In June 2009, the FASB issued FAS No. 168 FAS 168 or ASC 105, The FASB Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting Principles, a replacement of FASB No. 162 . FAS 168 (ASC 105) establishes the FASB Accounting Standards Codification (Codification), as the single source of authoritative accounting and reporting standards in the United States for all non-government entities, with the exception of the Securities and Exchange Commission and its staff. It does not include any new guidance or interpretations of US GAAP, but merely eliminates the existing hierarchy and codifies the previously issued standards and pronouncements into specific topic areas. The Codification was adopted on July 1, 2009 for the Company s consolidated financial statements for the period ended

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September 30, 2009.

In September 2009, FASB amended the ASC as summarized in Accounting Standards Update (ASU) 2009-13, Revenue Recognition (ASC 605): Multiple-Deliverable Revenue Arrangements. Guidance in ASC 605-25 on revenue arrangements with multiple deliverables has been amended to require an entity to allocate revenue to deliverables in an arrangement using its best estimate of selling prices if the vendor does not have vendor-specific objective evidence or third-party evidence of selling prices, and to eliminate the use of the residual method and require the entity to allocate revenue using the relative selling price method. The new guidance also requires expanded quantitative and qualitative disclosures about revenue from arrangements with multiple deliverables. The update is effective for fiscal years beginning on or after June 15, 2010, with early adoption permitted. Adoption may either be on a prospective basis for new revenue arrangements entered into after adoption of the update, or by retrospective application. The Company is assessing the potential impact of the update on its consolidated financial statements and is planning to adopt the update effective January 1, 2011.

Other recent accounting pronouncements issued by the FASB (including its Emerging Issues Task Force), the American Institute of Certified Public Accountants and the SEC did not or are not believed by management to have a material impact on the Company s present or future consolidated financial statements.

Note 2. Marketable Securities and Fair Value Measurements

The Company s short-term marketable securities as of September 30, 2009 and December 31, 2008 are as follows (in thousands):

September 30, 2009	Amortized Costs	Gross Unrealized Gains	Fair Value
U.S. government notes and bonds	$ 17,971	$ 6	$ 17,977
Corporate bonds	1,000	2	1,002
Total	$ 18,971	$ 8	$ 18,979

December 31, 2008	Amortized Costs	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. government notes and bonds	$ 9,971	$ 25	$	$ 9,996
Corporate bonds and certificates of deposit	3,774	1	(24)	3,751
Agency bonds and discount notes	8,499	20		8,519
Commercial paper	800			800
Total	$ 23,044	$ 46	$ (24)	$ 23,066

As of September 30, 2009, all short-term investments have maturity dates of less than one year. For the nine months ended September 30, 2009 and 2008, no significant losses were realized on the sale of marketable securities.

The Company s long-term marketable securities as of December 31, 2008 are as follows (in thousands):

December 31, 2008	Amortized Costs	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Agency bonds	$ 1,000	$ 1	$	$ 1,001
Corporate bonds	1,897		(35)	1,862
Total	$ 2,897	$ 1	$ (35)	$ 2,863

The long-term marketable securities are included in Other assets in the consolidated balance sheet. As of September 30, 2009, the Company did not hold any long-term marketable securities.

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Fair Value Measurements

The Company measures the fair value of its cash equivalents and marketable securities as the price that would be received from selling an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The Company uses the GAAP fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. This hierarchy requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. The three levels of inputs that may be used to measure fair value:

Level 1 Quoted (unadjusted) prices in active markets for identical assets or liabilities.

The Company s Level 1 assets consist of U.S. government debt securities and money market funds. The Company does not hold any Level 1 liabilities.

Level 2 Observable inputs other than quoted prices included in Level 1, such as quoted prices for similar assets or liabilities in active markets; quoted prices for identical or similar assets or liabilities in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the asset or liability.

The Company s Level 2 assets consist of agency bonds and discount notes, corporate bonds, and certificates of deposit. The Company does not hold any Level 2 liabilities.

Level 3 Unobservable inputs to the valuation methodology that are supported by little or no market activity and that are significant to the measurement of the fair value of the assets or liabilities. Level 3 assets and liabilities include those whose fair value measurements are determined using pricing models, discounted cash flow methodologies or similar valuation techniques, as well as significant management judgment or estimation.

The Company did not hold any Level 3 assets or liabilities during the quarter ended September 30, 2009.

The following table summarizes the Company s financial assets measured at fair value on a recurring basis as of September 30, 2009 (in thousands):

Description	Balance as of September 30, 2009	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)
Cash equivalents:			

Money market funds	$ 99,464	$ 99,464	$
U.S. government debt securities	7,000	7,000	
Short-term investments:			
U.S. government debt securities	17,977	17,977	
Corporate bonds	1,002		1,002
	$ 125,443	$ 124,441	$ 1,002

Note 3. Balance Sheet Components

Inventories, net are comprised of (in thousands):

	Septmber 30, 2009	December 31, 2008
Raw materials	$ 1,000	$ 1,066
Work in process	399	416
Finished goods	493	483
	$ 1,892	$ 1,965

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

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Accrued liabilities consist of the following (in thousands):

	September 30, 2009	December 31, 2008
Accrued payroll and benefits	$ 20,873	$ 17,795
Accrued income taxes	2,300	2,492
Accrued sales and marketing expenses	3,108	2,449
Accrued sales rebate	2,082	2,205
Accrued sales tax and value added tax	2,153	1,823
Accrued warranty	2,115	2,031
Accrued professional fees	872	922
Accrued restructuring	292	2,501
Other	3,689	6,064
	$ 37,484	$ 38,282

Note 4. Intangible Assets

The intangible assets represent non-compete agreements received in conjunction with the October 2006 OrthoClear Agreement at gross value of $14 million. These assets are amortized on a straight-line basis over the expected useful life of five years. As of September 30, 2009 and December 31, 2008, the net carrying value of these non-compete agreements was $5.7 million (net of $8.3 million of accumulated amortization) and $7.8 million (net of $6.2 million of accumulated amortization), respectively.

The Company performs an impairment test whenever events or changes in circumstances indicate that the carrying value of such assets may not be recoverable. Examples of such events or circumstances include significant underperformance relative to historical or projected future operating results, significant changes in the manner of use of acquired assets or the strategy for its business, significant negative industry or economic trends, and/or a significant decline in the Company s stock price for a sustained period. Impairments are recognized based on the difference between the fair value of the asset and its carrying value, and fair value is generally measured based on discounted cash flow analyses. There were no impairments of intangible assets during the periods presented.

The total estimated annual future amortization expense for these intangible assets as of September 30, 2009 is as follows (in thousands):

Fiscal Year	
2009 (remaining 3 months)	$ 700
2010	2,800
2011	2,188
Total	$ 5,688

Note 5. Legal Proceedings

Consumer Class Action

On May 18, 2007, Debra A. Weber filed a consumer class action lawsuit against Align, OrthoClear, Inc. and OrthoClear Holdings, Inc. (d/b/a OrthoClear, Inc.) in Syracuse, New York, U.S. District Court. The complaint alleges two causes of action against the OrthoClear defendants and one cause of action against Align for breach of contract. The cause of action against the Company, titled Breach of Third Party Benefit Contract references Align s agreement to make Invisalign treatment available to OrthoClear patients, alleging that the Company failed to provide the promised treatment to Plaintiff or any of the class members .

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On July 3, 2007, the Company filed an answer to the complaint and asserted 17 affirmative defenses. On July 20, 2007, the Company filed a motion for summary judgment on the Third Cause of Action (the only cause of action alleged against Align). On August 24, 2007, Weber filed a motion for class certification. On October 1, 2007, the Company filed an opposition to the motion for class certification and it is currently awaiting rulings from the Court. OrthoClear has filed a motion to dismiss. The initial case management conference and all discovery has been stayed pending the Court s decision on the motion for class certification, OrthoClear s motion to dismiss and the Company s motion for summary judgment. The Company believes the lawsuit to be without merit and intends to vigorously defend itself. Accordingly, the Company believes there is not sufficient evidence to conclude that a reasonable possibility exists that a loss had been incurred as of September 30, 2009.

Securities Litigation

In August 2009, Plaintiff Charles Wozniak filed a lawsuit against the Company and its Chief Executive Officer and President, Thomas M. Prescott (Mr. Prescott), in District Court for the Northern District of California on behalf of a claimed class consisting of all persons or entities who purchased the common stock of Align between January 30, 2007 and October 24, 2007. The complaint alleges that Align and Mr. Prescott violated Section 10(b) of the Securities Exchange Act of 1934 and that Mr. Prescott violated Section 20(a) of the Securities Exchange Act of 1934. Specifically, the complaint alleges that during the class period Align failed to disclose that it had shifted the focus of the sales force to clearing backlog, causing a significant decrease in the number of new case starts.

Two plaintiffs have filed motions to be appointed lead plaintiff. A hearing on these two motions is set for November 20, 2009. The Company believes the lawsuit to be without merit and intends to vigorously defend itself. Accordingly, the Company believes there is not sufficient evidence to conclude that a reasonable possibility exists that a loss had been incurred as of September 30, 2009.

Note 6. Ormco Litigation Settlement

On August 16, 2009, Align entered into three agreements with Ormco Corporation (Ormco), an affiliate of Danaher Corporation (Danaher): a Settlement Agreement, a Stock Purchase Agreement, and a Joint Development, Marketing and Sales agreement (Collaboration Agreement). The Settlement Agreement ended all pending litigation between the parties, and Align agreed to (1) make a cash payment of $13.2 million upon the execution of the agreement and (2) issue a total of 7.6 million non-assessable shares of common stock pursuant to the Stock Purchase Agreement. Under the Collaboration Agreement, Align and Ormco agreed to jointly develop and market an orthodontic product for the most complex orthodontic cases that combine the Invisalign system with Ormco s orthodontic brackets and arch wire systems over the next seven years. Because the Company entered into several agreements with Ormco on the same date, the guidance related to multiple element arrangements was considered in determining the allocation of the total settlement amount to the various elements of this arrangement.

In accordance with the Collaboration Agreement, each party will retain ownership of its pre-existing intellectual property, and each party will be granted intellectual property licenses in their respective field for jointly-developed combination products. The Collaboration Agreement, among other things, ensures mutual and equal participation, and equal share of the risks, costs, and benefits associated with developing the combination product. With the assistance of a third party valuation firm, Align concluded there was no value on the execution date of this agreement, as the Company has not contributed any assets or tendered any consideration. In addition, as part of its long-term strategic plan, the Company had the intention of collaborating with other orthodontic industry leaders to offer Invisalign in combination with traditional wires and brackets therapy, and it believes that the terms of such an agreement would have been similar to those it reached with Ormco.

Upon execution of the Settlement Agreement, 5.6 million shares were issued to Danaher and the remaining 2.0 million shares were issued upon the expiration of the waiting period under the provisions of the Hart-Scott-Rodino Antitrust Improvements Act, which occurred on September 21, 2009. In addition to other provisions of the Settlement Agreement, these shares may not be resold except pursuant to an effective registration statement under the Securities Act or an available exemption from registration. The Company is not obligated to affect any such registration prior to the one year anniversary of this agreement. In order to determine the fair value of the stock issued to Danaher, the Company considered the fair value guidance from FASB ASC 820-10-55-52. The fair value of the shares should reflect the value that market participants would demand because of the risk relating to the inability to access a public market for these securities for the specified period. With the assistance of a third party valuation firm, Align has concluded that 25% is an appropriate discount based on review of published restricted stock studies, comparison to restricted stock transactions of other companies in the industry in which Align operates, and the cost of hedging the restricted stock using the Black-Scholes option pricing model. The fair value of the unregistered shares was determined as of the market closing price on the dates the share were issued less the 25% discount rate, for a total value of $76.7 million, including the cash payment.

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In accordance with the Settlement Agreement, Ormco released Align from any and all past and future claims of infringement for the period September 9, 2003 through the expiration of the patent on January 19, 2010 (infringement period). In order to determine how to allocate the settlement value between past infringement and the future use of the patent, Align considered both past and estimated future case shipment volumes during the infringement period, and allocated the total settlement value across all case shipments. The value attributed to past infringement claims was recorded as litigation settlement costs and was based on case shipments from September 9, 2003 through August 16, 2009, totaling $69.7 million. The remaining $7.0 million was recorded to the balance sheet as prepaid royalties, and will be amortized to cost of revenues until the expiration of the patent in January 2010.

Note 7. Credit Facilities

On December 5, 2008, the Company renegotiated and amended its existing credit facility with Comerica Bank. Under this revolving line of credit, the Company has $25.0 million of available borrowings with a maturity date of December 31, 2010. This credit facility requires a quick ratio covenant and also requires the Company to maintain a minimum unrestricted cash balance of $10.0 million. The interest rate on borrowings will range from Libor plus 1.5% to 2.0% depending upon the amount of unrestricted cash the Company maintains at Comerica Bank above the $10.0 million minimum.

As of September 30, 2009, the Company had no outstanding borrowings under this credit facility and is in compliance with the financial covenants.

Note 8. Commitments and Contingencies

As of September 30, 2009, minimum future lease payments for non-cancelable leases are as follow (in thousands):

Years Ending December 31,		
2009 (remaining 3 months)	$	1,166
2010		3,156
2011		2,741
2012		1,813
2013 and thereafter		973
Total	$	9,849

In April 2009, the Company terminated its third party shelter services arrangement with IMS for order acquisition, the fabrication of aligner molds and finished aligners and the shipment of the completed product to customers. The Company is now a direct manufacturer of its clear aligners at the facility in Juarez, Mexico and directly coordinates order acquisition, including, (1) order entry, (2) digital scanning, (3) aligner manufacturing as well as product shipment from this location. IMS has assigned the lease for the facility in Juarez, Mexico to Align Mexico, a wholly-owned subsidiary of Align, and the Company guarantees the lease payments for its subsidiary which are included in the table above.

The Company warrants its products against material defects until the Invisalign case is completed. The Company accrues for warranty costs in cost of revenues upon shipment of products. The amount of accrued estimated warranty costs is primarily based on historical experience as to product failures as well as current information on replacement costs. The Company regularly reviews the accrued balances and updates these balances based on historical warranty trends. Actual warranty costs incurred have not materially differed from those accrued. However, future actual warranty costs could differ from the estimated amounts.

The following table reflects the change in the Company s warranty accrual during the nine months ended September 30, 2009 and 2008, respectively (in thousands):

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	Nine Months Ended September 30,	
	2009	2008
Balance at beginning of period	$ 2,031	$ 2,035
Charged to cost of revenues	2,046	1,910
Actual warranty expenses	(1,962)	(1,850)
Balance at end of period	$ 2,115	$ 2,095

Note 9. Stock-based Compensation

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, 2009 and 2008 is based on options ultimately expected to vest and has been reduced for estimated forfeitures. Forfeitures are 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. The following table summarizes stock-based compensation expense related to all of the Company s stock-based options and employee stock purchases for the three and nine months ended September 30, 2009 and 2008:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(In thousands)	2009	2008	2009	2008
Cost of revenues	$ 359	$ 437	$ 1,150	$ 1,298
Sales and marketing	1,243	1,390	3,559	4,069
General and administrative	1,885	2,009	5,839	6,122
Research and development	500	554	1,463	1,687
Total stock-based compensation expense	$ 3,987	$ 4,390	$ 12,011	$ 13,176

The fair value of stock options granted and the option component of the Purchase Plan shares 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,	
	2009	2008	2009	2008
Stock Options:				
Expected term (in years)	4.4	4.4	4.4	4.4
Expected volatility	64.0%	60.2%	61.6%	59.8%
Risk-free interest rate	2.1%	3.1%	1.6%	2.8%
Expected dividend				
Weighted average fair value at grant date	$ 5.42	$ 5.49	$ 4.15	$ 6.46
Employee Stock Purchase Plan:				
Expected term (in years)	1.2	1.2	1.3	1.2
Expected volatility	72.8%	64.7%	74.6%	67.2%
Risk-free interest rate	0.68%	2.2%	0.63%	2.2%

Expected dividend				
Weighted average fair value at grant date	$ 5.10	$ 4.49	$ 3.78	$ 4.89

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Options

The Company grants options 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. Stock option activity for the nine months ended September 30, 2009 under the stock incentive plans is set forth below:

	Total Shares Underlying Stock Options			In-The-Money Options		
	Number of Shares Underlying Stock Options (in thousands)	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Number of Shares Underlying Stock Options (in thousands)	Weighted Average Exercise Price	Aggregate Intrinsic Value (in thousands)
Outstanding as of December 31, 2008	7,309	$ 11.63				
Granted	1,088	8.30				
Cancelled or expired	(309)	12.35				
Exercised	(389)	6.19				
Outstanding as of September 30, 2009	7,699	$ 11.40	6.58	5,797	$ 9.07	$ 29,826
Vested and expected to vest at September 30, 2009	7,499	$ 11.41	6.52	5,619	$ 9.03	$ 29,139
Exercisable at September 30, 2009	4,897	$ 11.21	5.46	3,424	$ 8.04	$ 21,169

The aggregate intrinsic value in the table above represents the total pre-tax intrinsic value (the difference between the Company s closing stock price on the last trading day of the third quarter of 2009 of $14.22 and the number of in-the-money options multiplied by the respective exercise price) that would have been received by the option holders had all option holders exercised their options on September 30, 2009. This amount changes based on the fair market value of the Company s stock.

The total intrinsic value of stock options exercised for the three and nine months ended September 30, 2009 was $0.6 million and $1.7 million, respectively. As of September 30, 2009, the Company expects to recognize $15.7 million of total unamortized compensation cost related to stock options over a weighted average period of 2.3 years. The Company did not recognize tax benefits from exercised options for the nine months ended September 30, 2009 as the amount was not material to the consolidated financial statements.

Restricted Stock Units

The Company grants restricted stock units (RSUs) that generally vest over 4 years. Prior to October 2007, 25% of the grant vested on the one year anniversary of the date of grant and 6.25% vested quarterly thereafter. In October 2007, the Compensation Committee of the Board of Directors approved to change the vesting for prospective grants of RSUs to 25% annually. The fair value of each award is based on the Company s closing stock price on the date of grant. A summary of the nonvested shares for the nine months ended September 30, 2009 is as follows:

	Number of Shares Underlying RSUs (in thousands)	Weighted Average Grant Date Fair Value	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Nonvested as of December 31, 2008	872	$ 13.69		
Granted	314	8.25		
Vested and released	(202)	13.01		
Forfeited	(50)	12.45		
Nonvested as of September 30, 2009	934	$ 12.08	1.37	$ 13,281

The aggregate intrinsic value in the table above represents the total pre-tax intrinsic value (calculated by using Align s closing stock price on the last trading day of the third quarter of 2009 of $14.22 multiplied by the number of nonvested restricted stock units) that would have been received by the award holders had all restricted stock units been vested and released on September 30, 2009. This amount changes based on the fair market value of the Company s stock.

The total intrinsic value of restricted stock units vested and released for the three and nine months ended September 30, 2009 was $0.5 million and $2.0 million, respectively. As of September 30, 2009, the total unamortized compensation cost related to restricted stock units was $10.9 million, which the Company expects to recognize over a weighted average period of 2.3 years. The Company did not recognize tax benefits from restricted stock units that vested during the nine months ended September 30, 2009 as the amount was not material to the consolidated financial statements.

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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 Company accounts for the Purchase Plan as a compensatory plan and has valued the option component of the Purchase Plan shares at the date of grant using the Black-Scholes option pricing model.

As of September 30, 2009, the Company expects to recognize $2.2 million of total unamortized compensation cost related to employee stock purchases over a weighted average period of 0.4 years.

Note 10. Accounting for Income Taxes

The financial statement recognition of the benefit for an uncertain tax position is dependent upon the benefit being more-likely-than-not to be sustainable upon audit by the applicable taxing authority. If this threshold is met, the tax benefit is then measured and recognized at the largest amount that is greater than 50 percent likely of being realized upon ultimate settlement.

During the third quarter of fiscal 2009, the amount of unrecognized tax benefits was increased by approximately $0.5 million. The total amount of unrecognized tax benefits was $4.2 million as of September 30, 2009, which would impact the Company s effective tax rate if recognized. The Company recognizes interest and penalties related to unrecognized tax benefits as a component of income taxes. Interest and penalties are immaterial and are included in the unrecognized tax benefits. There were no significant changes to this amount as of September 30, 2009.

The Company is subject to taxation in the U.S. and various states and foreign jurisdictions. All of the Company s tax years will be open to examination by the U.S. federal and most state tax authorities due to the Company s net operating loss and overall credit carryforward position. With few exceptions, the Company is no longer subject to examination by foreign tax authorities for years before 2005.

Note 11. Net Profit (Loss) Per Share

Basic net profit (loss) per share is computed using the weighted average number of shares of common stock outstanding 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, include options, restricted stock units, and the dilutive component of Purchase Plan shares.

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):

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	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
Net profit (loss)	$ (49,942)	$ 5,157	$ (42,761)	$ 14,491
Weighted-average common shares outstanding, basic	69,528	67,367	67,278	68,330
Effect of potential dilutive common shares		1,337		1,576
Total shares, diluted	69,528	68,704	67,278	69,906
Basic net profit (loss) per share	$ (0.72)	$ 0.08	$ (0.64)	$ 0.21
Diluted net profit (loss) per share	$ (0.72)	$ 0.08	$ (0.64)	$ 0.21

For the three and nine months ended September 30, 2009, stock options and restricted stock units totaling 4.0 million and 5.1 million, respectively, were excluded from diluted net profit per share because of their anti-dilutive effect. For the three and nine months ended September 30, 2008, stock options and restricted stock units totaling 5.0 million and 4.5 million, respectively, were excluded from diluted net profit per share because of their anti-dilutive effect.

Note 12. Comprehensive Income

Comprehensive income includes net profit, foreign currency translation adjustments and unrealized gains and losses on available-for-sale securities. The components of comprehensive income are as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
Net profit	$ (49,942)	$ 5,157	$ (42,761)	$ 14,491
Foreign currency translation adjustments	214	(429)	20	(176)
Change in unrealized gain/(loss) on available-for-sale securities		(43)	242	(34)
Comprehensive income	$ (49,728)	$ 4,685	$ (42,499)	$ 14,281

Note 13. Segments and Geographical Information

Segment

The Company reports segment data based on the internal reporting that is used by management for making operating decisions and assessing performance. During all periods presented, the Company operated as a single business segment.

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Geographical Information

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
Net revenues:				
North America	$ 60,054	$ 59,627	$ 172,577	$ 182,910
Europe	18,206	15,056	50,986	45,522
Other international	1,009	490	2,154	1,419
Total net revenues	$ 79,269	$ 75,173	$ 225,717	$ 229,851

	As of September 30, 2009	As of December 31, 2008
Long-lived assets:		
North America	$ 90,893	$ 99,086
Europe	1,113	960
Other international	1,240	1,388
Total long-lived assets	$ 93,246	$ 101,434

Note 14. Restructuring

In July and October 2008, the Company announced restructuring plans to increase efficiencies across the organization and lower the overall cost structure. The July 2008 plan reduced full time headcount primarily through a phased-consolidation of order acquisition operations from the corporate headquarters in Santa Clara, California to Juarez, Mexico, which was completed by the end of 2008. In addition to headcount reductions, the October restructuring plan included the phased relocation of the Company s shared services organizations from Santa Clara, California to its facility in Costa Rica, which was completed during the second quarter of 2009.

Activity and liability balances related to restructuring activity for nine months ended September 30, 2009 are as follows (in thousands):

	Severance and Benefits
Balance at December 31, 2008	$ 2,501
Restructuring accrual	1,319
Cash payments	(3,528)
Balance at September 30, 2009	$ 292

The Company has included this amount in Accrued liabilities in the Consolidated Balance Sheets.

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, our expectations regarding the Proficiency Requirements and its impact on our case volume and revenues, including our belief that the Proficiency Requirements will not have a material impact on our 2009 revenues and results of operations, the anticipated impact our new products and product enhancements will have on doctor utilization and our market share, our expectations regarding product mix and product adoption, our expectations regarding the existence and impact of seasonality, our expectation that our utilization rate will improve over time, our expectations regarding our average selling prices and gross profits in 2009, our expectations regarding the continued growth of our international markets, our expectations regarding the impact of increased consumer marketing programs in Europe, our expectations that the decline in general economic conditions in 2009 may result in a decline in our North America product volumes and revenues, particularly in the GP channel, compared to 2008, the anticipated level of our

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operating expenses, and other factors beyond our control, 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 Item 2 Management s Discussion and Analysis of Financial Condition and Results of Operations , and in particular, the risks discussed below in Part II, Item 1A Risk Factors . We undertake no obligation to revise or update 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.

Align Technology, Inc. designs, manufactures and markets the Invisalign system, 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 metal arch wires and brackets, commonly referred to as braces. We received the United States Food and Drug Administration (FDA) clearance to market Invisalign in 1998. The Invisalign system is regulated by the FDA as a Class II medical device.

We distribute the vast majority of our products directly to our customers: the orthodontist and the general practitioner dentist, or GP. Orthodontists and GPs must complete an Invisalign training course in order to provide the Invisalign treatment solution to their patients. The Invisalign system is sold in North America, Europe, Asia Pacific, Latin America and Japan. We use a distributor model for the sale of our products in parts of the Asia Pacific and Latin American region.

Each Invisalign treatment plan is unique to the individual patient. Our Invisalign Full treatment consists of as many aligners as indicated by ClinCheck in order to achieve the doctors treatment goals. Our Invisalign Express is a dual arch orthodontic treatment for cases that meet certain predetermined clinical criteria and consist of up to ten sets of aligners. Invisalign Express treatment is intended to assist dental professionals to treat a broader range of patients by providing a lower-cost option for adult relapse cases, for minor crowding and spacing, or as a pre-cursor to restorative or cosmetic treatments such as veneers. Invisalign Teen, which was launched in July 2008, is designed to meet the specific needs of the non-adult comprehensive or teen treatment market. Invisalign Assist, launched in October 2008, is intended to help newly-trained and low volume Invisalign GPs accelerate the adoption and frequency of use of Invisalign into their practice. Upon completion of an Invisalign or non-Invisalign treatment, the patient may be prescribed our traditional retainer product, or our Vivera retainers, a clear aligner set designed for ongoing retention.

Our goal is to establish Invisalign as the standard method for treating malocclusion ultimately driving increased product adoption by dental professionals by focusing on four key objectives: driving product innovation, enhancing the customer experience, generating consumer demand and expanding into international markets.

Product innovation and enhancements to existing products. We believe that product performance and innovation is a cornerstone to our future long-term goal to drive and sustain product adoption. Until 2008, the Invisalign system was a single offering used by our primary channels GPs and orthodontists each with distinct and separate needs. In 2008, we launched additional products to better meet those distinct needs. Specifically, orthodontists want a more robust set of

tools for greater predictability, wider applicability and more flexibility in the use of the Invisalign system. On the other hand, typical GPs want greater ease of use, more efficient and simplified diagnostic tools, guidance through the case set-up process, minimal treatment intervention and self-help tools designed to simplify treatment of cases of mild to moderate malocclusion. Based on this knowledge, in July 2008, we announced the release of Invisalign Teen, predominantly marketed to the orthodontist. In October 2008, we announced the release of Invisalign Assist, predominantly marketed to the GP. More recently, in September 2009, we introduced new and enhanced features in all Invisalign products: Invisalign Full, Invisalign Teen, Invisalign Assist and Invisalign Express. The new product line features are designed to overcome barriers to treatment by addressing clinical issues that some orthodontists and GPs have traditionally perceived as challenging in Invisalign treatment, such as extrusion and rotation of teeth, root movements and interproximal reduction (IPR). These new and enhanced features include:

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- New optimized attachments for extrusions and rotations custom designed to be patient-specific and tooth-specific to consistently deliver the correct aligner forces to the teeth, helping to increase predictability of the movement.

- Power Ridges , previously available only with Invisalign Teen, have been expanded across all products for cases requiring certain types of movements, including lingual root torque.

- Velocity Optimization designed to provide more controlled movements for the entire tooth, including the root, and is designed to limit the speed of tooth movements to optimal ranges.

- Interproximal Reduction (IPR) Protocol Improvements designed to address a frequent doctor request regarding timing of IPR during treatment. IPR can now be set up in later stages of treatment when teeth are better aligned and contact points may be easier to access.

- New Invisalign Attachment Kit and attachment material designed to deliver greater bond strength, wear resistance, accuracy and ease of use.

Invisalign Teen

With the introduction of Invisalign Teen, our Invisalign product family includes a product designed to meet the specific needs of the non-adult comprehensive or younger teen market. Invisalign Teen features include an aligner wear indicator to help gauge patient compliance and specially engineered aligner features to address the natural eruption of key teeth and lingual root control. Predominantly marketed to orthodontists who treat the vast majority of malocclusion in teen patients, these features make it easier and more efficient for orthodontists to treat those younger patients. The launch of a teen-specific product makes the Invisalign system more applicable to an orthodontist s patient base, which we believe will increase our penetration into and our share of the teen treatment market over time. In addition, some of our customers believe the additional product features included in Invisalign Teen are desirable to use on all of their patients regardless of age. As a result, these customers are increasingly using Invisalign Teen rather than Invisalign Full on their adult patients. Although Invisalign Teen has grown from 11% of our total case volume in the second quarter of 2009 to 14% of our total case volume in the third quarter of 2009, we expect that orthodontists will continue to adopt Invisalign Teen slowly, after they experience multiple successful treatment outcomes.

Invisalign Assist

Invisalign Assist, is intended to help newly-trained and lower volume Invisalign GPs accelerate the adoption and frequency of use of Invisalign into their practice. Invisalign Assist features are intended to make it easier for doctors to select appropriate cases for their experience level or treatment approach. In addition, GPs can plan and submit cases efficiently, manage appointments with suggested tasks, and receive batch shipments of aligners based on treatment progress. In addition to the new features announced in September 2009 to our entire product line, additional features were added or enhanced in Invisalign Assist. These features are intended to expand the capabilities of Invisalign Assist and give doctors the confidence and control necessary to treat a wider range of patients. To date, Invisalign Assist has been used primarily for simple anterior alignment and aesthetically-oriented cases that can be treated with aligners only. We believe that with the introduction of these new and enhanced product features, Invisalign Assist can now be used to treat a broader range of cases while maintaining the benefits of built-in support. Additional enhancements include:

- More doctor input and control regarding case set-up and ClinCheck modifications.
- Improved progress tracking reports with more tooth-specific detail.
- More information for case-specific clinical tasks, including bonding attachments, performing IPR, and monitoring treatment progress.
- More tooth-specific details explaining why a case falls outside the Invisalign Assist treatment parameters.

We believe that Invisalign Assist will help GPs increase their confidence in prescribing Invisalign treatment.

We believe continuing to introduce new products and product features as well as enhancing the user experience will keep us at the forefront of the market and increase adoption of Invisalign. The launch of Invisalign Teen, Invisalign Assist and the recent launch of the new and enhanced features in all Invisalign products as well as other future products will rely on new features, tools and delivery options to meet specific clinical demands while providing a family of end-to-end solutions for our customers. Enhanced product performance and innovation should continue to drive the adoption and frequency of use (what we call utilization). Although we believe new product introduction to be a cornerstone to our future long-term growth, we expect that adoption of these new products will increase gradually over a number of years.

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Enhancing the customer experience. We are committed to enhancing the customer experience by focusing on specific customer touch points , or areas where we interact directly with our customers. Specifically, we are focused on improving our pre-selection process in order to attract new doctors that are motivated to become Invisalign providers and committed to making Invisalign a key part of their practices and strengthening our training programs in order to increase the rate that these newly trained customers submit Invisalign cases, as well as increase the rate that they move up the adoption curve to ultimately become leading Invisalign providers, or what we call promoters.

- *Improving Training Programs.* Ensuring Invisalign trained doctors are confident in using the Invisalign system is a key driver toward our ultimate goal of increasing product adoption. We continuously update our training programs to address the needs of our customers. For instance, we developed a pre-training course intended to familiarize doctors with the Invisalign system prior to attending the full training course. In addition, we recently updated our initial training program by focusing on Invisalign Assist, instead of Invisalign Full, since we believe Invisalign Assist is the right product for newly trained GPs. We anticipate that by using Invisalign Assist, newly trained GPs will exit this initial training program with increased confidence in prescribing Invisalign treatment. We have also incorporated the Invisalign technique into the curriculum of 38 university programs. 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.

- *Moving from Invisalign provider to a leading Invisalign provider.* Once a doctor is trained, our goal is to assist the doctor to move up the adoption curve to ultimately become a leading Invisalign provider, or a promoter. In order to increase the number of Invisalign promoters, we provide additional services to help our customers increase their confidence in using the Invisalign system through continuing education and clinical support as well as improving their practice management skills.

Furthermore, on June 2, 2009, we announced the implementation of the Invisalign Product Proficiency Requirements (or the Proficiency Requirements) in North America to help ensure that Invisalign-trained doctors have the experience and confidence necessary to achieve high quality treatment outcomes for Invisalign patients. Under the Proficiency Requirements, every Invisalign provider in North America must start 10 Invisalign cases (measured by case shipments) and complete at least 10 Invisalign-specific continuing education (CE) credits each calendar year. Doctors who do not meet the annual case start and CE requirements by the end of each calendar year will be able to continue treating in-progress cases but will not be able to submit new Invisalign cases or use Invisalign branding or marketing resources.

In September 2009, we updated the Proficiency Requirements in order to further support our customers through this significant change, (1) including launching a program to recognize doctors who achieve the annual proficiency requirements by December 31, 2009 and (2) providing an additional six-month qualification period to assist doctors who are unable to meet the proficiency requirements by December 31, 2009, but demonstrate a desire to continue using Invisalign. Doctors who achieve the annual proficiency requirements as of December 31, 2009, will benefit from a new addition to our consumer marketing program that encourages prospective patients to seek out Invisalign Preferred Providers on the Invisalign website and in television ads as a way to recognize doctors commitment to proficiency with Invisalign. For those doctors who are unable to achieve the proficiency requirements by December 31, 2009, we announced a one-time, additional six-month qualification period that will enable those doctors to secure their Invisalign provider status for 2010. The additional six-month qualification period stipulates that:

- Doctors who do not meet the proficiency requirements for 2009 but have at least one shipped case and at least one Invisalign CE hour at the end of calendar year 2009 will be allowed to maintain their active provider status through June 30, 2010.

- Doctors who qualify for the additional six-month qualification period can secure their provider status for the second half of 2010 by meeting half of the annual proficiency requirements (at least five shipped cases and five Invisalign CE hours) between January 1 and June 30, 2010.

- Doctors will still be responsible for meeting the total annual requirements of at least ten shipped cases and ten Invisalign CE hours by the end of 2010 to qualify as providers for the following year.

- Doctors that have not submitted any cases nor obtained any Invisalign CE hours during 2009 will not be eligible for the additional qualification period.

Doctors can reactivate their provider status by retaking Invisalign Clear Essentials I training and meeting the Proficiency Requirements during the new calendar year. In conjunction with the Proficiency Requirements, we have defined a Proficiency Pathway consisting of Invisalign educational opportunities that matches clinical education to case experience levels in order to help doctor s gain confidence with case selection and treatment planning, case submission and treatment management. We expect that the Proficiency Requirements will enable us to focus more effectively on those doctors who want to make Invisalign a key part of their practice and consequently increase the rate that they move up the adoption curve to ultimately become promoters.

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Other resources that we offer our doctors include the Aligntech Institute program (*www.aligntechinstitute.com*), which is an interactive website that provides clinical education and practice development training. These clinical education and practice development training opportunities include instructor-led training classes, seminars and workshops, conference calls, web-based videos, case studies, and other clinical resources. Many of these courses and resources are eligible for continuing education (CE) credits. Additionally, our VIP portal (Virtual Invisalign Practice) provides our trained doctors and their staff access to thousands of Invisalign cases and best practices as well as up-to-date support information, programs and marketing materials for continuous support and information access. By participating in these programs and the various events and educational offerings, we believe that our customers will emerge with a better understanding of the product and its applicability, and with a greater aptitude for starting and finishing Invisalign cases successfully.

Consumer demand generation for Invisalign. Marketing to the consumer and creating demand is one of our key strategic objectives to driving long-term growth. Our market research indicates that the majority of people with malocclusion who desire treatment forgo treatment rather than elect traditional treatment due to its many limitations, such as compromised aesthetics and oral discomfort. By communicating the benefits of Invisalign to both dental professionals and consumers, we intend to increase the number of patients who seek treatment using Invisalign. Historically, our marketing programs have been directed to an adult audience, however, with the introduction of Invisalign Teen, we will for the first time direct our communication efforts directly to teens and their parents. Despite the continuing challenges in the U.S. economy and weak consumer spending, we believe that consumer demand creation is a key component to our long-term growth. As a result, we will continue to invest in efforts to increase consumer awareness of Invisalign through a variety of media outlets. We will continue to drive consumer demand among the adult population through our traditional TV advertising, as well as digital online media. In 2009, we are focusing our efforts on the introduction of a new public relations program for Invisalign Teen intended to access print, TV and online media. We also have a teen specific website and will increasingly leverage online and mobile widgets, social media and blogs to directly target teens.

Growth of international markets. We will continue to focus our efforts towards increasing adoption of Invisalign by dental professionals in our key international markets, Europe and Japan. Similar to the North America market, our objective internationally is to increase the number of doctors that are motivated to becoming an Invisalign provider and committed to making Invisalign a key part of their practices. Through September 30, 2009, we have trained over 15,300 doctors, predominantly orthodontists in Europe, our primary international market. Product line expansion is key to providing doctors a solution that addresses a wider range of potential patient needs with greater treatment flexibility. In October 2008, we launched Invisalign Express in Europe expanding our international product offerings. In Europe, the vast majority of orthodontic case starts are children and teens. With the introduction of Invisalign Teen in Europe in March 2009, we expect the addressable market for our product to expand and ultimately increase adoption. In addition, we will carry on our efforts to increase brand awareness and consumer demand in Europe by continuing our consumer advertising campaign. Our overall brand awareness and consumer demand is lower in Europe, and thus, we expect customers to adopt Invisalign Teen more slowly than in North America. Additionally, although the vast majority of our international revenues are from direct sales, approximately 10% of our international sales are through distributors covering smaller international markets, specifically Asia Pacific and Latin America. We will consider selling through distributors in other markets as well as consider expanding directly into additional countries on a case-by-case basis. With these efforts, we expect our international revenues and case volumes to continue to increase in the foreseeable future.

In addition to whether we successfully execute our business strategy, a number of other factors, the most important of which are set forth below, may affect our results during the remainder of 2009 and beyond.

- *Introduction of Proficiency Requirements.* We have a large number of low volume doctors that make up a significant portion of our customer base. As awareness and acceptance of Invisalign has grown, so has consumer demand and the size of our trained doctor base. Today, there are more than 44,000 Invisalign-trained doctors in North America, and approximately 3,000,000 prospective patients visit our web site during the 12 month period. We want to direct these potential patients to an Invisalign practice and feel comfortable that the patient will receive the best treatment experience possible. To further this goal, on June 2, 2009, we announced the implementation of the Invisalign Product Proficiency Requirements in North America to help ensure that Invisalign-trained doctors have the experience and confidence necessary to achieve high quality treatment outcomes for Invisalign patients. *For a further description of the Proficiency Requirements see Moving from*

Invisalign provider to a leading Invisalign provider above. Although we want every doctor to achieve and maintain the Proficiency

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Requirements with Invisalign, we expect that a number of our lower volume doctors may be unwilling or unable to meet the requirements by the June 2010 qualification deadline. Although we believe that the Proficiency Requirements will not have a material impact on our results of operations in fiscal year 2009, if the number of customers that meet the Proficiency Requirements is less than we anticipate, our case volumes will decrease and our revenues will be harmed. *See Part I, Item 1A Risk Factors for risks related to our Proficiency Requirements.*

- *Impact on consumer spending due to a decline in the U.S. economy*. Consumer spending habits are affected by, among other things, prevailing economic conditions, levels of employment, salaries and wage rates, gas prices, consumer confidence and consumer perception of economic conditions. A general slowdown in the United States economy as well as an uncertain economic outlook have adversely affected U.S. consumer spending habits. As a result of the decline in general economic conditions, we expect that our North American product volumes and revenues will decline in 2009 compared to 2008, particularly in the GP channel.

- *Utilization Rates*. Our goal is to establish Invisalign as the standard method for treating malocclusion ultimately driving increased product adoption and frequency of use by dental professionals, or utilization. Our quarterly utilization rates from the second quarter of 2007 through the third quarter 2009 are as follows.

Utilization rates = # of cases shipped divided by # of doctors cases were shipped to

As set forth in the chart above, utilization rates improved sequentially for our North America channels from the second quarter to the third quarter of 2009, whereas utilization rates historically declined between the second to third quarters in both 2007 and 2008. The availability of Invisalign Teen and doctors striving to meet the Proficiency Requirements were the primary factors for the increase in the third quarter of 2009. For our international channel our utilization rate has declined slightly due to the summer holiday schedules in Europe. In addition, although we believe that the introduction of the Proficiency Requirements will not have a material impact on our results of operations in 2009, if a lesser number of our customers than we anticipate fail to maintain and/or increase utilization to meet the Proficiency Requirements, our utilization will

decrease further and our revenues will be harmed.

- *Impact of new products on deferred revenue.* We launched three new products in 2008: Vivera retainers in January 2008, Invisalign Teen in July 2008, and Invisalign Assist in October 2008. As a result of and depending upon customer adoption of these new products, our mix of products is shifting gradually. These new products will have a significantly higher amount of deferred revenue as a percentage of their average selling prices compared to Invisalign Full. The Vivera retainer includes four shipments per year; revenue is deferred upon the first shipment and then recognized as each shipment occurs. Revenue for the six replacement aligners included in the price of Invisalign Teen is deferred based on their fair market value until the earlier of the replacement aligners being used or until the case is completed. For Invisalign Assist, when the progress tracking feature is selected, aligners are shipped to the dental professional after every nine stages. As a result, for these cases, revenue and cost are deferred upon the first staged shipment and are recognized upon shipment of the final

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staged shipment. In addition, included in the price of Invisalign Full treatment, we offer case refinement, which is a finishing tool used to adjust a patient s teeth to the desired final position. Invisalign Teen, Invisalign Assist, and Invisalign Full include a deferral for case refinement. As these new products increase as a percentage of our total case volume, deferred revenue on our balance sheet will increase.

- *Reliance on international manufacturing operations.* Our manufacturing efficiency has been and will continue to be an important factor in our future profitability. Currently, two of our key production steps are performed in operations located outside of the U.S. San Jose, Costa Rica and Juarez, Mexico. At our facility in Costa Rica, dental technicians use a sophisticated, internally developed computer-modeling program to prepare digital treatment plans. In April 2009, we terminated our third party shelter services arrangement with IMS for order acquisition, the fabrication of aligner molds and finished aligners and the shipment of the completed product to customers. We are now a direct manufacturer of our clear aligners at our facility in Juarez, Mexico with approximately 495 employees and directly coordinate order acquisition and product shipment from this location. Our success will depend in part on the efforts and abilities of management to effectively manage these international operations, including any difficulties encountered by us with respect to a transition from a third party shelter services arrangement to a direct manufacturer, including difficulties hiring and retaining qualified personnel. If our management fails in any of these respects, we could experience production delays and lost or delayed revenue. In addition, even if we have case submissions, we may not have a sufficient number of trained dental technicians in Costa Rica to create the ClinCheck treatments, or if we are unable to ship our product to our customers on a timely basis, our revenue will be delayed or lost, which will cause our operating results to fluctuate. *See Part I, Item 1A Risk Factors for risks related to our international operations.*

- *Seasonal Fluctuations.* Seasonal fluctuations in the number of doctors in their offices and available to take appointments have affected, and are likely to continue to affect our business. Specifically, our customers often take vacation during the summer months and therefore tend to start fewer cases. In addition, summer is typically the busiest season for orthodontists with practices that have a high percentage of adolescent and teenage patients. Many parents want to get their teens started in treatment before the start of the school year. As a result, adult appointments, including adult Invisalign patient starts, are often pushed further into late summer or early fall. This year we did not experience the normal seasonality in our business and had sequential case growth in both the North American orthodontic and International channels. This year, with the availability of Invisalign Teen, was the first summer we were able to actively compete for a share of teen patient starts and believe that Invisalign Teen may have helped moderate the historical trend we have typically seen for our North American orthodontic and International customers during the summer months. We expect teenage case starts to be seasonally down in the fourth quarter of 2009, which is consistent with historical trends. These seasonal trends have caused and will likely continue to cause, fluctuations in our quarterly results, including fluctuations in sequential revenue growth rates.

- *Foreign Exchange Rates.* Although the U.S. dollar is our reporting currency, a portion of our revenues and profits are generated in foreign currencies. Revenues and profits generated by subsidiaries operating outside of the United States are translated into U.S. dollars using exchange rates effective during the respective period and as a result are affected by changes in exchange rates. We have generally accepted the exposure to exchange rate movements without using derivative financial instruments to manage this risk. Therefore, both positive and negative movements in currency exchanges rates against the U.S. dollar will continue to affect the reported amount of revenues and profits in our consolidated financial statements.

- *Restructuring.* During 2008, we announced restructuring plans in July and October to increase efficiencies across the organization and lower the overall cost structure. In July 2008, we implemented a restructuring plan to reduce our full time headcount including a phased consolidation of order acquisition from our corporate headquarters in Santa Clara, California, to Juarez, Mexico, which was completed by the end of 2008. In October 2008, we implemented a restructuring plan to reduce full time headcount in Santa Clara, California and created a new shared services organization in our existing Costa Rica facility that consolidates customer care, accounts receivable, credit and collections, and customer event registration organizations, which were previously located in Santa Clara, California. The relocation was completed during the second quarter of 2009. The relocation is accompanied by a number of risks and uncertainties that may affect our results of operations and statement of cash flows. *See Part II, Item 1A Risk Factors for risks related to the October restructuring, including the phased-relocation of*

our customer facing operations to Costa Rica.

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- *Ormco Litigation Settlement*. On August 16, 2009, the Company and Ormco entered into a Settlement Agreement, pursuant to which the Company (1) paid Ormco a cash amount equal to approximately $13.2 million, and (2) agreed to issue to Danaher Corporation (Danaher), an affiliate of Ormco, 7.6 million fully paid and nonassessable shares of the Company s Common Stock, 5.6 million and 2.0 million of which were issued to Danaher on August 16, 2009 and September 22, 2009, respectively, pursuant to the Stock Purchase Agreement entered into between the Company and Danaher on August 16, 2009.

Joint Development, Marketing and Sales Agreement. In connection with the settlement reached with Ormco, on August 16, 2009, Align and Ormco entered into the Joint Development, Marketing and Sales Agreement, pursuant to which the parties have agreed to an exclusive collaboration over the next seven years to jointly develop and commercialize a combination orthodontic treatment system involving the use of both Align s clear aligner system and Ormco s brackets and arch wire system, which system will be capable of treating even the most complex orthodontic cases. A copy of the Joint Development, Marketing and Sales Agreement is attached as an exhibit to this Form 10-Q.

See Footnote 6 Ormco Litigation Settlement for additional information about the settlement accounting.

- *Effective Tax Rate.* Our effective tax rate may vary significantly from period to period. Various internal and external factors may have favorable or unfavorable effects on our future effective tax rate. These factors include, but are not limited to, changes in tax laws, regulations and /or rates, changing interpretations of existing tax laws or regulations, the future levels of tax benefits of stock option deductions relating to incentive stock options and employee stock purchase plans and changes in overall levels of pretax earnings.

Results of Operations

Net revenues:

Invisalign product revenues by channel and other non-case revenues, which represents training, retainer and ancillary products, for the three and nine months ended September 30, 2009 and 2008 are as follows (in millions):

	Three Months Ended September 30,				Nine Months Ended September 30,			
Net revenues	**2009**	**2008**	**Net Change**	**% Change**	**2009**	**2008**	**Net Change**	**% Change**
North America:								
Ortho	$ 22.7	$ 22.0	$ 0.7	3.2%	$ 65.4	$ 67.5	$ (2.1)	(3.1%)
GP	33.9	33.9		0.0%	96.6	103.4	(6.8)	(6.6%)
Total North American Invisalign	56.6	55.9	0.7	1.3%	162.0	170.9	(8.9)	(5.2%)
International Invisalign	18.5	15.1	3.4	22.5%	50.8	45.8	5.0	10.9%
Total Invisalign revenues	75.1	71.0	4.1	5.8%	212.8	216.7	(3.9)	(1.8%)

Non-case revenues	4.2	4.2		0.0%	12.9	13.2	(0.3)	(2.3%)
Total net revenues	$ 79.3	$ 75.2	$ 4.1	5.5%	$ 225.7	$ 229.9	$ (4.2)	(1.8%)

Case volume data which represents Invisalign case shipments by channel, for the three and nine months ended September 30, 2009 and 2008 are as follows (in thousands):

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	Three Months Ended September 30,				Nine Months Ended September 30,			
Invisalign case volume	**2009**	**2008**	**Net Change**	**% Change**	**2009**	**2008**	**Net Change**	**% Change**
North America:								
Ortho	18.8	18.0	0.8	4.4%	53.2	53.6	(0.4)	(0.7%)
GP	25.6	25.7	(0.1)	(0.4%)	72.4	78.7	(6.3)	(8.0%)
Total North American Invisalign	44.4	43.7	0.7	1.6%	125.6	132.3	(6.7)	(5.1%)
International Invisalign	12.1	9.1	3.0	33.0%	33.9	27.1	6.8	25.1%
Total Invisalign case volume	56.5	52.8	3.7	7.0%	159.5	159.4	0.1	0.1%

Our total net revenues increased for the three months ended September 30, 2009 compared to the same period in 2008 mainly due to higher International Invisalign volumes partially offset by unfavorable exchange rates against the US dollar. Revenues for North American Invisalign improved slightly due to increased case volume and the impact of the price increases effective at the beginning of 2009 partially offset by the mix shift towards new products which have a greater proportion of revenue that is deferred.

Our total net revenues decreased slightly for the nine months period ended September 30, 2009 compared to the same period in 2008. In North America, revenue decreased due to lower case volumes particularly in the GP channel as well as higher promotional discounts. The price increases effective at the beginning of 2009 partially offset the reduction in revenue. International Invisalign revenue increased over the prior period mainly due to improved case volumes partially offset by unfavorable exchange rates.

For 2009, we expect our total net revenues to be comparable to 2008. North American revenues are expected to decrease due to lower case volumes and product mix shift toward products with higher amounts of deferred revenue. International revenue is expected to increase compared to 2008 due to increased case shipments.

Cost of revenues and gross profit:

	Three Months Ended September 30,			Nine Months Ended September 30,		
(In millions)	**2009**	**2008**	**Change**	**2009**	**2008**	**Change**
Cost of revenues	$ 20.3	$ 18.8	$ 1.5	$ 56.0	$ 58.6	$ (2.6)
% of net revenues	25.6%	25.0%		24.8%	25.5%	
Gross profit	$ 59.0	$ 56.4	$ 2.6	$ 169.7	$ 171.2	$ (1.5)
Gross margin	74.4%	75.0%		75.2%	74.5%	

Cost of revenues includes salaries for staff involved in the production process, the cost of materials, packaging, shipping costs, depreciation on capital equipment used in the production process, training costs and stock-based compensation expense. Cost of revenues also includes the cost of the third party shelter service provider, we utilized in Juarez, Mexico until April 2009.

Gross margin declined slightly for the three months ended September 30, 2009 compared to the same period in 2008 primarily due to the amortization of royalties of $1.9 million that were paid to Ormco in August 2009 in connection with the litigation settlement. This decrease was partially offset by reduced headcount and cost savings relating to the phased-consolidation of our order acquisition operations from Santa Clara, California to Juarez, Mexico, which was completed in December 2008. Furthermore, since the termination of our relationship with IMS in April 2009, we became a direct manufacturer of our aligners, which resulted in additional cost savings.

Gross margin improved for the nine months ended September 30, 2009 compared to the same period in 2008 primarily due to improved manufacturing efficiencies, including reduced headcount and cost savings relating to the phased-consolidation of order acquisition operations from Santa Clara, California to Juarez, Mexico, which was completed in December 2008. Furthermore, since the termination of our relationship with IMS in April 2009, we became a direct manufacturer of our aligners, which resulted in additional cost savings. These savings were reduced by the amortization of royalties paid to Ormco.

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We anticipate our gross margin in 2009 to be consistent with 2008 as we benefit from the 2008 restructuring and the transition from a third party shelter service provider to directly manufacturing our clear aligners. However, those benefits will be offset by the amortization of the prepaid Ormco royalties.

Sales and marketing:

	Three Months Ended September 30,			Nine Months Ended September 30,		
(In millions)	**2009**	**2008**	**Change**	**2009**	**2008**	**Change**
Sales and marketing	$ 27.7	$ 28.2	$ (0.5)	$ 84.6	$ 88.7	$ (4.1)
% of net revenues	34.9%	37.5%		37.5%	38.6%	

Sales and marketing expense includes sales force compensation (including travel-related costs), marketing personnel-related costs, media and advertising, clinical education, product marketing, customer care and stock-based compensation expense.

Our sales and marketing expense decreased in the three months ended September 30, 2009 as compared to the same period in 2008, as a result of a reduction of $1.8 million in marketing, travel, and other sales and marketing administrative costs. These costs were primarily offset by increases of $1.3 million related to media, clinical education, and public relations expenses.

For the nine months ended September 30, 2009 compared to the same period in 2008, the decrease in sales and marketing expense was due to a $3.5 million decrease in media and marketing, and $1.5 million decrease in other sales and marketing administrative costs. These decreases were partially offset by higher public relations expenses and payroll related costs.

We expect sales and marketing expense levels in 2009 to be slightly lower than 2008 as we benefit from the transition of our customer care organization from Santa Clara, California to Costa Rica, which was completed in the second quarter of 2009. These benefits will be partially offset by the continued investment in our international channel and consumer marketing programs.

General and administrative:

	Three Months Ended September 30,			Nine Months Ended September 30,		
(In millions)	**2009**	**2008**	**Change**	**2009**	**2008**	**Change**
General and administrative	$ 16.2	$ 14.4	$ 1.8	$ 46.2	$ 45.9	$ 0.3
% of net revenues	20.5%	19.1%		20.5%	20.0%	

General and administrative expense includes salaries for administrative personnel, outside consulting services, legal expenses and stock-based compensation expense.

General and administrative expense increased for the three months ended September 30, 2009 as compared to the same period in 2008 primarily due to increased legal fees and outside consulting services of approximately $0.8 million related to the Ormco litigation, and bad debt and other general and administration expenses of $0.7 million.

General and administrative expense increased slightly for the nine months ended September 30, 2009 compared to the same period in 2008. Increased depreciation, bad debt, and other general expenses of $3.7 million was offset by a reduction in payroll-related expenses of $1.5 million, resulting from a decrease in headcount and lower legal expense due to an insurance reimbursement of $1.5 million received in the first quarter of 2009.

We expect general and administrative expense for 2009 to be comparable to 2008 levels as we benefit from the October 2008 restructuring, including the transition of our shared services organizations to Costa Rica, which was completed in the second quarter of 2009.

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Research and development:

(In millions)	Three Months Ended September 30, 2009	2008	Change	Nine Months Ended September 30, 2009	2008	Change
Research and development	$ 5.6	$ 5.9	$ (0.3)	$ 16.5	$ 20.2	$ (3.7)
% of net revenues	7.1%	7.8%		7.3%	8.8%	

Research and development expense includes the personnel-related costs and outside consulting expenses associated with the research and development of new products and enhancements to existing products, conducting clinical and post-marketing trials and stock-based compensation expense.

Research and development expense was comparable for the three months ended September 30, 2009 compared to the same period in 2008.

Research and development expense decreased during the nine months ended September 30, 2009 compared to the same period in 2008 primarily due to decreases in payroll-related expenses of $2.4 million, as well as decreases in outside consulting, depreciation and other administration costs totaling approximately $1.2 million.

We expect research and development expense levels in 2009 will be lower than 2008 as a result of reduced headcount from the 2008 restructuring programs and lower consulting expenses.

Restructuring:

(In millions)	Three Months Ended September 30, 2009	2008	Change	Nine Months Ended September 30, 2009	2008	Change
Restructuring	$	$ 2.2	$ (2.2)	$ 1.3	$ 2.2	$ (0.9)
% of net revenues	0.0%	2.9%		0.6%	1.0%	

During 2008, we announced restructuring plans in July and October to increase efficiencies across the organization and lower the overall cost structure. In July 2008, we implemented a restructuring plan to reduce our full time headcount including a phased-consolidation of order acquisition operations from our corporate headquarters in Santa Clara, California to Juarez, Mexico, which was completed by the end of 2008.

In addition to headcount reductions, the October restructuring plan included the phased relocation of our shared services organizations from Santa Clara, California to our facility in Costa Rica, which we completed during the second quarter of 2009. For the three months ended September 30, 2009, we did not incur any restructuring expenses. We incurred approximately $1.3 million during the nine months ended September 30, 2009, which were related to severance and termination benefits. We do not expect to incur any additional restructuring charges under the October 2008 Plan for the remainder of 2009. Additionally, at the time the plans were implemented, we expected total net cost savings

of approximately $3.5 million per quarter starting in the first quarter of 2009 as a result these restructuring plans.

Litigation settlement:

	Three Months Ended September 30,			Nine Months Ended September 30,		
(In millions)	**2009**	**2008**	**Change**	**2009**	**2008**	**Change**
Litigation settlement	$ 69.7	$	$ 69.7	$ 69.7	$	$ 69.7
% of net revenues	87.9%	0.0%		30.9%	0.0%	

On August 16, 2009, we entered into a litigation settlement with Ormco valued at $76.7 million which was comprised of a cash payment of $13.2 million and a stock issuance of approximately 7.6 million shares of common stock. We recognized the litigation settlement of $69.7 million in our operating expenses for the quarter ended September 30, 2009. The remaining $7.0 million was recorded to prepaid expenses, of which $1.9 million was recognized in cost of sales during the quarter ended September 30, 2009. The remaining $5.1 million will be amortized based on case shipments during the fourth quarter of 2009 and first quarter of 2010.

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See Footnote 6 Ormco Litigation Settlement for additional information about the settlement accounting.

Interest and other income, net:

	Three Months Ended September 30,			Nine Months Ended September 30,		
(In millions)	**2009**	**2008**	**Change**	**2009**	**2008**	**Change**
Interest income	$ 0.1	$ 0.7	$ (0.6)	$ 0.5	$ 2.6	$ (2.1)
Other income (expense), net	(0.4)	(0.4)		(0.1)	(0.9)	0.8
Total interest and other, net	$ (0.3)	$ 0.3	$ (0.6)	$ 0.4	$ 1.7	$ (1.3)

Total interest and other income, net includes interest income earned on cash balances, and interest expense on debt, foreign currency translation gains and losses and other miscellaneous charges.

Interest income, net decreased for both the three and nine months ended September 30, 2009 compared to the same periods in 2008 primarily due to lower returns on our investments. We shifted our investments into more conservative securities with shorter durations, principally money market and US government securities, which generally bear lower interest rates than other securities. Furthermore, interest rates for investments throughout the marketplace are lower due to the low Federal Funds Rate established by the Federal Reserve.

Other income (expense), net for the three months ended September 30, 2009 was consistent with the same period in 2008. Other expense, net for the nine months ended September 30, 2009 decrease compared with the same period in 2008 due to the increase in foreign exchange gains during 2009.

Income tax:

	Three Months Ended September 30,			Nine Months Ended September 30,		
(In millions)	**2009**	**2008**	**Change**	**2009**	**2008**	**Change**
Provision for (benefit) from income taxes	$ (10.5)	$ 0.8	$ (11.3)	$ (5.5)	$ 1.4	$ (6.9)

We recorded an income tax provision (benefit) of $(10.5) million and $0.8 million for the three months ended September 30, 2009 and 2008, respectively, representing effective tax rates of 17.4% and 13.4%. We recorded an income tax provision (benefit) of $(5.5) million and $1.4 million for the nine months ended September 30, 2009 and 2008, respectively, representing effective tax rates of 11.3% and 8.6%. Our effective tax rate for the remainder of 2009 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.

We exercised significant judgment in regards to estimates of future market growth, forecasted earnings and projected taxable income, in determining the provision for income taxes, and for purposes of assessing our ability to utilize any future benefit from deferred tax assets. At December 31, 2008, based on an evaluation of the available positive and negative evidence, we determined that most of our deferred tax assets would be realized with the exception of certain capital loss and foreign net operating loss carryforwards. In making that determination, we considered the historical and projected pretax operating profit, excluding stock-based compensation, as well as the cyclical nature of our business and the uncertainty as to the impact of new product launches. Specifically, at December 31, 2008, the Company considered the following positive evidence:

- cumulative seven quarters of pretax operating profitability plus permanent items
- the then-projected pretax book income for 2009 and beyond suggesting that deferred tax assets will be utilized

The Company also considered the following negative evidence:

- history of operating losses in 2006 and prior to 2003

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- cyclical nature of the business and price volatility

We believe that the positive evidence is of sufficient quality and quantity to overcome the negative evidence and as a result, we released our tax valuation allowance of $64.6 million in the fourth quarter of 2008. The remaining valuation allowance of approximately $6.2 million is related to capital loss and foreign net operating loss carryforwards as of December 31, 2008 because we cannot forecast sufficient future capital gains or foreign source income to realize these deferred tax assets. These net operating loss carryforwards will result in an income tax benefit if and when we conclude it is more likely than not that the related deferred tax assets will be realized.

In February 2009, the California 2009-2010 budget legislation was signed into law. One of the major components of this legislation is the ability to elect to apply a single sales factor apportionment for years beginning after January 1, 2011. As a result of our anticipated election of the single sales factor, we are required to re-measure our deferred taxes taking into account the reversal pattern and the expected California tax rate under the elective single sales factor. We have determined that by electing a single sales factor apportionment, our deferred tax assets will decrease by approximately $0.6 million (net of federal benefit). The tax impact of $0.6 million has been recorded as a discrete item in the first quarter of fiscal year 2009.

Liquidity and Capital Resources

We fund our operations from product sales and proceeds from the sale of common stock. As of September 30, 2009 and December 31, 2008 we had the following cash and cash equivalents, and short-term marketable securities (in thousands):

	September 30, 2009	December 31, 2008
Cash and cash equivalents	$ 135,961	$ 87,100
Marketable securities, short-term	18,979	23,066
Total	$ 154,940	$ 110,166

Net cash provided by operating activities was $39.9 million for the nine months ended September 30, 2009 resulting primarily from our net loss of $42.8 million adjusted by $81.8 million for non-cash items such as, litigation settlement costs, stock based compensation expense, depreciation, and amortization of intangibles, as well as an $11.1 million increase in deferred revenue related to our new Invisalign Teen and Invisalign Assist products. These changes were offset by a $10.2 million increase in accounts receivable, prepaids, and other assets.

Net cash provided by operating activities was $31.0 million for the nine months ended September 30, 2008 resulting primarily from our net profit of $14.5 million adjusted by $23.1 million for non-cash items such as, stock-based compensation expense, depreciation, and amortization of intangibles, as well as a $3.1 million increase in deferred revenue. These changes were offset by a $4.1 million increase in accounts receivable and a decrease in accrued liabilities of $6.3 million.

Net cash provided by investing activities was $2.9 million for the nine months ended September 30, 2009, consisting largely of $7.0 million of net maturities of marketable securities partially offset by $4.1 million for the purchase of property, plant, and equipment.

Net cash used in investing activities was $10.5 million for the nine months ended September 30, 2008, largely consisted of $12.4 million used for the purchase of property and equipment and offset by $1.4 million of net maturities of marketable securities.

As a result of adverse financial market conditions, investments in some financial instruments may pose risks arising from liquidity and credit concerns. Although we believe our current investment portfolio has little risk of impairment, we cannot predict future market conditions or market liquidity and can provide no assurance that our investment portfolio will remain unimpaired.

Net cash provided by financing activities was $6.0 million for the nine months ended September 30, 2009, which primarily resulted from $6.4 million in proceeds from the issuance of our common stock for employee stock option exercises.

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Net cash used in financing activities was $29.6 million for the nine months ended September 30, 2008, which resulted primarily from our $39.4 million stock repurchase offset by $10.2 million in proceeds from the issuance of our common stock, primarily from exercises of employee stock options.

Contractual Obligations

In April 2009, we terminated our third party shelter services arrangement with IMS for order acquisition, the fabrication of aligner molds and finished aligners and the shipment of the completed product to customers. We are now a direct manufacturer of our clear aligners at the facility in Juarez, Mexico and directly coordinate order acquisition and product shipment from this location. IMS has assigned the lease to Align Mexico, a wholly-owned subsidiary of Align, and we guarantee the lease payments for our subsidiary.

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 year ended December 31, 2008.

We believe that our current cash and cash equivalents combined with our existing borrowing capacity 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 may need to make business decisions that could adversely affect our operating results such as modifications to our pricing policy, business structure or operations. Accordingly, the failure to obtain sufficient funds on acceptable terms when needed could have a material adverse effect on our business, results of operations and financial condition.

Critical Accounting Policies

Management s discussion and analysis of our financial condition and results of operations is based upon our Condensed Consolidated Financial Statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of financial statements requires our management to make estimates and judgments that affect the reported amounts of assets and liabilities, revenues 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, 2008.

- Revenue recognition;

- Stock-based compensation expense;

- Long-lived assets, including finite lived purchased intangible assets;

- Deferred tax valuation allowance.

There have been no significant changes in our critical accounting policies during the three months ended September 30, 2009 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, 2008.

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.

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ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

For quantitative and qualitative disclosures about market risk affecting us, see Item 7A, Quantitative and Qualitative Disclosures About Market Risk, in our Annual Report on Form 10-K for the year ended December 31, 2008, which is incorporated herein by reference. Our exposure to market risk has not changed materially since December 31, 2008.

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 Form 10-Q. Based upon that evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that our disclosure controls and procedures are effective as of September 30, 2009 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 SEC 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

Ormco

On January 6, 2003, Ormco Corporation (Ormco), a division of Sybron Dental Specialties (a Danaher Corporation subsidiary), filed suit against us in the United States District Court for the Central District, Orange County Division, asserting infringement of U.S. Patent Nos. 5,447,432,

5,683,243 and 6,244,861. The complaint sought unspecified monetary damages and injunctive relief. Also in 2003, we counterclaimed for infringement of our U.S. Patent No. 6,398,548, seeking unspecified monetary damages and injunctive relief. Ormco filed a first amended complaint for infringement of U.S. Patent No. 6,616,444 and 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, in 2004, the Court granted five motions for summary judgment that we filed. First, 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 (5,447,432, 5,683,243, 6,244,861 and 6,616,444). Second, the Court granted in part our motion for summary judgment of infringement, finding that Ormco and its subsidiary, Allesee Orthodontic Appliances, Inc. (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, the Court granted our motion for summary judgment of invalidity of Ormco s asserted patents claims (5,447,432, 5,683,243, 6,244,861 and 6,616,444). 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 February 24, 2005, the Court, on further summary judgment, confirmed 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 found certain claims of our 6,398,548 patent to be invalid in view of prior use evidence. 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 filed a notice of appeal with the Federal Circuit from the Permanent Injunction.

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There have been two appeals. After the Permanent Injunction was entered, Ormco and AOA appealed that injunction and the orders of the District Court on summary judgment on which the injunction was based. In April 2006, 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. 6,554,611 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 71 claims; only claims 10 and 17 were at issue in the first 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 the order in which the appliances are to be worn and use of the appliances in intervals of 2-20 days.

The 6,554,611 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 second appeal was from the final judgment. Ormco appealed the ruling of the District Court that 92 claims in four of its patents are not infringed by us and that the asserted claims are invalid. We appealed the ruling of the District Court that certain claims of our 6,398,548 patent which were found to be infringed by Ormco s and AOA s Red, White & Blue appliances were invalid. The CAFC issued a ruling on August 24, 2007, affirming the District Court s ruling that 86 out of 92 claims in Ormco s 5,447,432, 5,683,243, 6,244,861 and 6,616,444 patents are invalid and not infringed by us. The CAFC reversed the District Court s non-infringement and invalidity rulings on six claims in Ormco s 6,616,444 patent. Ormco filed a petition for review with the U.S. Supreme Court with respect to the portion of the CAFC s opinion that affirmed the District Court s ruling of non-infringement and non-enablement of Ormco s 86 claims. The Supreme Court denied Ormco s petition, and the case on the six claims in Ormco s 6,616,444 patent were returned to the District Court for a determination of validity and infringement of those claims. The District Court issued orders construing the claim terms at issue and granting our motion to amend our answer and counterclaim to assert Ormco s 6,616,444 patent is unenforceable due to inequitable conduct.

On February 25, 2009, the District Court issued rulings on various Summary Judgment and expert related motions. In summary, the District Court granted one of Ormco s motions on one theory of infringement and granted our motion on two theories of non-infringement. Our invalidity argument supported by over fifty prior art references was unaffected. The District Court also ruled that one of our inequitable conduct theories should be resolved at trial.

Trial on liability issues took place between June 9, 2009 and June 25, 2009. The jury returned a verdict finding (i) infringement under 35 U.S.C. §271(g), (ii) finding the six claims in Ormco s 6,616,444 patent to be not invalid and (iii) providing an advisory verdict on the equitable issues that Ormco did not commit prosecution laches or engage in unclean hands. On July 28, 2009, the Court entered judgment in favor of Ormco on our defenses of prosecution laches and unclean hands. Subsequent to the jury verdict, we filed a motion for judgment as a matter of law on all issues seeking to set aside the jury s verdict of liability. On August 3, 2009, the court denied our motion for judgment as a matter of law.

On July 13, 2009, Ormco filed a motion for permanent injunction against us seeking to enjoin the sale of the Invisalign system through the January 2010 expiration of the 6,616,44 patent, as well as other injunctive relief against us including (i) the destruction of all material, including software, created by Align from September 2003 to the present; (ii) the discontinuation of certification programs and the decertification of doctors certified from September 2003 to the present; and (iii) the destruction of sales representatives records developed during this time period. A hearing on the motion for permanent injunction was scheduled on August 17, 2009.

On August 16, 2009, Align and Ormco entered into a Settlement Agreement (the Settlement Agreement), pursuant to which we (1) paid Ormco a cash amount equal to approximately $13.15 million, and (2) agreed to issue to Danaher Corporation (Danaher), an affiliate of Ormco, up to 7,586,489 fully paid and nonassessable shares of our Common Stock (the Shares), 5,561,489 and 2,025,000 of which were issued to Danaher on August 16, 2009 and September 22, 2009, respectively, pursuant to the Stock Purchase Agreement entered into between Align and Danaher on August 16, 2009

Pursuant to the terms of the Settlement Agreement, judgment was entered on the claims resolved by the jury in the litigation involving the parties that was pending in the U.S. District Court for the Central District of California, Western Division, Case No. SACV 03-16 CAS (ANx), and all remaining claims in the Litigation were dismissed with prejudice.

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In addition, the Settlement Agreement includes the following terms:

- A release by Ormco of all past claims asserted by it against us based upon Ormco s U.S. Patent Number 6,616,444 (the Patent) and an agreement by Ormco not to assert against us any claim of infringement based upon the Patent as a result of our activities relating to removable aligners.

- A release by us of any and all past and future claims that claims 37, 38, 39, 40, and 69 of the Patent are not infringed by us, that claims 37, 38, 39, 40, 45 and 69 of the Patent are invalid, and that the Patent is unenforceable and a waiver by us of any right to appeal from or contest any of the findings, judgments, rulings or orders made by the court in the litigation;

- A covenant by Ormco that, with respect to our current products and processes (including any enhancements), it will not, anywhere in the world, initiate or cause to be initiated against us any claim of infringement of any claim in any patent owned or controlled by Ormco that is existing as of August 16, 2009, or that issues from any patent application having a filing date, or claiming priority to any patent application having a filing date *with the applicable government authority,* no later than August 16, 2009, solely with respect to any activities relating to removable dental aligners and/or processes for making removable dental aligners, including attachments, buttons and similar auxiliaries for use in connection with the removable dental aligners (and for the avoidance of doubt not to include any activities relating to non-removable appliances).

- A covenant by us that it will not, anywhere in the world, initiate or cause to be initiated against Ormco any claim of infringement of any patent owned or controlled by us that is existing as of August 16, 2009, or that issues from any patent application having a filing date, or claiming priority to any patent application having a filing date, no later than August 16, 2009, for any activities relating to those products currently being manufactured and/or sold by Ormco, including any enhancements to those products; provided, however, that those removable aligner products are created without using a computer or other digital means to create the physical model of the teeth on which the aligners are formed; and

A copy of the Settlement Agreement is filed as exhibits to this quarterly report on Form 10-Q.

- A Joint Development, Marketing and Sales Agreement with Ormco.

See Footnote 6 Ormco Litigation Settlement for additional information about the settlement accounting.

Other matters

USPTO

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. A Reexamination Certificate has been issued regarding the 6,309,215, 6,398,548, 6,705,863, 6,217,325, 6,722,880, 6,318,994 and 5,975,893 patents and therefore these patents are no longer in reexamination. We received an Action Closing Prosecution on the 6,685,469 patent. The status of the 6,629,840 patent is as follows:

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 the 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. A petition seeking a waiver was filed on February 15, 2007 and was granted on April 17, 2007, granting a single interview. The interview was held on May 22, 2007, and an Interview Summary was filed with the USPTO on June 21, 2007. We are awaiting further action by the USPTO.

As part of the OrthoClear Agreement, OrthoClear agreed to take no further action with respect to the Inter Parte Requests, including the 6,629,840 patent.

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Consumer Class Action

On May 18, 2007, Debra A. Weber filed a consumer class action lawsuit against us, OrthoClear, Inc. and OrthoClear Holdings, Inc. (d/b/a OrthoClear, Inc.) in Syracuse, New York, U.S. District Court. The complaint alleges two causes of action against the OrthoClear defendants and one cause of action against us for breach of contract. The cause of action against us titled Breach of Third Party Benefit Contract references our agreement to make Invisalign treatment available to OrthoClear patients, alleging that we failed to provide the promised treatment to Plaintiff or any of the class members .

On July 3, 2007, we filed our answer to the complaint and asserted 17 affirmative defenses. On July 20, 2007, we filed a motion for summary judgment on the Third Cause of Action (the only cause of action alleged against us). On August 24, 2007, Weber filed a motion for class certification. On October 1, 2007, we filed an opposition to the motion of class certification and we are currently awaiting rulings from the Court. OrthoClear has filed a motion to dismiss. The initial case management conference and all discovery has been stayed pending the Court s decision on the motion for class certification, OrthoClear s motion to dismiss and our motion for summary judgment. The Company believes the lawsuit to be without merit and intends to vigorously defend itself.

Securities Litigation

In August 2009, Plaintiff Charles Wozniak filed a lawsuit against the Company and our Chief Executive Officer and President, Thomas M. Prescott (Mr. Prescott), in District Court for the Northern District of California on behalf of a claimed class consisting of all persons or entities who purchased the common stock of Align between January 30, 2007 and October 24, 2007. The complaint alleges that Align and Mr. Prescott violated Section 10(b) of the Securities Exchange Act of 1934 and that Mr. Prescott violated Section 20(a) of the Securities Exchange Act of 1934. Specifically, the complaint alleges that during the class period we failed to disclose that we had shifted the focus of our sales force to clearing backlog, causing a significant decrease in the number of new case starts.

Two plaintiffs have filed motions to be appointed lead plaintiff. A hearing on these two motions is set for November 20, 2009. We believe the lawsuit to be without merit and intend to vigorously defend ourselves.

Litigating claims of the types discussed in 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.

ITEM 1A. RISK FACTORS

We depend on the sale of the Invisalign system for the vast majority of our revenues, and any decline in sales of Invisalign for any reason, including as a result of the introduction of the Proficiency Requirements or a decline in general economic conditions, or a

decline in average selling prices would adversely affect revenues, gross margin and net profits.

We expect that revenues from the sale of the Invisalign system 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 or GPs choose to use a competitive product rather than Invisalign or if the average selling price of our product declines, our operating results would be harmed. Factors that could cause the adoption of Invisalign to occur at a lower rate than we expect, as well as the risk related to declining average selling prices are described more fully below.

Consumers may not adopt Invisalign as rapidly as we anticipate due to a variety of factors including a continued decline in general economic conditions.

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Consumer spending habits are affected by, among other things, prevailing economic conditions, levels of employment, salaries and wage rates, gas prices, consumer confidence and consumer perception of economic conditions. A general slowdown in the United States economy and certain international economies or an uncertain economic outlook would adversely affect consumer spending habits which may, among other things, result in a decrease in the number of overall orthodontic case starts or a reduction in the demand for Invisalign generally either of which would have a material adverse effect on our sales and operating results. In addition, Invisalign represents a significant change from traditional orthodontic treatment, and consumers may be reluctant to accept it or may not find it preferable to traditional treatment. We have generally received positive feedback from 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, ease of use, reliability, aesthetics, greater comfort and hygiene compared to traditional orthodontic products and price for Invisalign compared to competing products.

Orthodontists and GPs may not adopt Invisalign in sufficient numbers or as rapidly as we anticipate for a number of reasons, including the introduction of the Proficiency Requirements or declining general economic conditions.

Our success depends upon increasing acceptance and frequency of use of the Invisalign system by dental professionals (what we refer to as utilization). We have a large number of low volume doctors that make up a large portion of our customer base. We want every Invisalign provider to be one we can comfortably direct a prospective patient to with an expectation of knowledgeable treatment and a great outcome. To further this goal, on June 2, 2009, we announced the implementation of the Invisalign Product Proficiency Requirements in North America to help ensure that Invisalign-trained doctors have the experience and confidence necessary to achieve high quality treatment outcomes for Invisalign patients. Under the Proficiency Requirements, every Invisalign provider in North America must start 10 Invisalign cases and complete at least 10 Invisalign-specific continuing education (CE) credits each calendar year. We announced in September 2009, updates to the Proficiency Requirements, including a new designation for doctors who meet the annual requirements and an additional qualification period in 2010. Under the updated Proficiency Requirements , doctors with zero cases shipped or zero Invisalign CE hours at the end of 2009 and doctors who ultimately do not meet the annual case and CE requirements in 2010 will be able to continue treating their in-progress cases, but will not be eligible to submit new Invisalign cases or to use Invisalign marketing resources. Doctors can reactivate their provider status by retaking Invisalign Clear Essentials I training and meeting the Proficiency Requirements in the new calendar year. Although we want every doctor to achieve and maintain the Proficiency Requirements with Invisalign, we expect that a number of our lower volume doctors may be unwilling or unable to meet these requirements. If the number of our other customers who fail to maintain and/or increase utilization to meet the Proficiency Requirements is greater than we anticipate, our case volumes will decrease and our revenues will be harmed. In addition, if GPs and Orthos do not attend our training courses in sufficient numbers for any reason, including the introduction of the Proficiency Requirements, or declining general economic conditions, our revenue may fail to grow as expected. In addition, increased competition from direct competitors could cause us to lose market share and reduce dental professionals efforts and commitment to expand their Invisalign practice. If adoption and utilization does not increase as we anticipate, our revenues may fail to grow as expected and our operating results may be harmed.

The frequency of use by orthodontists or GPs may not increase at the rate that we anticipate or at all.

One of our key objectives is to continue to increase utilization, or the adoption and frequency of use, of the Invisalign system by new and existing customers. If utilization of Invisalign by our existing and newly trained orthodontists or GPs does not occur or does not occur as quickly as we anticipate, our operating results could be harmed.

We may experience declines in average selling prices of our products.

In response to challenges in our business, including increased competition, we have in the past reduced the list price of our products. We also provide volume based discount programs to our doctors. In addition, we sell a number of products at different list prices. If we introduce any price reductions, expand our discount programs in the future, if participation in these programs increases or if our product mix shifts to newer products with a higher percentage of deferred revenue, our average selling price would be adversely affected and our revenues, gross margin and net profits (losses) may be reduced. Furthermore, although the U.S. dollar is our reporting currency, a portion of our revenues and profits are generated in foreign currencies. Revenues and profits generated by subsidiaries operating outside of the United States are translated into U.S. dollars using exchange rates effective during the respective period and are affected by changes in exchange rates. As a result, negative movements in currency exchange rates against the U.S. dollar will adversely affect our average selling price and consequently the amount of revenues and profits in our consolidated financial statements.

If we fail to sustain or increase profitability or revenue growth in future periods, the market price for our common stock may decline.

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If we are to sustain or increase profitability in future periods, we will need to continue to increase our revenues, while controlling our expenses. While we generated positive operating cash flow in 2008 and in 2009, 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.

Our financial results have fluctuated in the past and may fluctuate in the future which may cause volatility in our stock price.

Our operating results have fluctuated in the past and we expect our future quarterly and annual operating results to fluctuate as we focus on increasing doctor and consumer demand for our products. These fluctuations could cause our stock price to decline. Some of the factors that could cause our operating results to fluctuate include:

- limited visibility into and difficulty predicting the level of activity in our customers practices from quarter to quarter;
- disruptions to our business due to the impact on H1N1 virus, commonly referred to as swine flu or any other such epidemic that results in changes in consumer spending habits, consumers unable or unwilling to visit the orthodontist or general practitioners office, as well as any impact on workforce absenteeism;
- weakness in consumer spending as a result of the slowdown in the United States economy and global economies;
- changes in the timing of receipt of case product orders during a given quarter which, given our cycle time and the delay between case receipts and case shipments, could have an impact on which quarter revenue can be recognized;
- fluctuations in currency exchange rates against the U.S. dollar
- changes in product mix;
- seasonal fluctuations in the number of doctors in their offices and their availability to take appointments;
- success of marketing programs from quarter to quarter;
- changes in the timing of when revenue is recognized, including as a result of the introduction of new products or promotions;
- changes to our effective tax rate;
- unanticipated delays in production caused by insufficient capacity;
- any disruptions in the manufacturing process, including unexpected turnover in the labor force or the introduction of new production processes or natural or other disasters beyond our control;
- the development and marketing of directly competitive products by existing and new competitors;
- aggressive price competition from competitors;
- costs and expenditures in connection with litigation;
- inaccurate forecasting of revenues, production and other operating costs; and

- investments in research and development to develop new products and enhancements to Invisalign.

To respond to these and other factors, we may need to make business decisions that could adversely affect our operating results such as modifications to our pricing policy, business structure or operations. Most of our expenses, such as employee compensation and lease payment obligations, are relatively fixed in the short term. Moreover, our expense levels are based, in part, on our expectations regarding future revenue levels. As a result, if our revenues for a particular period fall below our expectations, whether caused by changes in consumer spending, consumer preferences, weakness in the U.S. or

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global economies, changes in customer behavior related to advertising and prescribing our product, or other factors, we may be unable to adjust spending quickly enough to offset any shortfall in revenues. Due to these and other factors, we believe that quarter-to-quarter comparisons of our operating results may not be meaningful. You should not rely on our results for any one quarter as an indication of our future performance.

Our future success may depend on our ability to develop, successfully introduce and achieve market acceptance of new products.

Our future success may depend on our ability to develop, manufacture, market, and obtain regulatory approval or clearance of new products. We launched Invisalign Teen in July 2008 and Invisalign Assist in October 2008. In September 2009, we introduced new and enhanced features in all Invisalign products. There can be no assurance that we will be able to successfully develop, sell and achieve market acceptance of these and other new products and applications and enhanced versions of our existing product. The extent of, and rate at which, market acceptance and penetration are achieved by future products is a function of many variables, which include, among other things, our ability to include functionality and features that address customer requirements, the availability of third-party reimbursement of procedures using our new products, the existence of competing products and general economic conditions affecting purchasing patterns. In addition, even if our new products are successfully introduced, it is unlikely that they will rapidly gain market share and acceptance primarily due to the relatively long period of time it takes to successfully treat a patient. Since it takes approximately 12 to 24 months to treat a patient, our customers may be unwilling to rapidly adopt our new products until they successfully complete at least one case or until more historical clinical results are available.

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 (FDA), and foreign government agencies. Any failure in our ability to successfully develop and introduce or achieve market acceptance of our new products or enhanced versions of existing products could have a material adverse effect on our operating results and could cause our revenues to decline.

A disruption in the operations of our primary freight carrier or higher shipping costs could cause a decline in our revenues or a reduction in our earnings.

We are dependent on commercial freight carriers, primarily UPS, to deliver our products. If the operations of these carriers are disrupted for any reason, we may be unable to deliver our products to our customers on a timely basis. If we cannot deliver our products in an efficient and timely manner, our customers may reduce their orders from us and our revenues and operating profits could materially decline. In a rising fuel cost environment, our freight costs will increase. If freight costs materially increase and we are unable to pass that increase along to our customers for any reason or otherwise offset such increases in our cost of revenues, our gross margin and financial results could be adversely affected.

We are dependent on our international operations, which exposes us to foreign operational, political and other risks that may harm our business.

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 digital treatment plans, which are then transmitted electronically to Juarez, Mexico. These digital files form the basis of ClinCheck and are used to manufacture aligner molds. Our order acquisition, aligner fabrication and shipping operations are conducted in Juarez, Mexico. In addition to the research and development efforts conducted in our Santa Clara,

California facility, we also carry out research and development at locations in San Jose, Costa Rica and Moscow, Russia. In October 2008, we announced the phased-consolidation of our customer-care, accounts receivable, credit and collections and customer event registration organizations, which was previously located in Santa Clara, California, to our facility in Costa Rica. We completed this relocation in the second quarter of 2009. Our increasing reliance on international operations exposes us to risks and uncertainties that may affect our business or results of operation, including:

- difficulties in hiring and retaining employees generally, as well as difficulties in hiring and retaining employees with the necessary skills to perform the more technical aspects of our operations;
- difficulties in managing international operations;
- fluctuations in currency exchange rates;
- import and export license requirements and restrictions;

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- controlling production volume and quality of the manufacturing process;
- political, social and economic instability, including as a result of increased levels of violence in Juarez, Mexico;
- acts of terrorism and acts of war;
- interruptions and limitations in telecommunication services;
- product or material transportation delays or disruption, including as a result of health epidemics such as the outbreak of the H1N1 virus commonly referred to as the Swine Flu in the event travel to and from Mexico is restricted;
- burdens of complying with a wide variety of local country and regional laws;
- trade restrictions and changes in tariffs; and
- potential adverse tax consequences.

If any of these risks materialize in the future, we could experience production delays and lost or delayed revenue.

We recently completed the transition from reliance on a shelter service arrangement to become a direct manufacturer of our products. If we fail to successfully manage our operations in Juarez, Mexico, our business may be harmed.

In April 2009, we terminated our third party shelter services arrangement with IMS, for order acquisition, fabrication of aligner molds and finished aligners and the shipment of the completed product to customers. In addition to the risks related to international operations described in the risk factor above, any difficulties encountered by us with respect to directly manufacturing our products, including difficulties hiring and retaining qualified personnel could disrupt our ability to deliver our products in a timely manner which could harm our business.

We recently completed the relocation of our customer facing organizations to Costa Rica.

In October 2008, we announced a restructuring plan to increase efficiencies across the organization and lower our overall cost structure. In addition to headcount reduction, the restructuring plan included the phased-relocation of our customer care, accounts receivable, credit and collections and customer event registration organizations from Santa Clara, California, to our facility in Costa Rica. We completed this relocation in the second quarter of 2009. In addition to the risks related to international operations described in the risk factor above, this relocation is accompanied by a number of risks and uncertainties that may affect our results of operations and statement of cash flows, including:

- due to the large number of new employees in these customer facing organizations, our customers may experience a decrease in service levels for a period of time;
- the relocation may continue to absorb the attention and resources of management and key employees that would otherwise be available for the ongoing business operations; and
- difficulties in hiring or retaining employees in Costa Rica with the necessary skills to perform these customer facing functions.

If any of these risks materialize in the future, our operating results, statement of operations and cash flows may be adversely affected.

A key step in our manufacturing process relies on sophisticated computer technology that requires new technicians to undergo a relatively long training process. If we are unable to accurately predict our volume growth, and fail to hire a sufficient number of technicians in advance of such demand, the delivery time of our products could be delayed which could adversely affect our results of operations.

Training technicians to use our sophisticated computer modeling program that produces the digital treatment plan that forms the basis of ClinCheck takes approximately 90 to 120 days. As a result, if we are unable to accurately predict our volume growth, we may not have a sufficient number of trained technicians to timely create ClinCheck treatment plans within the timeframe our customers expect. Any delay in ClinCheck processing time could delay the ultimate delivery of finished aligners to our customers. Such a delay could cause us to lose existing customers or fail to attract new customers. This could cause a decline in our revenues and net profits and could adversely affect our results of operations.

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Our headquarters, digital dental modeling processes, and other manufacturing processes are all principally located in regions that are subject to earthquakes and other natural disasters.

Our digital dental modeling is processed in our facility located in San Jose, Costa Rica. The operations team in Costa Rica creates ClinCheck treatment plans using sophisticated computer software. We recently completed the transition of our customer facing operations from Santa Clara, California to Costa Rica. In addition, our aligner molds and finished aligners are fabricated in Juarez, Mexico. Both Costa Rica and Mexico are in earthquake zones and may be subject to other natural disasters. If there is a major earthquake or any other natural disaster in a region where one of these facilities is located, our ability to create ClinCheck treatment plans or manufacture and ship our aligners could be compromised which could result in our customers experiencing a significant delay in receiving their completed aligners. In addition, our headquarters facility is located in the San Francisco Bay Area. An earthquake or other natural disaster in this region could result in a disruption in our operations. Any such business interruption could materially and adversely affect our business, financial condition and results of operations.

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 products manufactured and distributed by Ormco Orthodontics, a division of Sybron Dental Specialties (a Danaher Corporation subsidiary), and traditional braces manufactured by 3M Company and Dentsply International. These manufacturers 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 or combine technologies that make our product economically unattractive. 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 has resulted in the past 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 revenues, volume growth, net profit (losses) and stock price. 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. 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 develop 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, revenues and operating results.

We are currently focused on adding more functionality into our business enterprise systems to more efficiently integrate these systems with our other system applications, such as customer facing and manufacturing tools, and intend to continue this effort for the foreseeable future. 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. 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 on our business, financial condition or results of operations.

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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, 2009, we had 127 issued U.S. patents, 164 pending U.S. patent applications, and 57 issued foreign patents, and 117 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. In addition, any protection afforded by foreign patents may be more limited than that provided under U.S. patents and intellectual property laws. We also rely on protection of our copyrights, trade secrets, know-how and proprietary information. We generally enter into confidentiality agreements with our employees, consultants and our collaborative partners upon commencement of a relationship with us. However, these agreements may not provide meaningful protection against the unauthorized use or disclosure of our trade secrets or other confidential information, and adequate remedies may not exist if unauthorized use or disclosure were to occur. Our inability to maintain the proprietary nature of our technology through patents, copyrights or trade secrets would impair our competitive advantages and could have a material adverse effect on our operating results, financial condition and future growth prospects. In particular, a failure to protect 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. The potential effects on our business operations resulting from litigation that we may participate in the future, whether or not ultimately determined in our favor or settled by us, are costly and divert 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.

We are currently a party to various other legal proceedings and claims. 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.*

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 could have an adverse effect on our stock price.

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.

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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 provided by 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 may 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 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 or the price of raw materials used in our manufacturing process increases.

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, our scanning and stereolithography equipment are provided by a single supplier. We are also committed to purchasing all of our resin and polymer, the primary raw materials used in our manufacturing process, from a single source. In addition, 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 or increases in price for these items, our business and growth prospects may be harmed.

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

Our ability to sell our products and generate revenues depends upon our direct sales force within our North American and international markets. As of September 30, 2009, our North American sales organization consisted of 165 people, of which 135 were direct sales representatives and 30 were sales administration and regional sales management. Internationally, we had 44 people engaged in sales and sales support as of September 30, 2009. We do not have any long-term employment contracts with the members of our direct sales force. The loss of the services provided by these key personnel may harm our business. If we are unable to 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 establish 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. In addition, due to our large and fragmented customer base, we may not be able to provide all of our customers with product support immediately upon the launch of a new product. As a result, adoption of new products by our customers may be slower than anticipated and our ability to grow market share and increase our revenues may be harmed.

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

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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, manufacturing 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 pre-market approval of new products, new intended uses, or modifications to existing products;

- withdrawing clearance or pre-market 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. Our failure 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.

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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, Asia Pacific, Latin America and Japan and may expand into other countries from time to time. We do not know whether orthodontists, GPs and consumers outside our North American 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.

Historically, the market price for our common stock has been 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:

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- 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 economic 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. Historically, class action litigation is often brought against an issuing company following periods of volatility in the market price of a company s securities. Recently, a securities class action suit was filed against us on behalf of all persons or entities who purchased our common stock between January 30, 2007 and October 24, 2007. While we believe the lawsuit is without merit and intend to vigorously defend ourselves, we could incur substantial legal fees, and our management s attention and resources may be diverted from operating our business in order to respond to the litigation.

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

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

Changes in, or interpretations of, accounting rules and regulations, could result in unfavorable accounting charges.

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

- revenue recognition;
- accounting for share-based payments; and
- accounting for income taxes.

If we fail to manage our exposure to global financial and securities market risk successfully, our operating results and financial statements could be materially impacted.

The primary objective of most of our investment activities is to preserve principal. To achieve this objective, a majority of our marketable investments are investment grade, liquid, short-term fixed-income securities and money market instruments denominated in U.S. dollars. If the carrying value of our investments exceeds the fair value, and the decline in fair value is deemed to be other-than-temporary, we will be required to write down the value of our investments, which could materially harm our results of operations and financial condition. Moreover, the performance of certain securities in our investment portfolio correlates with the credit condition of the U.S. financial sector. With the current unstable credit environment, we might incur significant realized, unrealized or impairment losses associated with these investments.

We have adopted 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.

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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.

Our effective tax rate may vary significantly from period to period.

Various internal and external factors may have favorable or unfavorable effects on our future effective tax rate. These factors include, but are not limited to, changes in tax laws, regulations and/or rates, changing interpretations of existing tax laws or regulations, the future levels of tax benefits of stock option deductions relating to incentive stock options and employee stock purchase plans and changes in overall levels of pretax earnings. In June 2009, the Costa Rica Ministry of Foreign Trade, an agency of the Government of Costa Rica, granted a twelve year extension of the tax incentives which were previously granted in 2002. Under these incentives, all of the income we earn in Costa Rica during these twelve year incentive periods is subject to reduced rates of Costa Rica income tax. The incentive tax rates will expire in various years beginning in 2017. The Costa Rica corporate income tax rate that would apply, absent the incentives, is 30% for 2009. As a result of these incentives, income taxes decreased by $1.3 million in 2008. In order to receive the benefit of the incentives, we must hire specified numbers of employees and maintain minimum levels of fixed asset investment in Costa Rica. If we do not fulfill these conditions for any reason, our incentive could lapse and our income in Costa Rica would be subject to taxation at higher rates, which could have a negative impact on our operating results.

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

On August 16, 2009, we entered into a a Settlement Agreement with Ormco, pursuant to which we agreed, among other things, to issue to Danaher Corporation (Danaher), an affiliate of Ormco, 7,586,489 fully paid and nonassessable shares of our common stock.

In connection with the Settlement Agreement, we issued 5,561,489 of such shares of our common stock to Danaher on August 16, 2009 in accordance with a Stock Purchase Agreement. In accordance with the terms of the Stock Purchase Agreement, immediately following the expiration of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, we issued to Danaher 2,025,000 fully paid and nonassessable shares of our common stock on September 22, 2009. Additional information regarding the Stock Purchase Agreement the transactions related thereto, and the settlement was previously disclosed by Align in its Current Report on Form 8-K filed with the Securities and Exchange Commission on August 17, 2009.

The shares may not be resold except pursuant to an effective registration statement under the Securities Act of 1933, as amended (the Securities Act) or an available exemption from registration under the Securities Act and applicable state securities laws.

A copy of the Settlement Agreement and the Stock Purchase Agreement are filed as an exhibit to this quarterly report on Form 10-Q.

The sale and issuance of the securities issued pursuant to the Stock Purchase Agreement was deemed to be exempt from registration under the Securities Act in reliance upon Section 4(2) of the Securities Act, or Rule 506 of Regulation D promulgated thereunder. Danaher represented its intentions to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the securities. The sales of the securities were made without general solicitation or advertising. Danaher was an accredited investor and had adequate access, through its relationship with us, to information about us.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

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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	Filing	Date	Exhibit Number	Filed herewith
10.1	Settlement Agreement dated as if August 16, 2009 between Align Technology, Inc. and Ormco Corporation.				*
10.2	Stock Purchase Agreement dated as of the 16th day of August by and between Align Technology, Inc. and Danaher Corporation.				*
10.3	Joint Development, Marketing and Sales Agreement entered in as of August 16, 2009 by and between Align Technology, Inc. and Ormco Corporation.				*
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.				*

Portions of the exhibit have been omitted pursuant to a request for confidential treatment. The confidential portions have been filed with the SEC.

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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 5, 2009

ALIGN TECHNOLOGY, INC.

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

By: /s/ KENNETH B. AROLA
Kenneth B. Arola
Chief Financial Officer and Vice President, Finance

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