ALIGN TECHNOLOGY INC
Form 10-Q
May 07, 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 March 31, 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 April 30, 2009 was 66,238,234.

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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 March 31,	
	2009	**2008**
Net revenues	$ 70,132	$ 74,776
Cost of revenues	17,425	19,608
Gross profit	52,707	55,168
Operating expenses:		
Sales and marketing	27,854	28,059
General and administrative	13,468	15,188
Research and development	5,191	7,295
Restructurings	910	
Total operating expenses	47,423	50,542
Profit from operations	5,284	4,626
Interest and other income, net	148	966
Net profit before provision for income taxes	5,432	5,592
Provision for income taxes	(2,796)	(288)
Net profit	$ 2,636	$ 5,304
Net profit per share:		
Basic	$ 0.04	$ 0.08
Diluted	$ 0.04	$ 0.07
Shares used in computing net profit per share:		
Basic	65,983	69,053
Diluted	66,447	70,860

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)

	March 31, 2009	December 31, 2008
ASSETS		
Current assets:		
Cash and cash equivalents	$ 97,051	$ 87,100
Marketable securities, short-term	27,633	23,066
Accounts receivable, net of allowance for doubtful accounts of $811 and $612, respectively	51,665	52,362
Inventories, net	2,068	1,965
Prepaid expenses and other current assets	14,588	13,414
Total current assets	193,005	177,907
Property and equipment, net	26,000	26,979
Goodwill	478	478
Intangible assets, net	7,088	7,788
Deferred tax asset	61,133	61,696
Other assets	1,573	4,493
Total assets	$ 289,277	$ 279,341
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 6,064	$ 5,580
Accrued liabilities	35,656	38,282
Deferred revenues	19,654	16,710
Total current liabilities	61,374	60,572
Other long-term liabilities	204	229
Total liabilities	61,578	60,801
Commitments and contingencies (Notes 5 and 7)		
Stockholders equity:		
Preferred stock, $0.0001 par value (5,000 shares authorized; none issued)		
Common stock, $0.0001 par value (200,000 shares authorized; 66,182 and 65,633 shares issued, respectively; 66,182 and 65,633 shares outstanding, respectively)	7	7
Additional paid-in capital	446,354	439,494
Accumulated other comprehensive income (loss), net	(68)	269
Accumulated deficit	(218,594)	(221,230)
Total stockholders equity	227,699	218,540
Total liabilities and stockholders equity	$ 289,277	$ 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)

	Three Months Ended, March 31	
	2009	**2008**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net profit	$ 2,636	$ 5,304
Adjustments to reconcile net profit to net cash provided by operating activities:		
Deferred taxes	563	
Depreciation and amortization	2,443	2,353
Stock-based compensation	3,715	4,011
Amortization of intangibles	700	709
Provision (benefit) from doubtful accounts	201	(94)
Loss on retirement and disposal of fixed assets	6	126
Excess tax benefit from share-based payment arrangements		(45)
Changes in assets and liabilities:		
Accounts receivable	(81)	(1,838)
Inventories	(117)	(93)
Prepaid expenses and other current assets	(1,267)	698
Accounts payable	738	951
Accrued and other long-term liabilities	(2,038)	(9,736)
Deferred revenues	3,104	816
Net cash provided by operating activities	10,603	3,162
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	(1,886)	(5,192)
Proceeds from sale of property and equipment		185
Purchase of marketable securities	(13,977)	(10,725)
Maturities of marketable securities	12,293	30,859
Other assets	36	108
Net cash (used in) provided by investing activities	(3,534)	15,235
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock	3,252	6,247
Payments on short-term obligations	(136)	
Excess tax benefit from share-based payment arrangements		45
Employees taxes paid upon the vesting of restricted stock units	(107)	(170)
Net cash provided by financing activities	3,009	6,122
Effect of foreign exchange rate changes on cash and cash equivalents	(127)	21
Net increase in cash and cash equivalents	9,951	24,540
Cash and cash equivalents, beginning of the period	87,100	89,140
Cash and cash equivalents, end of the period	$ 97,051	$ 113,680

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 March 31, 2009, its results of operations for the three months ended March 31, 2009 and 2008, and its cash flows for the three months ended March 31, 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 and financial position.

The results of operations for the three months ended March 31, 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.

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 157, Fair Value Measurements (FAS 157) 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 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, 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) companies are allowed to delay the effective date of SFAS 157 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, or (FSP 157-3), was issued and effective upon issuance, including prior periods for which financial statements have not been issued. FSP 157-3 clarified the application of FAS 157 in a market that is not active. Effective January 1, 2008, the Company adopted the provisions of FAS 157 for all financial assets and liabilities. Effective January 1, 2009, the Company adopted FSP 157-2 and 157-3. The adoption of these FSPs did not have a material impact on the Company s consolidated financial statements.

In April 2009, the FASB issued FSP FAS 115-2 *Recognition and Presentation of Other-Than-Temporary Impairments* (FSP 115-2), which is effective for the Company for the quarterly period beginning April 1, 2009. FSP 115-2 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 FSP did not have a material effect on the Company s consolidated financial statements.

In April 2009, the FASB issued FSP No. FAS 157-4, *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 No. 157-4 is effective for interim and annual periods ending after June 15, 2009 and will be adopted by the Company beginning in the second quarter of 2009. Although the Company will continue to evaluate the application of FSP No. 157-4, management does not currently believe adoption of these accounting pronouncements will have a material impact on the Company s consolidated financial statements.

In April 2009, the FASB issued FSP 107-1 and APB 28-1, *Interim Disclosures about Fair Value of Financial Instruments.* This FSP amends FASB Statement No. 107, *Disclosures about Fair Value of Financial Instruments*, to require disclosures about fair value of financial instruments for interim reporting periods of publicly traded companies as well as in annual financial statements. This FSP also amends APB Opinion No. 28, *Interim Financial Reporting*, to require those disclosures in summarized financial information at interim reporting periods. FSP FAS 107-1 and APB 28-1 is effective for interim and annual reporting periods ending after June 15, 2009. The Company does not believe that the adoption of this standard will have a material impact on its consolidated financial statements.

In April 2009, the FASB issued FSP 141(R)-1, *Accounting for Assets Acquired and Liabilities Assumed in a Business Combination That Arise from Contingencies*. The FSP amends the guidance in FASB Statement No. 141 (Revised 2007) and require 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

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such an asset or liability cannot be reasonably estimated, the asset or liability would generally be recognized in accordance with FASB Statement No. 5, *Accounting for Contingencies,* and FASB Interpretation No. 14, *Reasonable Estimation of the Amount of a Loss.* This FSP 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 did not have a material effect on the Company s consolidated financial statements.

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 March 31, 2009 and December 31, 2008 are as follows (in thousands):

March 31, 2009	Amortized Costs	Unrealized Gains	Unrealized Losses	Fair Value
U.S. government notes and bonds	$ 20,969	$ 13	$	$ 20,982
Corporate bonds and certificates of deposit	4,656	1	(12)	4,645
Agency bonds and discount notes	2,000	6		2,006
Total	$ 27,625	$ 20	$ (12)	$ 27,633

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 March 31, 2009, all short-term investments have maturity dates of less than one year. For the three months ended March 31, 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 March 31, 2009, the Company did not hold any long term marketable securities.

Fair Value Measurements

The Company follows the provisions of FAS 157 for measuring the fair value of its cash equivalents and marketable securities effective January 1, 2008. FAS 157 defines fair value 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. FAS 157 establishes a 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. FAS 157 establishes three levels of inputs that may be used to measure fair value:

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

The Company s Level 1 assets and liabilities consist of U.S. government debt securities and money market funds.

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 and liabilities consist of agency bonds and discount notes, corporate bonds, and certificates of deposit.

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 and liabilities during the quarter ended March 31, 2009.

The following table summarizes the Company s financial assets measured at fair value on a recurring basis in accordance with FAS 157 as of March 31, 2009 (in thousands):

Description	Balance as of March 31, 2009	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)
Cash equivalents:			
Money market funds	$ 69,577	$ 69,577	$
U.S. government debt securities	4,000	4,000	
Short-term investments:			
Corporate bonds and certificates of deposit	4,645		4,645
U.S. government debt securities	20,982	20,982	
Agency bonds and discount notes	2,006		2,006
	$ 101,210	$ 94,559	$ 6,651

Note 3. Balance Sheet Components

Inventories, net are comprised of (in thousands):

	March 31, 2009	December 31, 2008
Raw materials	$ 916	$ 1,066
Work in process	402	416
Finished goods	750	483
	$ 2,068	$ 1,965

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

Accrued liabilities consist of the following (in thousands):

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	March 31, 2009	December 31, 2008
Accrued payroll and benefits	$ 15,270	$ 17,795
Accrued restructuring	1,647	2,501
Accrued sales and marketing expenses	3,164	2,449
Accrued sales rebate	1,972	2,205
Accrued warranty	1,995	2,031
Other	11,608	11,301
	$ 35,656	$ 38,282

Note 4. Intangible Assets

The following is a summary of the Company s purchased intangible assets as of March 31, 2009 and December 31, 2008 (in thousands):

		March 31, 2009			December 31, 2008		
	Estimated Useful Life (in years)	Gross Carrying Value	Accumulated Amortization	Net Carrying Value	Gross Carrying Value	Accumulated Amortization	Net Carrying Value
Non-compete agreements	5	$ 14,000	$ 6,912	$ 7,088	$ 14,000	$ 6,212	$ 7,788

These intangible assets are being amortized on a straight-line basis over the expected useful life of five years. 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.

Non-compete agreements represent the fair value of assets received in conjunction with the OrthoClear Agreement. These intangible assets are being amortized on a straight-line basis over the expected useful life of five years beginning in 2006.

The total estimated annual future amortization expense for these intangible assets as of March 31, 2009 is as follows (in thousands):

Fiscal Year	
2009 (remaining 9 months)	$ 2,100

2010		2,800
2011		2,188
Total	$	7,088

Note 5. Legal Proceedings

Ormco

On January 6, 2003, Ormco Corporation (Ormco), a division of Sybron Dental Specialties (a Danaher Corporation subsidiary), filed suit against the Company in the United States District Court for the Central District, Orange County Division, asserting infringement of certain patents. The complaint sought unspecified monetary damages and injunctive relief. On February 18, 2003, the Company answered the complaint and asserted counterclaims seeking a declaration by the Court of invalidity and non-infringement of the asserted patents. In addition, the Company counterclaimed for infringement of one of its patents, seeking unspecified monetary damages and injunctive relief. Ormco filed a reply to its counterclaims on

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March 10, 2003 and asserted counterclaims against the Company seeking a declaration by the Court of invalidity and non-infringement of the patent.

There have been two appeals. After the permanent injunction was entered, Ormco and Allesee Orthodontic Appliances, Inc. (AOA) appealed that injunction and the orders of the District Court on summary judgment on which the injunction was based. Oral arguments took place on April 3, 2006. Following oral arguments, the U.S. Court of Appeals for the Federal Circuit (CAFC) issued a ruling declaring two out of a total of seventy-one claims in the Company s US Patent No. 6,398,548 and four out of a total of ten claims in US Patent No. 6,554,611 to be invalid as obvious. The CAFC s decision reverses the California District Court summary judgment order of validity.

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 the Company and that the asserted claims are invalid. Align appealed the ruling of the District Court that certain claims of its 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 the four asserted Ormco patents are invalid and not infringed by Align. The CAFC reversed the District Court s non-infringement rulings on six claims in Ormco s 6,616,444 patent.

Ormco has filed a petition with the U.S. Supreme Court asking for an extension of time in which to file a petition for review by 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 the 86 claims. The Supreme Court denied Ormco s petition, and the case on the six claims in Ormco s 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 the Company s motion to amend its answer and counterclaim to assert Ormco s patent is unenforceable due to inequitable conduct. The parties are currently conducting discovery. Trial on liability issues is scheduled for June 2, 2009.

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 the Company s motion on two theories of non-infringement. The Company s invalidity argument supported by over fifty prior art references was unaffected. The District Court also ruled that one of the Company s inequitable conduct theories should be resolved at trial. A finding of inequitable conduct at trial could render the six claims at issue and possibly the family of Ormco patents related to the 6,616,444 patent unenforceable.

Trial on liability issues is scheduled for June 2, 2009. Despite the District Court s ruling of infringement on one of Ormco s theories, if the jury finds Ormco s six claims to be invalid or unenforceable, there can be no liability for infringement. The Company intends to vigorously pursue its invalidity and inequitable conduct counterclaims at trial.

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 .

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.

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

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Note 6. 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 March 31, 2009, the Company had no outstanding borrowings under this credit facility and is in compliance with the financial covenants.

Note 7. Commitments and Contingencies

As of March 31, 2009, minimum future lease payments for non-cancelable leases are as follow (in thousands):

Years Ending March 31,		
2009 (remaining 9 months)	$	2,677
2010		2,806
2011		2,206
2012		1,738
2013 and thereafter		1,085
Total	$	10,512

In July 2008, the Company entered into an agreement in favor and for the benefit of Elamex de Juarez, S.A. DE C.V., landlord to IMS, its third party shelter services provider, to guarantee IMS s lease payments for its facility located in Juarez, Mexico. The current lease for the facility expires in July 2013. Pursuant to the guarantee, the Company was obligated to pay Elamex de Juarez, S.A. DE C.V. for any rental payments in default by IMS. 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 and product shipment for this location. A wholly-owned subsidiary of Align in Mexico has assumed IMS lease obligations with Elamex, and the Company guarantees the lease payments for its subsidiary which are included in the table above. Additionally, the Company has agreed to an extended consulting services arrangement with IMS effective in April 2009 for transitional services to be performed for an additional twelve months at a total cost of approximately $0.2 million.

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 three months ended March 31, 2009 and 2008, respectively (in thousands):

	Three Months Ended March 31	
	2009	2008
Balance at beginning of period	$ 2,031	$ 2,035
Charged to cost of revenues	623	555
Actual warranty expenses	(659)	(588)
Balance at end of period	$ 1,995	$ 2,002

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Note 8. Stock-based Compensation

Summary of stock-based compensation expense

Stock-based compensation expense recognized in the Condensed Consolidated Statements of Operations for the three months ended March 31, 2009 and 2008 is based on options ultimately expected to vest and has been reduced for estimated forfeitures. FAS 123R requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Forfeitures were estimated based on historical experience. The following table summarizes stock-based compensation expense related to all of the Company s stock-based options and employee stock purchases under FAS 123R for the three months ended March 31, 2009 and 2008:

	Three Months Ended March 31,	
(In thousands)	**2009**	**2008**
Cost of revenues	$ 386	$ 390
Sales and marketing	951	1,239
General and administrative	1,954	1,834
Research and development	424	548
Total stock-based compensation expense	$ 3,715	$ 4,011

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 March 31,	
	2009	**2008**
Stock Options:		
Expected term (in years)	4.4	4.4
Expected volatility	61.4%	59.8%
Risk-free interest rate	1.55%	2.7%
Expected dividend		
Weighted average fair value at grant date	$ 3.90	$ 6.53
Employee Stock Purchase Plan:		
Expected term (in years)	1.3	1.3
Expected volatility	74.7%	70.4%
Risk-free interest rate	0.63%	2.2%
Expected dividend		
Weighted average fair value at grant date	$ 3.72	$ 5.40

Stock Incentive Plans

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

Options

Stock option activity for the three months ended March 31, 2009 under the stock incentive plans is set forth below:

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	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	940	7.82				
Cancelled or expired	(134)	13.68				
Exercised	(133)	6.05				
Outstanding as of March 31, 2009	7,982	$ 11.24	7.0	3,049	$ 6.66	3,884
Vested and expected to vest at March 31, 2009	7,703	$ 11.23	6.9	2,942	$ 6.62	3,867
Exercisable at March 31, 2009	4,711	$ 10.79	5.7	2,074	$ 6.16	3,677

The aggregate intrinsic value in the table above represents the total pre-tax intrinsic value (the difference between Align s closing stock price on the last trading day of the first quarter of 2009 of $7.93 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 March 31, 2009. This amount changes based on the fair market value of Align s stock.

The total intrinsic value of stock options exercised for the three months March 31, 2009 and 2008 was $0.3 million and $3.6 million. As of March 31, 2009, Align expects to recognize $19.9 million of total unamortized compensation cost related to stock options over a weighted average period of 2.7 years. The Company did not recognize tax benefits from exercised options for the three months ended March 31, 2009 as the amount was immaterial.

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 three months ended March 31, 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	280	7.81		
Vested and released	(103)	13.08		
Forfeited	(21)	12.82		
Nonvested as of March 31, 2009	1,028	$ 12.17	1.72	$ 8,150

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 first quarter of 2009 of $7.93 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 March 31, 2009. This amount changes based on the fair market value of Align s stock.

The total intrinsic value of restricted stock units vested and released for the three months ended March 31, 2009 and 2008 was $0.8 million and $1.2 million, respectively. As of March 31, 2009, the total unamortized compensation cost related to restricted stock units was $11.4 million, which Align expects to recognize over a weighted average period of 2.7 years. The Company did not recognize tax benefits from restricted stock units that vested during the three months ended March 31, 2009 as the amount was immaterial.

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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 shares in accordance with FAS 123R. The fair value of the option component of the Purchase Plan shares was estimated at the date of grant using the Black-Scholes option pricing model.

As of March 31, 2009, Align expects to recognize $3.8 million of total unamortized compensation cost related to employee stock purchases over a weighted average period of 0.8 years.

Note 9. Accounting for Income Taxes

The Company accounts for income tax uncertainties in accordance with FASB Interpretation No. 48, Accounting for Uncertainty in Income Taxes (FIN48). This interpretation clarifies the criteria for recognizing income tax benefits under FASB Statement No. 109, Accounting for Income Taxes , and requires additional disclosures about uncertain tax positions. Under FIN 48, the financial statement recognition of the benefit for a 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 first 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 $3.4 million as of March 31, 2009, which would impact the Company s effective tax rate if recognized. In accordance with FIN 48, 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 March 31, 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 2004.

Note 10. Net Profit Per Share

Basic net profit per share is computed using the weighted average number of shares of common stock during the period. Diluted net profit 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 per share attributable to common stock (in thousands, except per share amounts):

	Three Months Ended March 31,	
	2009	2008
Net profit	$ 2,636	$ 5,304
Weighted-average common shares outstanding, basic	65,983	69,053
Effect of potential dilutive common shares	464	1,807
Total shares, diluted	66,447	70,860
Basic net profit per share	$ 0.04	$ 0.08
Diluted net profit per share	$ 0.04	$ 0.07

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For the three months ended March 31, 2009 and 2008, stock options and restricted stock units totaling 5.9 million and 3.9 million, respectively, were excluded from diluted net profit per share because of their anti-dilutive effect.

Note 11. 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 March 31,	
	2009	2008
Net profit	$ 2,636	$ 5,304
Foreign currency translation adjustments	(206)	296
Changes in unrealized gain/(loss) on available-for-sale securities	4	46
Comprehensive income	$ 2,434	$ 5,646

Note 12. Segments and Geographical Information

Segment

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

Geographical Information

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

	Three Months Ended March 31,	
	2009	2008
Net revenues:		
North America	$ 55,293	$ 60,258
Europe	14,352	14,155
Other international	487	363
Total net revenues	$ 70,132	$ 74,776

	As of March 31, 2009	As of December 31, 2008
Long-lived assets:		
North America	$ 93,953	$ 99,086
Europe	1,005	960
Other international	1,314	1,388
Total long-lived assets	$ 96,272	$ 101,434

Note 13. Restructuring

During 2008, the Company announced restructuring plans in July and October to increase efficiencies across the organization and lower the overall cost structure. In July 2008, the Company implemented a restructuring plan to reduce its full time headcount including a phased-consolidation of order acquisition operations from its 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 is expected to complete in the first half of 2009.

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For the three months ended March 31, 2009, the Company incurred approximately $0.9 million in restructuring expense.

Activity and liability balances related to restructuring activity for the quarter ended March 31, 2009 are as follows (in thousands):

		Severance and Benefits
Balance at December 31, 2008	$	2,501
Restructuring accrual		1,032
Cash payments		(1,886)
Balance at March 31, 2009	$	1,647

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

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

In addition to historical information, this quarterly report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. These statements include, among other things, statements concerning our expectations regarding the expected 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 expectations regarding the relocation of several customer facing organizations from our Santa Clara, California facility to our facility in Costa Rica, including the timing of such relocation, 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 product volumes and revenues compared to 2008, the anticipated level of our 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.

Overview

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 the four key objectives: driving product innovation, enhancing the customer experience, generating consumer demand and expanding into international markets.

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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.

With the introduction of Invisalign Teen, our Invisalign product family now 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. We expect that orthodontists will adopt Invisalign Teen slowly, after they experience multiple successful treatment outcomes. As a result, we anticipate that Invisalign Teen volume may increase gradually and will not constitute a significant portion of our total product mix in the near-term.

Our most recently launched product, Invisalign Assist, is intended to help newly-trained and low 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. We believe 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 recent launch of Invisalign Teen and Invisalign Assist and 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.

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.* Increasing the number of Invisalign trained doctors and ensuring that these 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

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well as improving their practice management skills. In early 2008, we announced the introduction of 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. Lastly, as trained Invisalign providers grow their case starts with Invisalign, programs such as the Advantage Program provide tiered benefits including volume rebates, dedicated clinical support and a premium website position on the Invisalign Doctor Locator website to those leading providers. 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 will focus 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 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 March 31, 2009, we have trained over 14,000 doctors, predominantly orthodontists in core 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 that was first launched in March 2007. Additionally, although the vast majority of our international revenues are from direct sales, approximately 9% 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 smaller or less strategic markets as well as consider expanding directly into additional countries on a case-by-case basis. With these efforts, we expect our international revenues to continue to increase in absolute dollars and as a percentage of total net revenues 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.

- *Impact on consumer spending due to a decline in general economic conditions.* 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 as well as an uncertain economic outlook have adversely affected consumer spending habits. As a result of the decline in general economic conditions, we expect that our product volumes and revenues will decline in 2009 compared to 2008. In addition, the decline in general economic conditions

may further have the impact of decreasing the number of orthodontic case starts overall.

- *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

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utilization rates from the years ended 2007 and 2008 through the first 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, year over year utilization rates declined slightly for our North America channel in each quarter of 2008 compared to the same quarter in 2007 and in the first quarter of 2009 compared to the same quarter in 2008. Although for the first quarter of 2009 compared to the same quarter in 2008, the utilization rate remained relatively flat for our international channel, and declined slightly for our GP and Ortho channels. We believe that the continued economic slowdown has negatively impacted many of our customers and will continue to negatively impact our customers generally and our North America GP customers in particular.

- *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 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. 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 the facility in Juarez, Mexico and directly coordinate order acquisition and product shipment for 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

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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 or are on holiday during the summer months and therefore tend to start fewer cases. 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 as we create 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 are currently located in Santa Clara, California. We continue to phase the relocation to Costa Rica in an attempt to minimize disruptions to customer service levels and expect the relocation to be substantially completed during the second quarter of 2009. *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.*

- *Review of our investment portfolio and policies.* Our cash equivalent and short-term investment portfolio as of the date of this Form 10-Q consisted of U.S. government notes and bonds, corporate bonds and certificates of deposits, and agency bonds and discount notes. We follow an established investment policy and set of guidelines to monitor, manage and limit our exposure to interest rate, liquidity and credit risk. The policy sets forth credit quality standards and limits our exposure to any one issuer, as well as our maximum exposure to various asset classes. As a result of current adverse financial market conditions, investments in some financial instruments, such as structured investment vehicles, sub-prime mortgage-backed securities and collateralized debt obligations, may pose risks arising from liquidity and credit concerns. As of the date of this Form 10-Q, we had no direct holdings in these categories of investments and our indirect exposure to these financial instruments through our holdings in money market mutual funds was immaterial. Also, as of the date of this Form 10-Q, we had no impairment charge associated with our short-term investment portfolio relating to such adverse financial market conditions. Although we believe our current investment portfolio has very 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. See *Part II, Item 1A Risk Factors for risks related to global financial and securities markets.*

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Our short-term marketable securities as of March 31, 2009 are as follows (in thousands):

March 31, 2009	Amortized Costs	Unrealized Gains	Unrealized Losses	Fair Value
U.S. government notes and bonds	$ 20,969	$ 13	$	$ 20,982
Corporate bonds and certificates of deposit	4,656	1	(12)	4,645
Agency bonds and discount notes	2,000	6		2,006
Total	$ 27,625	$ 20	$ (12)	$ 27,633

- *Effective Tax Rate.* Our effective tax rate may vary significantly from period to period. Various internal and external factors may have favorable 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.

- *Stock-based compensation.* We implemented Statement of Financial Accounting Standards No. 123 (Revised 2004), Share-based Payment (FAS 123R) in 2006, and we expect stock-based compensation to increase on an annual basis until at least 2010, which corresponds to our standard 4 year vesting term. Thereafter, new grants will continue to be expensed over the vesting period, however, the additional expense from new grants may be offset by fully vested grants that are no longer expensed. For the three months ended March 31, 2009 and 2008, stock-based compensation expense recognized in accordance with FAS 123R is as follows (in thousands):

	Three Months Ended March 31, 2009		Three Months Ended March 31, 2008	
	Stock-based Compensation	% of net revenues	Stock-based Compensation	% of net reveues
Cost of revenues	$ 386	0.6%	$ 390	0.5%
Sales and marketing	951	1.4%	1,239	1.7%
General and administrative	1,954	2.8%	1,834	2.5%
Research and development	424	0.6%	548	0.7%
Total stock-based compensation expense	$ 3,715	5.3%	$ 4,011	5.4%

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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 months ended March 31, 2009 and 2008 are as follows (in millions):

	Three Months Ended March 31,			
Net revenues	**2009**	**2008**	**Net Change**	**% Change**
North America:				
Ortho	$ 21.1	$ 22.5	$ (1.4)	(6.5)%
GP	30.9	34.0	(3.1)	(8.9)%
Total North American Invisalign	52.0	56.5	(4.5)	(7.9)%
International Invisalign	14.3	14.2	0.1	0.5%
Total Invisalign revenues	66.3	70.7	(4.4)	(6.2)%
Non-case revenues	3.8	4.1	(0.3)	(5.7)%
Total net revenues	$ 70.1	$ 74.8	$ (4.7)	(6.2)%

Case volume data which represents Invisalign case shipments by channel, for the three months ended March 31, 2009 and 2008 are as follows (in thousands):

	Three Months Ended March 31,			
Invisalign case volume	**2009**	**2008**	**Net Change**	**% Change**
North America:				
Ortho	16.9	17.6	(0.7)	(4.0)%
GP	23.3	25.9	(2.6)	(10.0)%
Total North American Invisalign	40.2	43.5	(3.3)	(7.6)%
International Invisalign	9.9	8.3	1.6	19.3%
Total Invisalign case volume	50.1	51.8	(1.7)	(3.3)%

Our total net revenues decreased for the three months ended March 31, 2009 compared to the same period in 2008. Revenues for North America Invisalign were negatively impacted predominantly by lower case volumes and by a slight shift in product mix towards our new products which have a higher amount of deferred revenue as a percentage of their average selling prices. The decline in revenue was partially offset by the price increases effective at the beginning of 2009. Our international Invisalign revenues were comparable to the first quarter of 2008. Although international case volumes grew from the same period in 2008, the growth was offset by unfavorable exchange rates against the U.S. dollar.

For 2009, we expect our total net revenues to decrease compared to 2008 primarily due to case volume decreases in North America partially offset by expected growth in international revenue. We expect our mix of products to continue to shift in 2009 due to new products introduced in the second half of 2008. These new products have a significantly higher amount of deferred revenue as a percentage of their average selling price compared to Invisalign Full.

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Cost of revenues and gross profit:

(In millions)	Three Months Ended March 31, 2009	2008	Change
Cost of revenues	$ 17.4	$ 19.6	$ (2.2)
% of net revenues	24.8%	26.2%	
Gross profit	52.7	55.2	$ (2.5)
Gross profit%	75.2%	73.8%	

Cost of revenues includes salaries for staff involved in the production process, costs incurred by IMS, a third party shelter service provider in Juarez, Mexico, the cost of materials, packaging, shipping costs, depreciation on capital equipment used in the production process, training costs and stock-based compensation expense.

Gross margin improved in the three months ended March 31, 2009 compared to the same period in 2008 primarily due to improved operating efficiencies, 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. Additionally, lower training revenue in the same period resulting from a decrease in the number of training events and doctors trained had a favorable impact as training carries nominal gross margins.

We anticipate our gross profit in 2009 to improve from 2008 levels as we benefit from the 2008 restructuring and improved operating efficiencies.

Sales and marketing:

(In millions)	Three Months Ended March 31, 2009	2008	Change
Sales and marketing	$ 27.9	$ 28.1	$ (0.2)
% of net revenues	39.7%	37.5%	

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

Our sales and marketing expenses slightly decreased in the three months ended March 31, 2009 as compared to the same period in 2008 primarily due to lower spending on advertising and promotions, media and research of approximately $2.1 million, which was partially offset by increases in clinical education and public relations costs of approximately $1.2 million. In addition, the decrease in marketing related expenses also included lower stock-based compensation expense of $0.3 million, which was offset by higher personnel expenses of approximately $1.5 million primarily relating to an increase in commissions resulting from target attainment for the three months ended March 31, 2009.

We expect sales and marketing expense levels in 2009 to be lower than 2008. In 2009, we expect to invest in our international channel, including consumer advertising and sales force expansion, and continue commercialization of new products in North America, offset by benefits from the transition of our customer care organization, a part of our shared services organization, to Costa Rica in 2009, which was part of the October 2008 restructuring.

General and administrative:

	Three Months Ended March 31,		
(In millions)	**2009**	**2008**	**Change**
General and administrative	$ 13.5	$ 15.2	$ (1.7)
% of net revenues	19.2%	20.3%	

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

General and administrative expenses decreased in the three months ended March 31, 2009 as compared to the same period in 2008 primarily due to proceeds from an insurance reimbursement of $1.5 million that we received in March 2009 relating to the OrthoClear settlement. In addition, payroll related expenses, including stock-based compensation expense, were lower by $0.2 million in the three months ended March 31, 2009.

We expect general and administrative expense in 2009 to be lower than 2008 levels as we begin to benefit from the October 2008 restructuring and the transition of our shared services organizations to Costa Rica in 2009.

Research and development:

	Three Months Ended March 31,		
(In millions)	**2009**	**2008**	**Change**
Research and development	$ 5.2	$ 7.3	$ (2.1)
% of net revenues	7.4%	9.8%	

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 expenses were lower during the three months ended March 31, 2009 compared to the same period in 2008 primarily due to a $1.4 million decrease in payroll-related expenses, including stock-based compensation, resulting from lower headcount.

We expect research and development expense to decrease in 2009 as compared to 2008 as a result of reduced headcount from the 2008 restructuring and lower consulting expenses.

Restructuring:

	Three Months Ended March 31,		
(In millions)	**2009**	**2008**	**Change**
Restructuring	$ 0.9	$	$ 0.9
% of net revenues	1.3%	0.0%	

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 expect to substantially complete during the second quarter of 2009. For the three months ended March 31, 2009, we incurred approximately $0.9 million in restructuring expenses, which were related to severance and termination benefits.

Interest and other income, net:

	Three Months Ended March 31,		
(In millions)	**2009**	**2008**	**Change**
Interest income	$ 0.2	$ 1.1	$ (0.9)
Other income (expense), net	(0.1)	(0.1)	
Total interest and other, net	$ 0.1	$ 1.0	$ (0.9)

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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 for the three months ended March 31, 2009 decreased compared to the same period in 2008 primarily due to lower average cash, cash equivalents and marketable securities balances and lower interest rates from shifting our investments into more conservative securities principally, US government securities, which bear lower interest rates.

Other income (expense), net in the three months ended March 31, 2009 was consistent with the same period in 2008.

*Income tax provision***:**

	Three Months Ended March 31,		
(In millions)	**2009**	**2008**	**Change**
Provision for income taxes	$ 2.8	$ 0.3	$ 2.5

We recorded an income tax provision of $2.8 million for the three months ended March 31, 2009 and income tax provision of $0.3 million for the three months ended March 31, 2008. These represented effective tax rates of 51.5% and 5.2% for the three months ended March 31, 2009 and March 31, 2008, respectively. Our income tax provision is 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 available positive 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 as we cannot forecast sufficient future capital gains or foreign source income to realize these deferred tax assets. Therefore, we recorded a tax valuation allowance release of $64.6 million in the fourth quarter of 2008. The remaining valuation allowance of approximately $6.2 million relating to capital loss and foreign net operating loss carryforwards as of December 31, 2008, 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 under SFAS 109 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 included in the effective tax rate at 51.5%.

Liquidity and Capital Resources

We fund our operations from product sales, the proceeds from the sale of common stock, and from occasional borrowings under our available credit facility. As of March 31, 2009 and December 31, 2008 we had the following cash and cash equivalents, and shirt-terms marketable securities (in thousands):

	March 31, 2009	December 31, 2008
Cash and cash equivalents	$ 97,051	$ 87,100
Marketable securities, short-term	27,633	23,066
Total	$ 124,684	$ 110,166

Net cash provided by operating activities was $10.6 million for the three months ended March 31, 2009 resulting primarily from our net profit of $2.6 million adjusted for non-cash items such as depreciation, amortization of intangibles and stock-based compensation expense totaling $6.9 million. These increases in cash flows from operating activities were due primarily to a $4.4 million increase in accounts payable, deferred revenue, and deferred taxes, which were offset by a $3.5 million decrease in accrued liabilities, prepaids, and other assets.

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Net cash provided by operating activities was $3.2 million for the three months ended March 31, 2008, resulting primarily from our net profit of $5.3 million adjusted for non-cash items such as depreciation and amortization, amortization of intangibles and stock-based compensation expense totaling $7.1 million. These increases in cash flows from operating activities were partially offset by a $9.2 million decrease in net assets, primarily due to a $9.7 million decrease in accrued and other long-term liabilities.

Net cash used in investing activities was $3.5 million for the three months ended March 31, 2009, largely consisted of $14.0 million used for the purchase of marketable securities and $1.9 million on property, plant, and equipment, which were partially offset by $12.3 million of proceeds from net maturities of marketable securities. Net cash provided by investing activities was $15.2 million for the three months ended March 31, 2008, largely consisting of $20.1 million of net maturities of marketable securities partially offset by $5.2 million used for the purchase of capital assets.

As a result of current 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 very 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 $3.0 million for the three months ended March 31, 2009, which primarily resulted from $3.3 million in proceeds from the issuance of our common stock. Net cash provided by financing activities was $6.1 million for the three months ended March 31, 2008 resulting primarily from $6.2 million in proceeds from the issuance of our common stock, primarily from exercises of employee stock options.

In July 2008, we entered into an agreement in favor and for the benefit of Elamex de Juarez, S.A. DE C.V., landlord to IMS, our third party shelter services provider, to guarantee IMS s lease payments for its facility located in Juarez, Mexico. The current lease for the facility expires in July 2013. Pursuant to the guarantee, we were obligated to pay Elamex de Juarez, S.A. DE C.V. for any rental payments in default by IMS. 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 for this location. A wholly-owned subsidiary of Align in Mexico has assumed IMS lease obligations with Elamex, and we guarantee the lease payments for our subsidiary. Additionally, we have agreed to an extended consulting services arrangement with IMS effective in April 2009 for transitional services to be performed for an additional twelve months at a total cost of approximately $0.2 million.

Contractual Obligations

As of March 31, 2009 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.

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.

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There have been no significant changes in our critical accounting policies during the three months ended March 31, 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.

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 March 31, 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

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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.

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. The parties are currently completing fact discovery.

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. A finding of inequitable conduct at trial could render the six claims at issue and possibly the family of Ormco patents related to the 6,616,444 patent unenforceable.

Trial on liability issues is scheduled for June 2, 2009. Despite the District Court s ruling of infringement on one of Ormco s theories, if the jury finds Ormco s six claims to be invalid or unenforceable, there can be no liability for infringement. We intend to vigorously pursue our invalidity and inequitable conduct counterclaims at trial.

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,

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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.

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.

Litigating claims of the types discussed in this Annual Report on Form 10-K, 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.

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ITEM 1A. RISK FACTORS

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

Although we maintained profitability in 2008 and in the first quarter 2009, 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 the first quarter 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;
- 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;
- 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

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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 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.

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 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 adoption of Invisalign 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.

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 both orthodontists, GPs and consumers regarding Invisalign as both an alternative to braces and as a clinical method for treatment of malocclusion, but a number of dental professionals believe that Invisalign is appropriate for only a limited percentage of their patients. Market acceptance will depend in part upon the recommendations of dental professionals, as well as other factors including effectiveness, safety, 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.

Our success depends upon increasing acceptance and frequency of use of the Invisalign system by dental professionals (what we refer to as utilization). Invisalign requires orthodontists, GPs and their staff to undergo special training and learn to interact with patients in new ways. If GPs and Orthos do not attend these training courses in sufficient numbers for any reason, including as a result of declining general economic conditions or if newly trained GPs and Orthos do not increase their adoption and frequency of use as anticipated, our revenue may fail to grow as expected. Increasing adoption and cumulative use by orthodontists and GPs will depend on factors such as the capability, safety, efficacy, ease of use, price, quality and reliability of our products, our ability to provide effective sales support, training and service and the availability of competing products, technologies and alternative treatments. In addition, unanticipated poor clinical performance of Invisalign could result in

significant adverse publicity and, consequently, reduced acceptance by dental professionals. Also increased competition from direct competitors could cause us to lose market share and reduce dental professionals efforts and commitment to expand their Invisalign practice. If 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.

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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 from higher priced products to lower price products, 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 as a result 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.

We may experience unexpected problems and expenses associated with the phased-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 currently located in Santa Clara, California, to our facility in Costa Rica. We expect this relocation to be completed by the end of July 2009. This relocation is accompanied by a number of risks and uncertainties that may affect our results of operations and statement of cash flows, including:

- failure to successfully coordinate and phase the relocation of these customer facing organizations may cause our customers to experience decrease in service levels;

- the relocation may absorb significant management and key employee attention and resources that would otherwise be available for the ongoing business operations;

- failure to retain key employees who possess specific knowledge or expertise and upon whom we are depending upon for the timely and successful transition to Costa Rica; and

- difficulties in hiring 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.

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. 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.

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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 the 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 are currently located in Santa Clara, California, to our facility in Costa Rica. We expect this relocation to be completed 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;
- 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.

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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.

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.

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 are also transitioning 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

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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.

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 March 31, 2009, we had 121 issued U.S. patents, 179 pending U.S. patent applications, and 47 issued foreign patents, and 129 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. Management does not believe that the ultimate outcome of these other legal proceedings and claims will have a material adverse effect on our financial position or results of operations. In addition, litigation is subject to inherent uncertainties and unfavorable rulings could occur. An unfavorable ruling could include monetary damages or, in cases where injunctive relief is sought, an injunction prohibiting us from selling our products. Any of these results from our litigation could adversely affect our results of operations and stock price. *See Part II, Item 1 of this Quarterly Report Form 10-Q for a summary of our material pending legal proceedings.*

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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.

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.

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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 March 31, 2009, our North American sales organization consisted of 162 people, of which 134 were direct sales representatives and 28 were sales administration and regional sales management. Internationally, we had 41 people engaged in sales and sales support as of March 31, 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.

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 or the failure of IMS 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

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lengthy and time-consuming process. Even though the devices we market have obtained the necessary clearances from the FDA, we may be unable to maintain such clearances in the future. Furthermore, we may be unable to obtain the necessary clearances for new devices that we intend to market in the future. Our inability to maintain or obtain regulatory clearances or approvals could materially harm our business.

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

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

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

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

The healthcare market itself is highly regulated and subject to changing political, economic and regulatory influences. Regulations implemented pursuant to the Health Insurance Portability and Accountability Act (HIPAA), including regulations affecting the security and privacy of patient healthcare information held by healthcare providers and their business associates may require us to make significant and unplanned enhancements of software applications or services, result in delays or cancellations of orders, or result in the revocation of endorsement of our products and services by healthcare participants. The effect of HIPAA and newly enforced regulations on our business is difficult to predict, and there can be no assurance that we will adequately address the business risks created by HIPAA and its implementation or that we will be able to take advantage of any resulting business opportunities.

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

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

- storage, transmission and disclosure of medical information and healthcare records;

- prohibitions against the offer, payment or receipt of remuneration to induce referrals to entities providing healthcare services or goods or to induce the order, purchase or recommendation of our products; and

- the marketing and advertising of our products.

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

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

We currently sell our products in Europe, 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

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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:

- 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. In the past, class action litigation has often been brought against the issuing company following periods of volatility in the market price of a company s securities. If a securities class action suit is filed against us in the future, we would incur substantial legal fees, and our management s attention and resources would be diverted from operating our business in order to respond to the litigation.

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

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

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

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

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- 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.

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 addition, we have negotiated tax incentives with the Costa Rica Ministry of Foreign Trade, an agency of the Government of Costa Rica. Under these incentives, all of the income we earn in Costa Rica during these eight to 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 2010. 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

Not applicable.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

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

None.

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ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

(a) Exhibits:

Exhibit Number	Description	Filing	Date	Exhibit Number	Filed herewith
10.1	Summary of 2008 Incentive Awards for Named Executive Officers.	Form 8-K and Form 8-K/A	01/13/2009 and 01/22/2009	Item 5.02 only	
10.2	Employment Agreement between Sheila Tan and Align Technology, Inc. dated March 3, 2009.				*
31.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				*
31.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				*
32.1	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				*

Management contract or compensatory plan or arrangement

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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: May 7, 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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EXHIBIT INDEX

Exhibit Number	Description	Filing	Date	Exhibit Number	Filed herewith
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