

ALIGN TECHNOLOGY INC
Form 10-Q
May 06, 2010
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2010

OR

☐ **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)

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Delaware
(State or other jurisdiction of
incorporation or organization)

94-3267295
(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 ☒ No ☐

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 ☐ No ☐

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 ☒

Accelerated filer ☐

Non-accelerated filer ☐ (Do not check if a smaller reporting company)

Smaller reporting company ☐

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

The number of shares outstanding of the registrant's Common Stock, \$0.0001 par value, as of April 30, 2010 was 75,677,254.

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ALIGN TECHNOLOGY, INC.

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

Table of Contents**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,	
	2010	2009
Net revenues:		
Invisalign	\$ 85,422	\$ 66,270
Non-case	4,668	3,862
Total net revenues	90,090	70,132
Cost of revenues		
Invisalign	18,607	15,391
Non-case	1,773	2,034
Total cost of revenues	20,380	17,425
Gross profit	69,710	52,707
Operating expenses:		
Sales and marketing	27,946	27,854
General and administrative	14,951	13,468
Research and development	6,116	5,191
Restructurings		910
Total operating expenses	49,013	47,423
Profit from operations	20,697	5,284
Interest and other income (expense), net	(553)	148
Net profit before provision for income taxes	20,144	5,432
Provision for income taxes	5,214	2,796
Net profit	\$ 14,930	\$ 2,636
Net profit per share:		
Basic	\$ 0.20	\$ 0.04
Diluted	\$ 0.19	\$ 0.04
Shares used in computing net profit per share:		
Basic	75,166	65,983

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Diluted

77,597

66,447

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

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

	March 31, 2010	December 31, 2009
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 190,407	\$ 166,487
Marketable securities, short-term	14,991	19,978
Accounts receivable, net of allowance for doubtful accounts of \$589 and \$1,033, respectively	58,801	54,537
Inventories	2,356	2,046
Prepaid expenses and other current assets	18,055	18,251
Total current assets	284,610	261,299
Property and equipment, net	25,418	24,971
Goodwill	478	478
Intangible assets, net	4,288	4,988
Deferred tax asset	56,560	61,535
Other assets	2,198	1,969
Total assets	\$ 373,552	\$ 355,240
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 4,513	\$ 6,122
Accrued liabilities	34,690	42,822
Deferred revenues	37,047	32,299
Total current liabilities	76,250	81,243
Other long-term liabilities	946	961
Total liabilities	77,196	82,204
Commitments and contingencies (Notes 5 and 8)		
Stockholders' equity:		
Preferred stock, \$0.0001 par value (5,000 shares authorized; none issued)		
Common stock, \$0.0001 par value (200,000 shares authorized; 75,608 and 74,568 shares issued, respectively; 75,608 and 74,568 shares outstanding, respectively)	8	7
Additional paid-in capital	533,808	525,073
Accumulated other comprehensive income, net	109	455
Accumulated deficit	(237,569)	(252,499)
Total stockholders' equity	296,356	273,036
Total liabilities and stockholders' equity	\$ 373,552	\$ 355,240

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

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

	Three Months Ended, March 31,	
	2010	2009
Cash Flows from Operating Activities:		
Net profit	\$ 14,930	\$ 2,636
Adjustments to reconcile net profit to net cash provided by operating activities:		
Deferred income taxes	4,975	563
Depreciation and amortization	2,938	2,443
Amortization of intangibles	700	700
Stock-based compensation	3,473	3,715
Amortization of prepaid royalties	827	
Provision for doubtful accounts	(200)	201
Loss on retirement and disposal of fixed assets	6	6
Changes in assets and liabilities:		
Accounts receivable	(4,857)	(81)
Inventories	(319)	(117)
Prepaid expenses and other current assets	(738)	(1,267)
Accounts payable	(271)	738
Accrued and other long-term liabilities	(7,927)	(2,038)
Deferred revenues	5,108	3,104
Net cash provided by operating activities	18,645	10,603
Cash Flows from Investing Activities:		
Purchase of property and equipment	(4,530)	(1,886)
Purchases of marketable securities		(13,977)
Maturities of marketable securities	4,988	12,293
Other assets	(246)	36
Net cash provided by (used in) investing activities	212	(3,534)
Cash Flows from Financing Activities:		
Proceeds from issuance of common stock	6,016	3,252
Payments on short-term obligations		(136)
Employees' taxes paid upon the vesting of restricted stock units	(755)	(107)
Net cash provided by financing activities	5,261	3,009
Effect of foreign exchange rate changes on cash and cash equivalents	(198)	(127)
Net increase in cash and cash equivalents	23,920	9,951
Cash and cash equivalents at beginning of period	166,487	87,100
Cash and cash equivalents at end of period	\$ 190,407	\$ 97,051

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. (we or our) 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 our financial position as of March 31, 2010, our results of operations for the three months ended March 31, 2010 and 2009, and our cash flows for the three months ended March 31, 2010 and 2009. The Condensed Consolidated Balance Sheet as of December 31, 2009 was derived from the December 31, 2009 audited financial statements. Revenues and cost of revenues in prior period amounts have been reclassified to conform with the current period presentation. These reclassifications had no impact on previously reported gross profit or financial position.

The results of operations for the three months ended March 31, 2010 are not necessarily indicative of the results that may be expected for the year ending December 31, 2010 or any other future period, and we make 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 our Annual Report on Form 10-K for the year ended December 31, 2009.

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

Recent Accounting Pronouncements

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

In January 2010, the FASB issued ASU 2010-06, Fair Value Measurements and Disclosures (ASC 820): Improving Disclosures about Fair Value Measurements. This update will require (1) an entity to disclose separately the amounts of significant transfers in and out of Levels 1 and 2 fair value measurements and to describe the reasons for the transfers; and (2) information about purchases, sales, issuances and settlements to be presented separately (i.e. present the activity on a gross basis rather than net) in the reconciliation for fair value measurements using significant unobservable inputs (Level 3 inputs). This guidance clarifies existing disclosure requirements for the level of disaggregation used for classes of assets and liabilities measured at fair value and requires disclosures about the valuation techniques and inputs used to measure fair value for both recurring and nonrecurring fair value measurements using Level 2 and Level 3 inputs. The new disclosures and clarifications of existing disclosure are effective for fiscal years beginning after December 15, 2009, except for the disclosure requirements for related to the purchases, sales, issuances and settlements in the rollforward activity of Level 3 fair value measurements. Those disclosure requirements are effective for fiscal years ending after December 31, 2010. We are still assessing the impact of this guidance and do not believe the adoption of this guidance will have a material impact to our consolidated financial statements.

On February 24, 2010, FASB issued ASU 2010-09, Subsequent Events (ASC 855): Amendments to Certain Recognition and Disclosure Requirements. The amendments in the ASU remove the requirement for a Securities and Exchange Commission (SEC) filer to disclose a date through which subsequent events have been evaluated in both issued and revised financial statements. Revised financial statements include financial statements revised as a result of either correction of an error or retrospective application of U.S. GAAP. The FASB also clarified that

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if the financial statements have been revised, then an entity that is not an SEC filer

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should disclose both the date that the financial statements were issued or available to be issued and the date the revised financial statements were issued or available to be issued. We have adopted this guidance for the period ended March 31, 2010.

On March 5, 2010, FASB issued ASU 2010-11, Derivatives and Hedging (ASC 815): Scope Exception Related to Embedded Credit Derivatives. The FASB believes this ASU clarifies the type of embedded credit derivative that is exempt from embedded derivative bifurcation requirements. Specifically, only one form of embedded credit derivative qualifies for the exemption one that is related only to the subordination of one financial instrument to another. As a result, entities that have contracts containing an embedded credit derivative feature in a form other than such subordination may need to separately account for the embedded credit derivative feature. The amendments in the ASU are effective for each reporting entity at the beginning of its first fiscal quarter beginning after June 15, 2010. We are still assessing the impact of this guidance and do not believe the adoption of this guidance will have a material impact to our 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 our present or future consolidated financial statements.

Note 2. Marketable Securities and Fair Value Measurements

Our short-term marketable securities as of March 31, 2010 and December 31, 2009 are as follows (in thousands):

		Amortized Costs	Gross Unrealized Gains	Fair Value	
March 31, 2010					
U.S. government notes and bonds		\$ 14,984	\$ 7	\$ 14,991	
		Amortized Costs	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
December 31, 2009					
U.S. government notes and bonds		\$ 18,972	\$ 6	\$	\$ 18,978
Corporate bonds		1,000			1,000
Total		\$ 19,972	\$ 6	\$	\$ 19,978

As of March 31, 2010, all short-term investments have maturity dates of less than one year. For the three months ended March 31, 2010 and 2009, no significant gains or losses were realized on the sale of marketable securities.

Fair Value Measurements

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

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

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Our Level 1 assets consist of U.S. government debt securities and money market funds. We did not hold any Level 1 liabilities as of March 31, 2010.

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.

We did not hold any Level 2 assets or liabilities as of March 31, 2010.

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

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significant management judgment or estimation.

We did not hold any Level 3 assets or liabilities during the quarter ended March 31, 2010.

The following table summarizes our financial assets measured at fair value on a recurring basis as of March 31, 2010 (in thousands):

Description	Balance as of March 31, 2010	Quoted Prices in Active Markets for Identical Assets (Level 1)
Cash equivalents:		
Money market funds	\$ 122,085	\$ 122,085
Short-term investments:		
U.S. government debt securities	14,991	14,991
	\$ 137,076	\$ 137,076

Note 3. Balance Sheet Components

Inventories are comprised of (in thousands):

	March 31, 2010	December 31, 2009
Raw materials	\$ 1,161	\$ 1,079
Work in process	977	746
Finished goods	218	221
	\$ 2,356	\$ 2,046

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):

	March 31, 2010	December 31, 2009
Accrued payroll and benefits	\$ 16,750	\$ 25,847
Accrued income taxes	2,866	2,920
Accrued sales rebate	2,895	2,610
Accrued sales tax and value added tax	2,376	2,392

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Accrued warranty	2,463	2,376
Accrued sales and marketing expenses	1,978	1,954
Other	5,362	4,723
	\$ 34,690	\$ 42,822

Note 4. Intangible Assets

The intangible assets represent non-compete agreements received in conjunction with the October 2006 OrthoClear Agreement at gross value of \$14 million. These assets are amortized on a straight-line basis over the expected useful life of five years. As of March 31, 2010 and December 31, 2009, the net carrying value of these non-compete agreements was \$4.3 million (net of \$9.7 million of accumulated amortization) and \$5.0 million (net of \$9.0 million of accumulated amortization), respectively.

We perform 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 our stock price for a sustained period. Impairments

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are recognized based on the difference between the fair value of the asset and its carrying value, and fair value is generally measured based on discounted cash flow analyses. There were no impairments of intangible assets during the periods presented.

The total estimated annual future amortization expense for these intangible assets as of March 31, 2010 is as follows (in thousands):

Fiscal Year	
2010 (for the remaining 9 months)	\$ 2,100
2011	2,188
Total	\$ 4,288

Note 5. Legal Proceedings***Consumer Class Action***

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

On July 3, 2007, we filed an 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 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 our motion for summary judgment. We believe the lawsuit to be without merit and we intend to vigorously defend ourselves. Accordingly, we believe there is not sufficient evidence to conclude that a reasonable possibility exists that a loss had been incurred as of March 31, 2010.

Securities Litigation

In August 2009, Plaintiff Charles Wozniak filed a lawsuit against us and our Chief Executive Officer and President, Thomas M. Prescott (Mr. Prescott), in District Court for the Northern District of California on behalf of a claimed class consisting of all persons or entities who purchased our common stock between January 30, 2007 and October 24, 2007. The complaint alleges that we and Mr. Prescott violated Section 10(b) of the Securities Exchange Act of 1934 and that Mr. Prescott violated Section 20(a) of the Securities Exchange Act of 1934. Specifically, the complaint alleges that during the class period, we failed to disclose that we had shifted the focus of our sales force to clearing backlog, causing a significant decrease in the number of new case starts. On November 13, 2009, the Court appointed Plumbers and Pipefitters National Pension Fund as lead plaintiff (Lead Plaintiff). Lead Plaintiff filed an amended complaint on January 29, 2010. The amended complaint alleges that we and Mr. Prescott issued a number of purportedly false and misleading statements throughout the class period concerning the Patients First program, our production capacity, a purported backlog, and the focus of our sales force. On March 26, 2010, we and Mr. Prescott filed a motion to dismiss the amended complaint. The motion is currently scheduled to be heard by the Court on July 9, 2010. We believe the lawsuit to be without merit and intend to vigorously defend ourselves. Accordingly, we believe there is not sufficient evidence to conclude that a reasonable possibility exists that a loss had been incurred as of March 31, 2010.

Note 6. Ormco Litigation Settlement

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

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ALIGN TECHNOLOGY, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(unaudited)

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

Upon execution of the Settlement Agreement, 5.6 million shares were issued to Danaher and the remaining 2.0 million shares were issued upon the expiration of the waiting period under the provisions of the Hart-Scott-Rodino Antitrust Improvements Act, which occurred on September 21, 2009. In addition to other provisions of the Settlement Agreement, these shares may not be resold except pursuant to an effective registration statement under the Securities Act or an available exemption from registration. We are not obligated to affect any such registration prior to the one year anniversary of this agreement. The fair value of the shares should reflect the value that market participants would demand because of the risk relating to the inability to access a public market for these securities for the specified period. The fair value of the unregistered shares was determined as of the market closing price on the dates the shares were issued less a 25% non-marketability discount, for a total value of \$76.7 million, including the cash payment.

We have concluded that 25% is an appropriate discount based primarily on an analysis utilizing the Black-Scholes model to value a hypothetical put option to approximate the cost of hedging the restricted stock over the expected period of non-marketability. This approach calculates the amount required to buy the right to sell the presently restricted stock at the then-current market price on the date the holder can count on the shares becoming saleable on the public exchange. The assumptions input into the Black-Scholes option pricing model were based on the stock price on the dates of the share issuances, an expected term of 1 year, expected volatility of 70%, risk-free interest rate of 4.38% to 4.90% and no expected dividends.

We corroborated the conclusion indicated by the Black-Scholes model by assessing that the discount was generally consistent with the ranges noted from published restricted stock studies and comparable to discounts on restricted stock transactions completed by other companies operating in similar industries.

In accordance with the Settlement Agreement, Ormco released us from any and all past and future claims of infringement for the period September 9, 2003 through the expiration of the patent on January 19, 2010 (infringement period). In order to determine how to allocate the settlement value between past infringement and the future use of the patent, we considered both past and estimated future case shipment volumes during the infringement period, and allocated the total settlement value across all case shipments. We attributed \$69.7 million to past infringement claims, based on case shipments from September 9, 2003 through August 16, 2009. This was recorded as litigation settlement costs and included in operating expenses during the period ended September 30, 2009. Additional royalty costs based on case shipments between August 17, 2009 through January 19, 2010 totaling \$7.0 million were recorded as prepaid royalties. We amortized \$6.2 million of the prepaid royalties to cost of sales for the year ended December 31, 2009 and the remaining \$0.8 million was amortized during first quarter of 2010.

Note 7. Credit Facilities

On December 5, 2008, we renegotiated and amended our existing credit facility with Comerica Bank. Under this revolving line of credit, we have \$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 us 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 we maintain at Comerica Bank above the \$10.0 million minimum.

As of March 31, 2010, we had no outstanding borrowings under this credit facility and are in compliance with the financial covenants.

Note 8. Commitments and Contingencies

Leases

As of March 31, 2010, minimum future lease payments for non-cancelable leases are as follow (in thousands):

Table of Contents**ALIGN TECHNOLOGY, INC.****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****(unaudited)**

Fiscal Year	
2010 (for the remaining 9 months)	\$ 3,349
2011	3,960
2012	3,374
2013	2,752
2014 and thereafter	7,101
 Total	 \$ 20,536

On January 26, 2010, we entered into an agreement to lease new corporate headquarters of approximately 129,024 square feet in San Jose, California. The lease agreement commences on the earlier of August 1, 2010 or the date we first commence conducting business in the premises, which is expected to be on or about June 28, 2010, and will continue for an initial term of seven years and two months. Our agreement for the current corporate headquarters in Santa Clara, California, expires on June 30, 2010.

Warranty

We warrant our products against material defects until the Invisalign case is completed. We accrue 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. We regularly review the accrued balances and update 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 our warranty accrual during the three months ended March 31, 2010 and 2009, respectively (in thousands):

	Three Months Ended March 31,	
	2010	2009
Balance at beginning of period	\$ 2,376	\$ 2,031
Charged to cost of revenues	788	623
Actual warranty expenses	(701)	(659)
 Balance at end of period	 \$ 2,463	 \$ 1,995

Note 9. Stock-based Compensation***Summary of stock-based compensation expense***

The following table summarizes stock-based compensation expense related to all of our stock-based options and employee stock purchases for the three months ended March 31, 2010 and 2009 (in thousands):

**Three Months Ended
March 31,**

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	2010	2009
Cost of revenues	\$ 435	\$ 386
Sales and marketing	847	951
General and administrative	1,813	1,954
Research and development	378	424
 Total stock-based compensation expense	 \$ 3,473	 \$ 3,715

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

Table of Contents**ALIGN TECHNOLOGY, INC.****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****(unaudited)**

	Three Months Ended March 31,	
	2010	2009
Stock Options:		
Expected term (in years)	4.4	4.4
Expected volatility	63.3%	61.4%
Risk-free interest rate	2.0%	1.6%
Expected dividend		
Weighted average fair value per share at grant date	\$ 9.26	\$ 3.90

Options

Stock option activity for the three months ended March 31, 2010 under the stock incentive plans is set forth below:

	Total Shares Underlying Stock Options			
	Number of Shares Underlying Stock Options (in thousands)	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding as of December 31, 2009	7,488	\$ 11.49		
Granted	1,221	17.97		
Cancelled or expired	(132)	13.83		
Exercised	(560)	7.04		
Outstanding as of March 31, 2010	8,017	\$ 12.75	6.45	\$ 53,327
Vested and expected to vest at March 31, 2010	7,711	\$ 12.67	6.40	\$ 51,920
Exercisable at March 31, 2010	4,908	\$ 11.78	5.59	\$ 37,494

As of March 31, 2010, we expect to recognize \$20.3 million of total unamortized compensation cost related to stock options over a weighted average period of 2.7 years.

Restricted Stock Units

A summary of the nonvested shares for the three months ended March 31, 2010 is as follows:

	Number of Shares Underlying RSUs (in thousands)	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Nonvested as of December 31, 2009	876		
Granted	340		
Vested and released	(225)		

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Forfeited

(38)

Nonvested as of March 31, 2010	953	1.71	\$ 18,433
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As of March 31, 2010 the total unamortized compensation cost related to restricted stock units was \$11.3 million, which we expect to recognize over a weighted average period of 2.6 years.

Employee Stock Purchase Plan

The fair value of the option component of the Purchase Plan shares was estimated at the grant date using the Black-Scholes options pricing model with the following weighted average assumptions:

Table of Contents**ALIGN TECHNOLOGY, INC.****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****(unaudited)**

	Three Months Ended March 31,	
	2010	2009
Employee Stock Purchase Plan:		
Expected term (in years)	1.3	1.3
Expected volatility	58.3%	74.7%
Risk-free interest rate	0.5%	0.6%
Expected dividend		
Weighted average fair value per share at grant date	\$ 7.57	\$ 3.72

As of March 31, 2010, we expect to recognize \$1.3 million of the total unamortized compensation cost related to employee purchases over a weighted average period of 0.3 years.

Note 10. Accounting for Income Taxes

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

During the first quarter of fiscal 2010, the amount of unrecognized tax benefits was increased by approximately \$0.8 million. The total amount of unrecognized tax benefits was \$6.7 million as of March 31, 2010, which would impact our effective tax rate if recognized. We recognize 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.

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

Note 11. Net Profit Per Share

Basic net profit per share is computed using the weighted average number of shares of common stock outstanding 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,	
	2010	2009
Net profit	\$ 14,930	\$ 2,636
Weighted-average common shares outstanding, basic	75,166	65,983
Effect of potential dilutive common shares	2,431	464

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Total shares, diluted	77,597	66,447
Basic net profit per share	\$ 0.20	\$ 0.04
Diluted net profit per share	\$ 0.19	\$ 0.04

For the three months ended March 31, 2010 and 2009, stock options and restricted stock units totaling 2.1 million and 5.9 million, respectively, were excluded from diluted net profit per share because of their anti-dilutive effect.

Table of Contents**ALIGN TECHNOLOGY, INC.****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****(unaudited)****Note 12. Comprehensive Income**

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

	Three Months Ended March 31,	
	2010	2009
Net profit	\$ 14,930	\$ 2,636
Foreign currency translation adjustments	(347)	(357)
Change in unrealized gain on available-for-sale securities	1	20
Comprehensive income	\$ 14,584	\$ 2,299

Note 13. Segments and Geographical Information***Segment***

We report segment data based on the internal reporting that is used by management for making operating decisions and assessing performance. During all periods presented, we 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,	
	2010	2009
Net revenues:		
North America	\$ 68,854	\$ 55,293
Europe	20,378	14,352
Other international	858	487
Total net revenues	\$ 90,090	\$ 70,132
	As of March 31, 2010	As of December 31, 2009
Long-lived assets:		
North America	\$ 86,700	\$ 91,548
Europe	819	1,018
Other international	1,423	1,375
Total long-lived assets	\$ 88,942	\$ 93,941

Note 14. Restructuring

In July and October 2008, we announced restructuring plans to increase efficiencies across the organization and lower the overall cost structure. The July 2008 plan reduced full time headcount primarily through a phased-consolidation of order acquisition operations from 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 was completed during the second quarter of 2009.

In 2009, we incurred approximately \$1.3 million of costs related to severance and termination benefits, of which \$0.9 million were in the first quarter of 2009. There were no costs incurred relating to the restructuring plans during the first quarter of 2010.

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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, our expectations regarding the Proficiency Requirements and its impact on our case volume and revenues, the anticipated impact of 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 continued growth of our international markets, our expectations regarding the impact of increased consumer marketing programs in Europe, the anticipated level of our gross margins, 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.

We design, manufacture and market 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 initial Invisalign training course in order to begin providing 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, Latin American and EMEA (Europe, Middle East and Africa) regions.

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 is designed to meet the specific needs of the non-adult comprehensive or teen treatment market. Invisalign Assist is intended to help newly-trained and lower volume Invisalign GPs accelerate the adoption and frequency of use of Invisalign into their practice. Upon completion of an Invisalign or non-Invisalign treatment, the patient may be prescribed our traditional retainer product, or our Viverra 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 and clinical effectiveness, enhancing the customer experience, generating consumer demand and expanding into international markets. Each of these four key objectives is described more fully in *Item 1 Business Strategy* of our 2009 Annual Report on Form 10-K. In addition to the successful execution of our business strategy, a number of other factors may affect our results in 2010 and beyond, the most important of which are set forth in our Annual Report in Form 10-K as updated below.

Proficiency Program. Our success depends upon increasing acceptance and frequency of use of the Invisalign system by dental professionals (what we refer to as utilization). We have a large number of low volume doctors that make up a large portion of our customer base. We want every Invisalign provider to be one we can comfortably direct a prospective patient to with an expectation of knowledgeable treatment and a great outcome. On April 22, 2010, we announced a significant change to the Invisalign Product Proficiency Requirements (or the proficiency program) launched in North America in June 2009. Under the modified proficiency program, doctors will no longer be required to have 10 Invisalign case starts (measured by ClinCheck acceptance) in each calendar year to maintain their active provider status. We will continue to emphasize the importance of Invisalign professional education in treatment success by requiring the annual ten Invisalign continuing education (CE) hour requirements. Doctors who do not complete a minimum of 10 Invisalign CE hours in a calendar year will have their Invisalign account temporarily suspended until they complete the minimum

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CE hours. In addition, we will continue to promote the benefits of Invisalign Preferred Provider status for doctors who start ten or more cases each year.

Approximately 22,000 doctors in North America either achieved the proficiency requirements in 2009 or qualified for the additional six month qualification period and will have until December 31, 2010 to meet the new proficiency program requirements. With the elimination of the minimum case requirements we expect that a greater number of doctors will meet the requirements of the proficiency program and will continue to be Invisalign providers in 2010 and beyond, however, it is uncertain how case volumes, particularly for lower volume doctors, will be impacted. We expect to experience variability in customer activity over the next several quarters as doctors adjust to the changes to the proficiency program requirements. In addition, if GPs and Orthos do not attend our continuing dental education courses in sufficient numbers for any reason, we may have to suspend the accounts of more doctors in 2011 than we currently anticipate and our revenue may fail to grow as expected.

Number of new doctors trained. Prior to 2009, we historically have trained at least 5,000 new doctors per year in North America. With the introduction of the proficiency program and a renewed focus on attracting the right kind of customer, we trained approximately 2,825 new doctors in North America in 2009 and 390 in the first quarter of 2010. Our new doctor training in North America is evolving to identify and focus on practices that are interested in gaining the skills and experience necessary to be successful with Invisalign. As a result, we expect that the number of new doctors trained in North America will be relatively comparable to 2009.

Utilization Rates. Our goal is to establish Invisalign as the treatment of choice for treating malocclusion ultimately driving increased product adoption and frequency of use by dental professionals, or utilization. Our quarterly utilization rates for the previous nine quarters are as follows:

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

Although utilization rates in the first quarter of 2010 for each of our Ortho, GP, and International channels were higher than the same quarter last year mainly due to fewer numbers of North American doctor submitters and higher international shipments, we do expect to continue to see fluctuation in our utilization rates as practices adjust to the proficiency program and our customer base evolves throughout the year. As a result of eliminating the annual case requirements, we expect that the number of doctors we ship to over the next several quarters will fluctuate. We therefore believe that quarter-to-quarter comparisons of utilization rates may not be as meaningful in 2010.

Impact of product mix on deferred revenue. Many of our products launched in 2008 (Vivera retainers, Invisalign Teen, Invisalign Assist) include features of staged delivery or the option to receive replacement aligners during the course of treatment. As a result of these features, these products have a significantly higher amount of deferred revenue as a percentage of their average selling prices compared to Invisalign Full. Vivera retainers are delivered in four shipments over the course of a year, and revenue is initially deferred and then recognized as each shipment occurs. Invisalign Teen which includes up to six replacement aligners, is delivered in a single shipment except for the replacement aligners. Currently, the revenue for the six replacement aligners is 100 percent deferred based on the fair market value

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and recognized as the replacement aligners are used or when the case is completed. Although Invisalign Teen has been available since July 2008, we do not have sufficient evidence to support a usage rate less than 100 percent for the six replacement aligners at this time, however, we are continually gathering and evaluating our historical experience. If and when we gather sufficient historical experience to support a usage rate for the six replacement aligners less than 100 percent, we would adjust our deferred revenue balance to the estimated usage rate and prospectively apply this rate to future Invisalign Teen shipments. For Invisalign Assist, when the progress tracking feature is selected, aligners are shipped every nine stages. As a result, revenue for these cases is deferred upon the first shipment and will be recognized upon the final shipment. Depending on customers' adoption of these products, our mix of products may continue to gradually shift towards these products, which will result in an increase in deferred revenue on our balance sheet.

Seasonal fluctuations. Seasonal fluctuations in the number of doctors in their offices and available to take appointments have affected, and are likely to continue to affect our business. Specifically, our customers often take vacation during the summer months and therefore tend to start fewer cases, especially in Europe. In addition, summer is typically the busiest season for orthodontists with practices that have a high percentage of adolescent and teenage patients. Many parents want to get their teens started in treatment before the start of the school year. As a result, adult appointments, including adult Invisalign patient starts, are often pushed further into late summer or early fall. In 2009, we did not experience the normal seasonality in our business and had sequential case growth in the North American orthodontic from second quarter to the third quarter. With the availability of Invisalign Teen, 2009 was the first summer we were able to actively compete for a share of teen patient starts and believe that Invisalign Teen may have helped moderate the historical downward trend we have typically seen for our North American orthodontic customers during the summer months. However, there can be no assurance that our historical seasonal trends will not 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.

Gross margin. In the second quarter of 2010 we will introduce a consumer rebate program that will run through the end of the quarter, as well as an additional volume rebate for our highest volume customers. These programs are expected to have a negative impact on revenue and gross margin during the second quarter compared to the first quarter of 2010.

Results of Operations*Net revenues and case volume by channel and product:*

Invisalign product revenues by channel and other non-case revenues, which represents training, retainer and ancillary products, for the three months ended March 31, 2010 and 2009 are as follows (in millions):

	Three Months Ended March 31,			
	2010	2009	Net Change	% Change
Net revenues				
North America:				
Ortho	\$ 28.2	\$ 21.0	\$ 7.2	34.3%
GP	37.2	30.9	6.3	20.4%
Total North American Invisalign	65.4	51.9	13.5	26.0%
International Invisalign	20.0	14.3	5.7	39.9%
Total Invisalign revenues	85.4	66.2	19.2	29.0%
Non-case revenues	4.7	3.9	0.8	20.5%

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Total net revenues	\$ 90.1	\$ 70.1	\$ 20.0	28.5%
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Case volume data which represents Invisalign case shipments by channel, for the three months ended March 31, 2010 and 2009 are as follows (in thousands):

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Invisalign case volume	Three Months Ended March 31,			
	2010	2009	Net Change	% Change
North America:				
Ortho	22.1	16.9	5.2	30.8%
GP	28.5	23.3	5.2	22.3%
Total North American Invisalign	50.6	40.2	10.4	25.9%
International Invisalign	13.0	9.9	3.1	31.3%
Total Invisalign case volume	63.6	50.1	13.5	26.9%

Invisalign revenues by product and other non-case revenues, which represents training, retainer and ancillary products, for the three months ended March 31, 2010 and 2009 are as follows (in millions):

Net revenues	Three Months Ended March 31,			
	2010	2009	Net Change	% Change
Invisalign Full	\$ 65.7	\$ 55.3	\$ 10.4	18.8%
Invisalign Express	8.6	6.8	1.8	26.5%
Invisalign Teen	8.2	3.5	4.7	134.3%
Invisalign Assist	2.9	0.6	2.3	383.3%
Other non-case revenues	4.7	3.9	0.8	20.5%
Total net revenues	\$ 90.1	\$ 70.1	\$ 20.0	28.5%

Case volume data which represents Invisalign case shipments by product, for the three months ended March 31, 2010 and 2009 are as follows (in thousands):

Invisalign case volume	Three Months Ended March 31,			
	2010	2009	Net Change	% Change
Invisalign Full	43.7	37.3	6.4	17.2%
Invisalign Express	9.2	8.0	1.2	15.0%
Invisalign Teen	7.4	3.9	3.5	89.7%
Invisalign Assist	3.3	0.9	2.4	266.7%
Total Invisalign case volume	63.6	50.1	13.5	26.9%

Total net revenues increased for the three months ended March 31, 2010 compared to the same period in 2009 as a result of worldwide volume growth across all of our customer channels and products. We believe the United States economic downturn adversely impacted consumer spending habits in 2009, and doctors tended to focus on more traditional dental procedures. As a result, sales of Invisalign were negatively impacted in 2009. In the first quarter of 2010, the North America channel grew approximately 26% in revenue and case volume compared to the same period of 2009. However, as Invisalign Teen and Assist grow as a percentage of our overall volume, revenues may not increase in a similar proportion, as these products have higher amounts of deferred revenue. Our International Invisalign also increased for the three months ended March 31, 2010 compared to the same period in 2009 due to 31.3% higher case volumes supplemented by favorable exchange rates of the Euro against the U.S. dollar.

Other non-case revenues, consisting of training fees and sales of ancillary products, were higher for the three months ended March 31, 2010 compared to March 31, 2009 primarily due to increased sales of our Viverra and retainer products.

Cost of revenues and gross profit (in millions):

	Three Months Ended March 31,		
	2010	2009	Change
Cost of revenues	\$ 20.4	\$ 17.4	\$ 3.0
% of net revenues	22.6%	24.8%	
Gross profit	\$ 69.7	\$ 52.7	\$ 17.0
Gross margin	77.4%	75.2%	

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

Gross margin improved for the three months ended March 31, 2010 compared to the same period in 2009 primarily due to increased cost absorption due to higher production volumes along with continued improvement in operating efficiencies as well as cost savings from the commencement of direct fabrication of our aligners. These savings were partially offset by Ormco royalties of \$0.8 million and net training costs associated with continuing education courses of approximately \$0.5 million that were historically charged to sales and marketing, however, as a result of finalizing the educational requirements for the Proficiency Program, these costs are included in gross margin starting January 1, 2010.

Sales and marketing (in millions):

	Three Months Ended March 31,		
	2010	2009	Change
Sales and marketing	\$ 27.9	\$ 27.9	\$
% of net revenues	31.0%	39.7%	

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 expense for the three months ended March 31, 2010 was comparable to the same period in 2009. The first quarter of 2010 reflects a \$1.1 million increase in marketing, media, and advertising expenses, which was partially offset by a \$1.0 million decrease in clinical education costs, of which \$0.5 million was included in gross margin as a result of finalizing the educational requirements for the Proficiency Program.

General and administrative (in millions):

	Three Months Ended March 31,		
	2010	2009	Change
General and administrative	\$ 15.0	\$ 13.5	\$ 1.5
% of net revenues	16.6%	20.3%	

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

General and administrative expenses increased in the three months ended March 31, 2010 as compared to the same period in 2009 primarily due to proceeds from an insurance reimbursement of \$1.5 million that we received in March 2009 relating to the OrthoClear settlement. The reimbursement was partially offset by higher legal expenses which were related to the Ormco litigation during the first quarter of 2009.

Research and development (in millions):

	Three Months Ended March 31,		
	2010	2009	Change
Research and development	\$ 6.1	\$ 5.2	\$ 0.9
% of net revenues	6.8%	7.4%	

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.

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Research and development expenses were slightly higher during the three months ended March 31, 2010 compared to the same period in 2009 primarily due to \$0.5 million of costs related to higher payroll-related and temporary contractor expenses during the first quarter of 2010.

Restructuring (in millions):

	Three Months Ended March 31,		
	2010	2009	Change
Restructuring	\$	\$ 0.9	\$ (0.9)
% of net revenues	0.0%	1.3%	

During 2008, we announced restructuring plans in July and October to increase efficiencies across the organization and with the expectation of lowering the overall cost structure by approximately \$3.5 million per quarter. We incurred approximately \$0.9 million during the first quarter of 2009 of cost related to severance and termination benefits. There were no restructuring costs during the first quarter of 2010.

Interest and other income, net (in millions):

	Three Months Ended March 31,		
	2010	2009	Change
Interest income	\$ 0.1	\$ 0.2	\$ (0.1)
Other (expense), net	(0.7)	(0.1)	(0.6)
Total interest income and other (expense), net	\$ (0.6)	\$ 0.1	\$ (0.7)

Interest and other income (expense), net, include interest income earned on cash balances, interest expense, foreign currency translation gains and losses and other miscellaneous charges.

Interest income, net for the three months ended March 31, 2010 decreased slightly compared to the same period in 2009 primarily due to lower returns on our investments as we shifted into more conservative US government securities and money market funds which bear lower interest rates.

Other expense, net for the three months ended March 31, 2010 increased as compared with the same period in 2009 reflecting increases in foreign exchange losses during the first quarter of 2010.

Income tax (in millions):

	Three Months Ended March 31,		
	2010	2009	Change
Provision for (benefit) from income taxes	\$ 5.2	\$ 2.8	\$ 2.4

We recorded an income tax provision of \$5.2 million and \$2.8 million for the three months ended March 31, 2010 and 2009, respectively, representing effective tax rates of 25.9% and 51.5%. Our effective tax rate for the remainder of 2010 may fluctuate based upon our operating results for each taxable jurisdiction in which we operate and the amount of statutory tax that we incur in each jurisdiction.

We exercised significant judgment in regards to estimates of future market growth, forecasted earnings and projected taxable income, in determining the provision for income taxes, and for purposes of assessing our ability to utilize any future benefit from deferred tax assets. As of March 31, 2010, we have recorded a valuation allowance of approximately \$6.2 million related to capital loss and foreign loss carryforwards because we cannot forecast sufficient future capital gains or foreign source income to realize these deferred tax assets. These net operating loss and capital loss carryforwards will result in an income tax benefit if and when we conclude it is more likely than not that the related deferred tax assets will be realized.

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

Liquidity and Capital Resources

We fund our operations from product sales and proceeds from the sale of common stock. As of March 31, 2010 and December 31, 2009 we had the following cash and cash equivalents, and short-term marketable securities (in thousands):

	March 31, 2010	December 31, 2009
Cash and cash equivalents	\$ 190,407	\$ 166,487
Marketable securities, short-term	14,991	19,978
Total	\$ 205,398	\$ 186,465

Net cash provided by operating activities was \$18.6 million for the three months ended March 31, 2010 resulting primarily from our net profit of \$14.9 million adjusted for non-cash items largely from depreciation, amortization of intangibles and royalties, deferred taxes of \$9.4 million and \$3.5 million of stock-based compensation expenses. Additionally, cash flows from operating activities increased due to a \$5.1 million increase in deferred revenues, which were partially offset by an increase in accounts receivable of \$4.9 million and decreases in accrued liabilities, prepaids, and other assets of \$9.2 million.

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. Additionally, cash flows from operating activities increased due 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.

Net cash provided by investing activities was \$0.2 million for the three months ended March 31, 2010 primarily consisted of maturities of our marketable securities of \$5.0 million, which were partially offset by property, plant, and equipment purchases of \$4.5 million.

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 maturities of marketable securities.

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

Net cash provided by financing activities was \$5.3 million for the three months ended March 31, 2010 primarily resulting from \$6.0 million in proceeds from the issuances of our common stock, which were partially offset by \$0.7 million of taxes paid on the vesting of restricted stock units related to our employee stock plan.

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.

Contractual Obligations

On January 26, 2010, we entered into an agreement for new corporate headquarters to lease approximately 129,024 square feet in San Jose, California. The lease agreement commences on the earlier of August 1, 2010 or the date we first commence conducting business in the premises, which is expected to be on or about June 28, 2010 and will continue for an initial term of seven years and two months. The lease

agreement for our current office headquarters in Santa Clara, California, expires on June 30, 2010.

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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, 2009.

We believe that our current cash and cash equivalents combined with our existing borrowing capacity will be sufficient to fund our operations for at least the next 12 months. If we are unable to generate adequate operating cash flows, we may need to seek additional sources of capital through equity or debt financing, collaborative or other arrangements with other companies, bank financing and other sources in order to realize our objectives and to continue our operations. There can be no assurance that we will be able to obtain additional debt or equity financing on terms acceptable to us, or at all. If adequate funds are not available, we may need to make business decisions that could adversely affect our operating results such as modifications to our pricing policy, business structure or operations. Accordingly, the failure to obtain sufficient funds on acceptable terms when needed could have a material adverse effect on our business, results of operations and financial condition.

Critical Accounting Policies

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

We believe the following critical accounting policies reflect our most significant estimates, judgments and assumptions used in the preparation of our consolidated financial statements. These critical accounting policies and related disclosures appear in our Annual Report on Form 10-K for the year ended December 31, 2009.

Revenue recognition;

Stock-based compensation expense;

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

Deferred tax valuation allowance.

There have been no significant changes in our critical accounting policies during the three months ended March 31, 2010 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, 2009.

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, 2009, which is incorporated herein by reference. Our exposure to market risk has not changed materially since December 31, 2009.

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, 2010 to provide reasonable assurance that information required to be

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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

Consumer Class Action

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

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

Securities Litigation

In August 2009, Plaintiff Charles Wozniak filed a lawsuit against the Company and our Chief Executive Officer and President, Thomas M. Prescott ("Mr. Prescott"), in District Court for the Northern District of California on behalf of a claimed class consisting of all persons or entities who purchased the common stock of Align between January 30, 2007 and October 24, 2007. The complaint alleges that Align and Mr. Prescott violated Section 10(b) of the Securities Exchange Act of 1934 and that Mr. Prescott violated Section 20(a) of the Securities Exchange Act of 1934. Specifically, the complaint alleges that during the class period we failed to disclose that we had shifted the focus of our sales force to clearing backlog, causing a significant decrease in the number of new case starts. On November 13, 2009, the Court appointed Plumbers and Pipefitters National Pension Fund as lead plaintiff ("Lead Plaintiff"). Lead Plaintiff filed an amended complaint on January 29, 2010. The amended complaint alleges that Align and Mr. Prescott issued a number of purportedly false and misleading statements throughout the class period concerning the Patients First program, Align's production capacity, a purported backlog, and the focus of our sales force. On March 26, 2010, Align and Mr. Prescott filed a motion to dismiss the amended complaint. The motion is currently scheduled to be heard by the Court on July 9, 2010. We believe the lawsuit to be without merit and intend to vigorously defend ourselves.

Table of Contents**ITEM 1A. RISK FACTORS**

We depend on the sale of the Invisalign system for the vast majority of our revenues, and any decline in sales of Invisalign for any reason, including as a result of changes to the proficiency program, a continued weakness in general economic conditions, or a decline in average selling prices would adversely affect revenues, gross margin and net profits.

We expect that revenues from the sale of the Invisalign system will continue to account for the vast majority of our total revenues for the foreseeable future. Continued and widespread market acceptance of Invisalign by orthodontists, GPs and consumers is critical to our future success. If orthodontists and GPs experience a reduction in consumer demand for orthodontic services, if consumers prove unwilling to adopt Invisalign as rapidly as we anticipate or in the volume that we anticipate, if orthodontists or GPs choose to use a competitive product rather than Invisalign or if the average selling price of our product declines, our operating results would be harmed. Factors that could cause the adoption of Invisalign to occur at a lower rate than we expect, as well as the risk related to declining average selling prices are described more fully below.

Consumers may not adopt Invisalign as rapidly as we anticipate due to a variety of factors including a continued weakness 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 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. Increased market acceptance will depend in part upon the recommendations of dental professionals, as well as other factors including effectiveness, safety, ease of use, reliability, aesthetics, greater comfort and hygiene compared to traditional orthodontic products and price for Invisalign compared to competing products.

Orthodontists and GPs may not adopt Invisalign in sufficient numbers or as rapidly as we anticipate for a number of reasons, including, changes to the proficiency program or as a result of continued weakness in general economic conditions.

Our success depends upon increasing acceptance and frequency of use of the Invisalign system by dental professionals (what we refer to as utilization). We have a large number of low volume doctors that make up a large portion of our customer base. We want every Invisalign provider to be one we can comfortably direct a prospective patient to with an expectation of knowledgeable treatment and a great outcome. On April 22, 2010, we announced significant changes to the Invisalign proficiency program in North America. Under the proficiency program (as modified), we eliminated the requirement that every Invisalign provider in North America must have 10 Invisalign case starts (measured by ClinCheck acceptance). We will continue to emphasize the importance of Invisalign professional education in treatment success by maintaining the annual ten Invisalign CE hour requirements.

If the elimination of the case start requirements causes customers to slow the pace of case submissions or the number of doctors submitting cases does not increase as anticipated or if GPs and Orthos do not attend our continuing education courses in sufficient numbers for any reason, our revenue may fail to grow as expected. In addition, increased competition from direct competitors could cause us to lose market share and reduce dental professionals' efforts and commitment to expand their Invisalign practice. If adoption and utilization does not increase as we anticipate, our revenues may fail to grow as expected and our operating results may be harmed.

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

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

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

In response to challenges in our business, including increased competition, we have in the past reduced the list price of our products. We also provide volume based discount programs to our doctors. In addition, we sell a number of products at different list prices. If we introduce any price reductions, or consumer rebate programs, expand our discount programs in the future, if participation in these programs increases, if our product mix shifts to lower priced products or newer products that have a higher percentage of deferred revenue, or if sales by our international

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distributors, particularly in the Asia-Pacific region, grows at a faster pace than our direct sales, our average selling price would be adversely affected and our revenues, gross margin and net profits (losses) may be

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reduced. Furthermore, although the U.S. dollar is our reporting currency, a portion of our revenues and profits are generated in foreign currencies. Revenues and profits generated by subsidiaries operating outside of the United States are translated into U.S. dollars using exchange rates effective during the respective period and are affected by changes in exchange rates. As a result, negative movements in currency exchange rates against the U.S. dollar will adversely affect our average selling price and consequently the amount of revenues and profits in our consolidated financial statements.

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

If we are to sustain or increase profitability in future periods, we will need to continue to increase our revenues, while controlling our expenses. While we generated positive operating cash flow in 2008 and in 2009, we cannot be certain that we will be able to achieve positive cash flow from operations, from period to period, in the future. Because our business is evolving, it is difficult to predict our future operating results or levels of growth, and we have in the past not been and may in the future not be able to sustain our historical growth rates. If we do not increase profitability or revenue growth or otherwise meet the expectations of securities analysts or investors, the market price of our common stock will likely decline.

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

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

limited visibility into and difficulty predicting the level of activity in our customers' practices from quarter to quarter;

disruptions to our business due to the impact of an epidemic, such as the H1N1 virus, that results in changes in consumer spending habits, consumers unable or unwilling to visit the orthodontist or general practitioners office, as well as any impact on workforce absenteeism;

weakness in consumer spending as a result of the slowdown in the United States economy and global economies;

changes in the timing of receipt of case product orders during a given quarter which, given our cycle time and the delay between case receipts and case shipments, could have an impact on which quarter revenue can be recognized;

fluctuations in currency exchange rates against the U.S. dollar;

changes in product mix;

seasonal fluctuations in the number of doctors in their offices and their availability to take appointments;

success of marketing programs from quarter to quarter;

changes in the timing of when revenue is recognized, including as a result of the introduction of new products or promotions or as a result of changes to critical accounting estimates or new accounting pronouncements;

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changes to our effective tax rate;

unanticipated delays in production caused by insufficient capacity;

any disruptions in the manufacturing process, including unexpected turnover in the labor force or the introduction of new production processes or natural or other disasters beyond our control;

the development and marketing of directly competitive products by existing and new competitors;

aggressive price competition from competitors;

costs and expenditures in connection with litigation;

inaccurate forecasting of revenues, production and other operating costs; and

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

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

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operating results may not be meaningful. You should not rely on our results for any one quarter as an indication of our future performance.

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

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

Our ability to market and sell new products may also be subject to government regulation, including approval or clearance by the United States Food and Drug Administration (FDA), and foreign government agencies. Any failure in our ability to successfully develop and introduce or achieve market acceptance of our new products or enhanced versions of existing products could have a material adverse effect on our operating results and could cause our revenues to decline.

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

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

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

Our key production steps are performed in operations located outside of the U.S. At our facility in Costa Rica, technicians use a sophisticated, internally developed computer-modeling program to prepare digital treatment plans, which are then transmitted electronically to Juarez, Mexico. These digital files form the basis of ClinCheck and are used to manufacture aligner molds. Our order acquisition, aligner fabrication and shipping operations are conducted in Juarez, Mexico. In addition to the research and development efforts conducted in our Santa Clara, California facility, we also carry out research and development at locations in San Jose, Costa Rica and Moscow, Russia. In addition, our customer-care, accounts receivable, credit and collections and customer event registration organizations are located at our facility in Costa Rica. Our 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 in the event travel to and from Mexico is restricted or as a result of natural disasters, such as earthquakes or volcanic eruptions;

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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.

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. In addition, our customer facing operations are located in Costa Rica. 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, respond to customer inquiries or manufacture and ship our aligners could be compromised which could result in our customers experiencing a significant delay in receiving their completed aligners and a decrease in service levels for a period of time. 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's Unitek and Dentsply International. These manufacturers have substantially greater financial resources and manufacturing and marketing experience than we do and may, in the future, attempt to develop an orthodontic system similar to ours or combine technologies that make our product economically unattractive. Large consumer product companies may also enter the orthodontic supply market. Furthermore, we may face competition in the future from new companies that may introduce new technologies. We may be unable to compete with these competitors and one or more of these competitors may render our technology obsolete or economically unattractive. If we are unable to compete effectively with existing products or respond effectively to any products developed by new or existing competitors, our business could be harmed. Increased competition has resulted in the past and may in the future result in volume discounting and price reductions, reduced gross margins, reduced profitability and loss of market share, any of which could have a material adverse effect on our revenues, volume growth, net profit (losses) and stock price. We cannot assure you that we will be able to compete successfully against our current or future competitors or that competitive pressures will not have a material adverse effect on our business, results of operations and financial condition.

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

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

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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

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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, 2010, we had 136 issued U.S. patents, 154 pending U.S. patent applications, and 65 issued foreign patents, and 127 pending foreign patent applications.

We intend to rely on our portfolio of issued and pending patent applications in the U.S. and in other countries to protect a large part of our intellectual property and our competitive position. However, our currently pending or future patent filings may not result in the issuance of patents. Additionally, any patents issued to us may be challenged, invalidated, held unenforceable, circumvented, or may not be sufficiently broad to prevent third parties from producing competing products similar in design to our products. In addition, any protection afforded by foreign patents may be more limited than that provided under U.S. patents and intellectual property laws. We also rely on protection of our copyrights, trade secrets, know-how and proprietary information. We generally enter into confidentiality agreements with our employees, consultants and our collaborative partners upon commencement of a relationship with us. However, these agreements may not provide meaningful protection against the unauthorized use or disclosure of our trade secrets or other confidential information, and adequate remedies may not exist if unauthorized use or disclosure were to occur. Our inability to maintain the proprietary nature of our technology through patents, copyrights or trade secrets would impair our competitive advantages and could have a material adverse effect on our operating results, financial condition and future growth prospects. In particular, a failure to protect our proprietary rights might allow competitors to copy our technology, which could adversely affect our pricing and market share. In addition, in an effort to protect our intellectual property we have in the past been and may in the future be involved in litigation. The potential effects on our business operations resulting from litigation that we may participate in the future, whether or not ultimately determined in our favor or settled by us, are costly and divert the efforts and attention of our management and technical personnel from normal business operations. Any of these results from our litigation could adversely affect our results of operations and stock price.

We are currently a party to various other legal proceedings and claims. Litigation is subject to inherent uncertainties and unfavorable rulings could occur. An unfavorable ruling could include monetary damages or, in cases where injunctive relief is sought, an injunction prohibiting us from selling our products. Any of these results from our litigation could adversely affect our results of operations and stock price. See *Part II, Item 1 of this Quarterly Report on Form 10-Q for a summary of our material pending legal proceedings.*

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

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

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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.

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, 2010, our North American sales organization consisted of 164 people, of which 150 were direct sales representatives and 14 were sales administration. Internationally, we 47 people engaged in sales and sales support as of March 31, 2010. 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.

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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 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.

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

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

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

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

Participants in the healthcare industry are subject to extensive and frequently changing regulations under numerous laws administered by governmental entities at the federal, state and local levels, some of which are, and others of which may be, applicable to our business. In response to perceived increases in health care costs in recent years, Congress recently passed health care reform legislation that President Obama signed into law in March 2010. The enacted legislation contains many provisions designed to generate the revenues necessary to fund the coverage expansions. The most relevant of these provisions are those that impose fees or taxes on certain health-related industries, including medical device manufacturers. Beginning in 2013, each medical device manufacturer will have to pay an excise tax in an amount equal to 2.3 percent of the price for which such manufacturer sells its

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medical devices. This tax applies to all medical devices, including our products. These taxes, will result in a significant increase in the tax burden on our industry, which could have a material, negative impact on our results of operations and our cash flows.

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

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

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

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

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

the marketing and advertising of our products.

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

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

We currently sell our products in Europe, Asia Pacific, Latin America and Japan and may expand into other countries from time to time. We do not know whether orthodontists, GPs and consumers outside our North American market will adopt Invisalign in sufficient numbers or as rapidly as we anticipate. In addition, sales of our products outside the U.S. are subject to foreign regulatory requirements that vary widely from country to country. The time required to obtain clearances or approvals required by other countries may be longer than that required for FDA clearance or approval, and requirements for such approvals may differ from FDA requirements. We may be unable to obtain regulatory approvals in one or more of the other countries in which we do business or in which we may do business in the future. We may also incur significant costs in attempting to obtain and maintain foreign regulatory approvals. If we experience delays in receipt of approvals to market our products outside of the U.S., or if we fail to receive these approvals, we may be unable to market our products or enhancements in international markets in a timely manner, if at all.

Our business exposes us to potential product liability claims, and we may incur substantial expenses if we are subject to product liability claims or litigation.

Medical devices involve an inherent risk of product liability claims and associated adverse publicity. We may be held liable if any product we develop or any product that uses or incorporates any of our technologies causes injury or is otherwise found unsuitable. Although we intend to continue to maintain product liability insurance, adequate insurance may not be available on acceptable terms, if at all, and may not provide adequate coverage against potential liabilities. A product liability claim, regardless of its merit or eventual outcome, could result in significant legal defense costs. These costs would have the effect of increasing our expenses and diverting management's attention away from the operation of our business, and could harm our business.

Historically, the market price for our common stock has been volatile.

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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

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general economic market conditions.

In addition, the stock market in general, and the market for technology and medical device companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated to or disproportionate to the operating performance of those companies. These broad market and industry factors may seriously harm the market price of our common stock, regardless of our operating performance. Historically, class action litigation is often brought against an issuing company following periods of volatility in the market price of a company's securities. Recently, a securities class action suit was filed against us on behalf of all persons or entities who purchased our common stock between January 30, 2007 and October 24, 2007. While we believe the lawsuit is without merit and intend to vigorously defend ourselves, we could incur substantial legal fees, and our management's attention and resources may be diverted from operating our business in order to respond to the litigation.

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

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

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

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

revenue recognition;

accounting for share-based payments; and

accounting for income taxes.

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

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

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

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 negotiation, purchase or redemption of the rights issued under the shareholder rights plan.

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

Various internal and external factors may have favorable or unfavorable effects on our future effective tax rate. These factors include, but are not limited to, changes in tax laws, regulations and/or rates, changing interpretations of existing tax laws or regulations, the future levels of tax benefits of stock option deductions relating to incentive stock options and employee stock purchase plans and changes in overall levels of pretax earnings. In June 2009, the Costa Rica Ministry of Foreign Trade, an agency of the

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Government of Costa Rica, granted a twelve year extension of the tax incentives which were previously granted in 2002. Under these incentives, all of the income we earn in Costa Rica during these twelve year incentive periods is subject to reduced rates of Costa Rica income tax. The incentive tax rates will expire in various years beginning in 2017. The Costa Rica corporate income tax rate that would apply, absent the incentives, is 30% for 2010. Because Costa Rica incurred a net loss in 2009, no tax benefit was realized from these incentives in 2009. 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. RESERVED

Not applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

(a) Exhibits:

Exhibit Number	Description	Filing	Date	Exhibit Number	Filed herewith
10.1	Lease Agreement between Align and Carr N.P. Properties, L.L.C. dated January 26, 2010	Form 8-K	01/29/2010	10.1	
10.2	Summary of cash incentive awards (bonuses) to Align's named executive officers	Form 8-K	02/08/2010	N/A	
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.				*

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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.

ALIGN TECHNOLOGY, INC.

Date: May 6, 2010

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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