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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 June 30, 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)

Delaware	**94-3267295**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification Number)**

2560 Orchard Parkway
San Jose, California 95131
(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 July 30, 2010 was 76,162,316.

ALIGN TECHNOLOGY, INC.

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PART I—FINANCIAL INFORMATION

ITEM 1 FINANCIAL STATEMENTS
ALIGN TECHNOLOGY, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except per share data)
(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2010	2009	2010	2009
Net revenues:				
Invisalign (1)	$102,821	$71,388	$188,243	$137,658
Non-case	5,375	4,928	10,043	8,790
Total net revenues	108,196	76,316	198,286	146,448
Cost of revenues				
Invisalign	18,583	16,397	36,888	31,788
Non-case	2,595	1,941	4,670	3,975
Total cost of revenues	21,178	18,338	41,558	35,763
Gross profit	87,018	57,978	156,728	110,685
Operating expenses:				
Sales and marketing	28,939	29,108	56,885	56,962
General and administrative	15,005	16,539	29,956	30,007
Research and development	6,396	5,669	12,512	10,860
Restructurings	—	409	—	1,319
Insurance settlement	(8,666)	—	(8,666)	—
Total operating expenses	41,674	51,725	90,687	99,148
Profit from operations	45,344	6,253	66,041	11,537
Interest and other income (expense), net	156	557	(397)	705
Net profit before provision for income taxes	45,500	6,810	65,644	12,242
Provision for income taxes	12,897	2,265	18,111	5,061
Net profit	$ 32,603	$ 4,545	$ 47,533	$ 7,181
Net profit per share:				
Basic	$ 0.43	$ 0.07	$ 0.63	$ 0.11
Diluted	$ 0.42	$ 0.07	$ 0.61	$ 0.11
Shares used in computing net profit per share:				
Basic	75,703	66,285	75,436	66,135
Diluted	77,607	67,373	77,644	66,941

(1) The three and six months ended June 30, 2010 include a $14.3 million release of previously deferred revenue for Invisalign Teen replacement aligners.

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

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

	June 30, 2010	December 31, 2009
ASSETS		
Current assets:		
Cash and cash equivalents	$ 235,801	$ 166,487
Marketable securities, short-term	8,998	19,978
Accounts receivable, net of allowance for doubtful accounts of $573 and $1,033, respectively	62,930	54,537
Inventories	2,487	2,046
Prepaid expenses and other current assets	20,881	18,251
Total current assets	331,097	261,299
Property and equipment, net	27,249	24,971
Goodwill	478	478
Intangible assets, net	3,588	4,988
Deferred tax asset, net	44,171	61,535
Other assets	2,109	1,969
Total assets	$ 408,692	$ 355,240
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 5,316	$ 6,122
Accrued liabilities	41,455	42,822
Deferred revenues	27,036	32,299
Total current liabilities	73,807	81,243
Other long-term liabilities	932	961
Total liabilities	74,739	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; 75,759 and 74,568 shares issued and outstanding, respectively)	8	7
Additional paid-in capital	539,160	525,073
Accumulated other comprehensive (loss) income, net	(249)	455
Accumulated deficit	(204,966)	(252,499)
Total stockholders' equity	333,953	273,036
Total liabilities and stockholders' equity	$ 408,692	$ 355,240

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

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

	Six Months Ended, June 30,	
	2010	2009
Cash Flows from Operating Activities:		
Net profit	$ 47,533	$ 7,181
Adjustments to reconcile net profit to net cash provided by operating activities:		
Deferred income taxes	17,364	563
Depreciation and amortization	5,955	4,979
Amortization of intangibles	1,400	1,400
Stock-based compensation	7,724	8,024
Amortization of prepaid royalties	827	—
(Benefit from) provision for doubtful accounts	(150)	517
Loss on retirement and disposal of fixed assets	11	11
Changes in assets and liabilities:		
Accounts receivable	(10,126)	(1,370)
Inventories	(462)	(150)
Prepaid expenses and other current assets	(3,705)	(1,843)
Accounts payable	(9)	1,240
Accrued and other long-term liabilities	(730)	2,141
Deferred revenues	(4,391)	6,420
Net cash provided by operating activities	61,241	29,113
Cash Flows from Investing Activities:		
Purchase of property and equipment	(8,849)	(3,044)
Purchases of marketable securities	—	(20,972)
Maturities of marketable securities	10,980	26,027
Other assets	(172)	100
Net cash provided by investing activities	1,959	2,111
Cash Flows from Financing Activities:		
Proceeds from issuance of common stock	7,213	4,185
Payments on short-term obligations	—	(136)
Employees' taxes paid upon the vesting of restricted stock units	(849)	(199)
Net cash provided by financing activities	6,364	3,850
Effect of foreign exchange rate changes on cash and cash equivalents	(250)	8
Net increase in cash and cash equivalents	69,314	35,082
Cash and cash equivalents at beginning of period	166,487	87,100
Cash and cash equivalents at end of period	$235,801	$122,182

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

ALIGN TECHNOLOGY, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(unaudited)

Note 1. Summary of Significant Accounting Policies

Basis of presentation

The accompanying unaudited Condensed Consolidated Financial Statements have been prepared by Align Technology, Inc. ("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 June 30, 2010, our results of operations for the three and six months ended June 30, 2010 and 2009, and our cash flows for the six months ended June 30, 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 and six months ended June 30, 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.

Revenue recognition

In the second quarter of 2010, we established a usage rate for the six replacement aligners that are included with the Invisalign Teen product. Invisalign Teen is delivered in a single shipment except for the six replacement aligners which may be ordered at any time throughout treatment. We use vendor specific objective evidence of fair value to allocate revenue to the replacement aligners and recognize the residual revenue upon initial shipment. We deferred 100 percent of the fair value for the six replacement aligners until we collected sufficient historical evidence to establish a usage rate. This deferred revenue is subsequently recognized as the replacement aligners are shipped or when the case is completed.

Since the launch of Invisalign Teen nearly two years ago, management has evaluated the actual usage of replacement aligners and believes that there is sufficient historical evidence to establish an estimated usage rate. As a result, in June 2010, we reduced deferred revenue for Invisalign Teen replacement aligners by $14.3 million to reflect the estimated usage for in-process cases. We believe that this estimated usage is reasonable and appropriate because of the relative stability of the Invisalign Teen replacement utilization since it was first offered. Although we are not expecting any material changes, we will continue to analyze the usage of replacement aligners and may adjust the estimated usage rate as necessary.

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.

ALIGN TECHNOLOGY, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS—(Continued)
(unaudited)

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 if the financial statements have been revised, then an entity that is not an SEC filer 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 adopted this guidance in the first quarter of 2010.

Note 2. Marketable Securities and Fair Value Measurements

Our short-term marketable securities as of June 30, 2010 and December 31, 2009 are as follows (in thousands):

June 30, 2010	Amortized Cost	Gross Unrealized Gains	Fair Value
U.S. government notes and bonds	$ 8,994	$ 4	$ 8,998

December 31, 2009	Amortized Cost	Gross Unrealized Gains	Fair Value
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 June 30, 2010, all short-term investments have maturity dates of less than one year. For the six months ended June 30, 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.

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 June 30, 2010.

ALIGN TECHNOLOGY, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS—(Continued)
(unaudited)

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 June 30, 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 significant management judgment or estimation.

We did not hold any Level 3 assets or liabilities as of June 30, 2010.

The following table summarizes our financial assets measured at fair value on a recurring basis as of June 30, 2010 (in thousands):

Description	Balance as of June 30, 2010	Quoted Prices in Active Markets for Identical Assets (Level 1)
Cash equivalents:		
Money market funds	$ 166,312	$ 166,312
Short-term investments:		
U.S. government debt securities	8,998	8,998
	$ 175,310	$ 175,310

Note 3. Balance Sheet Components

Inventories are comprised of (in thousands):

	June 30, 2010	December 31, 2009
Raw materials	$1,209	$ 1,079
Work in process	1,096	746
Finished goods	182	221
	$2,487	$ 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):

	June 30, 2010	December 31, 2009
Accrued payroll and benefits	$21,796	$ 25,847
Accrued income taxes	3,060	2,920
Accrued sales rebate	4,008	2,610
Accrued sales tax and value added tax	2,347	2,392
Accrued warranty	2,535	2,376
Accrued sales and marketing expenses	2,259	1,954
Other	5,450	4,723
	$41,455	$ 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 June 30, 2010 and December 31, 2009, the net carrying value of these non-compete agreements was $3.6 million (net of $10.4 million of accumulated amortization) and $5.0 million (net of $9.0 million of accumulated amortization), respectively.

ALIGN TECHNOLOGY, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS—(Continued)
(unaudited)

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 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 June 30, 2010 is as follows (in thousands):

Fiscal Year	
2010 (for the remaining 6 months)	$1,400
2011	2,188
Total	$3,588

Note 5. Legal Proceedings

Weber

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 June 2, 2010, the Court granted our motion for summary judgment and dismissed us from the action.

On June 29, 2010, Weber requested that the Court enter final judgment as to Align pursuant to Federal Rule of Civil Procedure 54(b) in order to certify Align’s dismissal for immediate appeal. We filed an opposition to Weber’s request on July 19, 2010, on the grounds that Weber failed to show that exceptional circumstances warranted the entry of a final judgment where fewer than all claims or parties had been dismissed. We await the Court’s ruling on Weber’s motion. We believe there is not sufficient evidence to conclude that a reasonable possibility exists that a loss had been incurred as of June 30, 2010.

Leiszler

On May 10, 2010, Christopher J. Leiszler filed a complaint against us in the United States District Court for the Northern District of California. The complaint alleges that we implemented unfair and fraudulent requirements for the prescription of Invisalign through the Invisalign Proficiency Requirements. Dr. Leiszler, a general practice dentist in Kansas City, Missouri, attended Invisalign training in 2008 and had started one Invisalign case since that time. His Invisalign provider status was changed in January 2010 for failing to meet the Proficiency Requirements. Dr. Leiszler purports to sue on behalf of himself and all others similarly situated. The complaint seeks a refund of the price paid to us for Invisalign training. On July 7, 2010, we filed a motion to dismiss. We intend to vigorously defend ourselves against the litigation. We believe there is not sufficient evidence to conclude that a reasonable possibility exists that a loss had been incurred as of June 30, 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 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 . The 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 was heard by the Court on July 9, 2010, and the Court has not yet released a ruling on the motion. We believe the lawsuit to be without merit and intend to vigorously defend ourselves. We believe there is not sufficient evidence to conclude that a reasonable possibility exists that a loss had been incurred as of June 30, 2010.

ALIGN TECHNOLOGY, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS—(Continued)
(unaudited)

Note 6. Settlements

Ormco

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. The settlement value was allocated between past infringement and future use of the patent based on total case shipments during the period of infringement. 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 as of the settlement date. 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.

OrthoClear

In June 2010, we received an $8.7 million insurance settlement over a disputed coverage under our general liability umbrella that was not previously reimbursed by our insurer related to the OrthoClear litigation.

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 June 30, 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 June 30, 2010, minimum future lease payments for non-cancelable leases are as follow (in thousands):

Fiscal Year	
2010 (for the remaining 6 months)	$ 2,133
2011	3,996
2012	3,358
2013	2,752
2014 and thereafter	7,101
Total	$19,340

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 commenced on June 28, 2010 and will continue for an initial term of seven years and two months. The agreement for our previous corporate headquarters in Santa Clara, California, expired on June 30, 2010.

ALIGN TECHNOLOGY, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS—(Continued)
(unaudited)

Warranty

We warrant our products against material defects until the Invisalign case is complete. 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 six months ended June 30, 2010 and 2009, respectively (in thousands):

	Six Months Ended June 30,	
	2010	2009
Balance at beginning of period	$ 2,376	$ 2,031
Charged to cost of revenues	1,475	1,227
Actual warranty expenses	(1,316)	(1,354)
Balance at end of period	$ 2,535	$ 1,904

Note 9. Stock-based Compensation

Summary of stock-based compensation expense

On May 20, 2010 the Shareholders voted to approve an amendment to the 2005 Incentive Plan. The amendment increased the plan by 3,300,000 shares for a total reserved for issuance of 13,283,379 shares, plus up to an aggregate of 5,000,000 shares that would have been returned to our 2001 Stock Incentive Plan as a result of termination of options or repurchase of shares on or after March 28, 2005.

The following table summarizes stock-based compensation expense related to all of our stock-based options and employee stock purchases for the three and six months ended June 30, 2010 and 2009 (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2010	2009	2010	2009
Cost of revenues	$ 401	$ 406	$ 837	$ 791
Sales and marketing	1,261	1,364	2,108	2,316
General and administrative	2,007	2,000	3,819	3,954
Research and development	582	539	960	963
Total stock-based compensation expense	$ 4,251	$ 4,309	$7,724	$8,024

Options

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:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2010	2009	2010	2009
Stock Options:				
Expected term (in years)	4.4	4.4	4.4	4.4
Expected volatility	63.0%	62.4%	63.3%	61.4%
Risk-free interest rate	1.9%	1.8%	2.0%	1.6%
Expected dividend	—	—	—	—
Weighted average fair value per share at grant date	$8.72	$6.09	$9.20	$4.08

ALIGN TECHNOLOGY, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS—(Continued)
(unaudited)

Stock option activity for the six months ended June 30, 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	1,350	17.88		
Cancelled or expired	(169)	14.21		
Exercised	(672)	7.65		
Outstanding as of June 30, 2010	7,997	$ 12.83	6.20	$ 26,825
Vested and expected to vest at June 30, 2010	7,694	$ 12.75	6.15	$ 26,272
Exercisable at June 30, 2010	5,033	$ 11.85	5.46	$ 21,010

As of June 30, 2010, we expect to recognize $22.5 million of total unamortized compensation cost related to stock options over a weighted average period of 2.6 years.

Restricted Stock Units

In the amended 2005 Incentive Plan any shares subject to an award of restricted stock, restricted stock units, performance shares or performance units will be counted against the authorized share reserve as one and one-half (1 1/2) shares for every one share subject to the award, and any shares cancelled will be returned to the Plan at the same ratio.

A summary of the nonvested shares for the six months ended June 30, 2010 is as follows:

	Number of Shares Underlying RSUs (in thousands)	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value (in thousands)
Nonvested as of December 31, 2009	876		
Granted	384		
Vested and released	(271)		
Forfeited	(50)		
Nonvested as of June 30, 2010	939	1.55	$ 13,972

As of June 30, 2010 the total unamortized compensation cost related to restricted stock units was $13.0 million, which we expect to recognize over a weighted average period of 2.5 years.

Employee Stock Purchase Plan

Our current 2005 Employee Stock Purchase Plan (the “Purchase Plan”) consists of overlapping twenty-four month offering periods with four six-month purchase periods in each offering period and will expire on January 31, 2011. In May 2010, the shareholders approved the 2010 Employee Stock Purchase Plan. The 2010 plan consists of overlapping twenty-four month offering periods with four six- month purchase periods in each offering period. The plan will continue until terminated by either the Board or its administrator. Employees purchase shares at 85% of the fair market value of the common stock at either the beginning of the offering period or the end of the purchase period, whichever is lower. The maximum number of shares available under the 2010 Employee Stock Purchase Plan is 2,400,000 shares.

As of June 30, 2010, we expect to recognize $0.8 million of the total unamortized compensation cost related to employee purchases over a weighted average period of 0.2 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 fifty percent likely of being realized upon ultimate settlement.

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(unaudited)

During the second quarter of fiscal 2010, the amount of unrecognized tax benefits was increased by approximately $1.0 million. The total amount of unrecognized tax benefits was $7.7 million as of June 30, 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 not significant 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 June 30		Six Months Ended June 30,	
	2010	2009	2010	2009
Net profit	$32,603	$ 4,545	$47,533	$ 7,181
Weighted-average common shares outstanding, basic	75,703	66,285	75,436	66,135
Effect of potential dilutive common shares	1,904	1,088	2,208	806
Total shares, diluted	77,607	67,373	77,644	66,941
Basic net profit per share	$ 0.43	$ 0.07	$ 0.63	$ 0.11
Diluted net profit per share	$ 0.42	$ 0.07	$ 0.61	$ 0.11

For the three and six months ended June 30, 2010, stock options and restricted stock units totaling 3.3 million and 2.9 million, respectively, were excluded from diluted net profit per share because of their anti-dilutive effect. For the three and six months ended June 30, 2009, stock options and restricted stock units totaling 5.4 million and 5.6 million, respectively, were excluded from diluted net profit per share because of their anti-dilutive effect.

Note 12. Comprehensive Income

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2010	2009	2010	2009
Net profit	$32,603	$4,545	$47,533	$7,181
Foreign currency translation adjustments	(354)	384	(702)	26
Change in unrealized gains (losses) on available-for-sale securities	(4)	1	(2)	21
Comprehensive income	$32,245	$4,930	$46,829	$7,228

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.

ALIGN TECHNOLOGY, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS—(Continued)
(unaudited)

Geographical Information

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2010	2009	2010	2009
Net revenues:				
North America	$ 81,732	$57,230	$150,586	$112,523
Europe	25,427	18,428	45,805	32,780
Other international	1,037	658	1,895	1,145
Total net revenues	$108,196	$76,316	$198,286	$146,448

	As of June 30, 2010	As of December 31, 2009
Long-lived assets:		
North America	$ 75,152	$ 91,548
Europe	759	1,018
Other international	1,684	1,375
Total long-lived assets	$ 77,595	$ 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. There were no costs incurred relating to the restructuring plans during the first half of 2010.

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 fall launch of significant innovations in product features and functionality and customer facing systems, including the timing of the launch, 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.

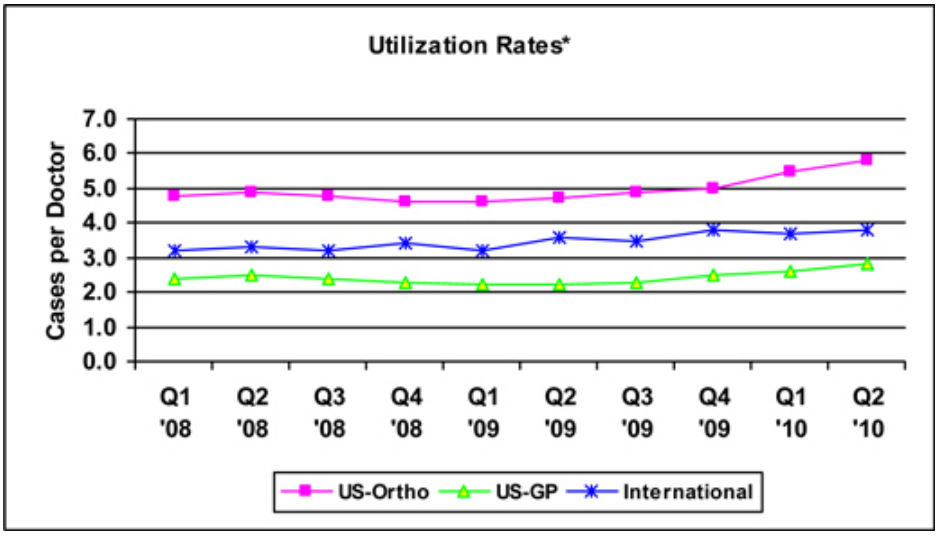
Each Invisalign treatment plan is unique to the individual patient. Our Invisalign Full treatment consists of as many aligners as indicated by ClinCheck in order to achieve the doctors' treatment goals. Our Invisalign Express is a dual arch orthodontic treatment for cases that meet certain predetermined 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. In April 2010, we replaced Invisalign Express in Europe and Japan with the launch of Invisalign Lite. Invisalign Lite offers doctors a new option for less complex orthodontic cases, such as short-term aesthetic cases, relapsed cases and pre-restorative treatments, using up to 14 stages. 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 Vivera retainers, a clear aligner set designed for ongoing retention. Our goal is to establish Invisalign as the standard method for treating malocclusion ultimately driving increased product adoption by dental professionals by focusing on the four key objectives: driving product innovation 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 I—Business—Business Strategy* of our 2009 Annual Report on Form 10-K. As we execute on our business strategy, we will continue to deliver significant evolutions in product features and functionality, as well as customer facing systems. This fall, we expect to launch a collection of innovation that will touch every product and virtually every system at Align. These improvements have been engineered to deliver even better, more predictable clinical results with wider applicability to allow our doctors to treat more complex and challenging cases. 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 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 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. In the first two quarters of 2010, we trained approximately 1,395 doctors in North America (including 440 doctors who had their account suspended as a result of the Proficiency Requirements at the end of 2009). 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 and reactivated doctors trained in North America will be moderately lower in 2010 compared to 2009. Internationally, we expect that the number of new doctors trained to be 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 ten quarters are as follows:



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

Utilization rates in the second quarter of 2010 for all channels increased compared to the same period of last year primarily because the number of cases submitted by high volume doctors increased while case submissions by low volume doctors declined. However, 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.

- *Release of previously deferred revenue*. In the second quarter of 2010, we released $14.3 million of previously deferred revenue for Invisalign Teen replacement aligners. Invisalign Teen, which was launched in July 2008, includes up to six replacement aligners which may be ordered at any time throughout treatment. Revenue for these replacement aligners was previously deferred based on 100 percent of the fair value of the aligners until the replacement aligners were used or the case completed. Over the past two years, we have evaluated the usage experience of the Invisalign Teen replacement aligners and now believe that we have sufficient historical evidence to support an estimated usage rate. Since the deferral rate for estimated usage is significantly lower than our previous rate, we expect some favorable impact to revenue from the second quarter to the third quarter of 2010.
- *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 North America GPs and European doctors.

  However, in 2009, we did not experience the normal seasonality in our business and the North American Ortho channel had sequential case growth from second quarter to the third quarter. With the availability of Invisalign Teen, the summer of 2009 was the first summer we were able to actively compete for a share of teen patient starts. 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. We 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. Although we expect the number of teenage cases will continue to grow in the third quarter of 2010, there can be no assurance that the historical downward trend we have experienced in the Ortho channel will not occur and that our historical seasonal trends will not generally continue to cause fluctuations in our quarterly results, including fluctuations in sequential revenue growth rates.

  The third quarter of 2009 was also a stronger quarter for our GP channel than we historically experience. We believe that this was due, in part, to lower volume doctors trying to meet the minimum case requirements in effect at that time. However, with the elimination of the minimum case requirements, in the third quarter of 2010, we expect GPs to be down sequentially from the second quarter.
- *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.
- *Operating Expenses*. In the third quarter of 2010, we expect operating expenses to increase reflecting additional spending in media advertising and consumer demand programs in North America and International as well as continued investment in product and technology innovation.

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 and six months ended June 30, 2010 and 2009 are as follows (in millions):

	Three Months Ended June 30,				Six Months Ended June 30,			
Net revenues	2010	2009	Net Change	% Change	2010	2009	Net Change	% Change
North America:								
Ortho	$ 29.1	$21.6	$ 7.5	34.7%	$ 57.3	$ 42.7	$ 14.6	34.2%
GP	37.4	31.7	5.7	18.0%	74.6	62.6	12.0	19.2%
Total North American Invisalign	66.5	53.3	13.2	24.8%	131.9	105.3	26.6	25.3%
International Invisalign	22.0	18.1	3.9	21.5%	42.0	32.4	9.6	29.6%
Total Invisalign revenues	88.5	71.4	17.1	23.9%	173.9	137.7	36.2	26.3%
Teen deferred revenue release	14.3	—	14.3	N/A	14.3	—	14.3	N/A
Non-case revenues	5.4	4.9	0.5	10.2%	10.1	8.7	1.4	16.1%
Total net revenues	$108.2	$76.3	$ 31.9	41.8%	$198.3	$146.4	$ 51.9	35.5%

Case volume data which represents Invisalign case shipments by channel, for the three and six months ended June 30, 2010 and 2009 are as follows (in thousands):

	Three Months Ended June 30,				Six Months Ended June 30,			
Invisalign case volume	2010	2009	Net Change	% Change	2010	2009	Net Change	% Change
North America:								
Ortho	23.1	17.5	5.6	32.0%	45.2	34.4	10.8	31.4%
GP	28.5	23.5	5.0	21.3%	57.0	46.8	10.2	21.8%
Total North American Invisalign	51.6	41.0	10.6	25.9%	102.2	81.2	21.0	25.9%
International Invisalign	15.9	12.0	3.9	32.5%	28.9	21.9	7.0	32.0%
Total Invisalign case volume	67.5	53.0	14.5	27.4%	131.1	103.1	28.0	27.2%

Invisalign revenues by product and other non-case revenues, which represents training, retainer and ancillary products, for the three and six months ended June 30, 2010 and 2009 are as follows (in millions):

	Three Months Ended June 30,				Six Months Ended June 30,			
Net revenues	2010	2009	Net Change	% Change	2010	2009	Net Change	% Change
Invisalign Full	$ 67.5	$57.6	$ 9.9	17.2%	$133.2	$112.9	$ 20.3	18.0%
Invisalign Express/Lite	8.8	7.1	1.7	23.9%	17.4	13.9	3.5	25.2%
Invisalign Teen (1)	22.7	5.5	17.2	312.7%	30.9	9.0	21.9	243.3%
Invisalign Assist	3.8	1.2	2.6	216.7%	6.7	1.9	4.8	252.6%
Other non-case revenues	5.4	4.9	0.5	10.2%	10.1	8.7	1.4	16.1%
Total net revenues	$108.2	$76.3	$ 31.9	41.8%	$198.3	$146.4	$ 51.9	35.5%

(1) The three and six months ended June 30, 2010 include a $14.3 million release of previously deferred revenue for Invisalign Teen replacement aligners.

Case volume data which represents Invisalign case shipments by product, for the three and six months ended June 30, 2010 and 2009 are as follows (in thousands):

	Three Months Ended June 30,				Six Months Ended June 30,			
Invisalign case volume	2010	2009	Net Change	% Change	2010	2009	Net Change	% Change
Invisalign Full	47.1	37.9	9.2	24.3%	90.8	75.2	15.6	20.7%
Invisalign Express/Lite	9.6	8.0	1.6	20.0%	18.8	16.0	2.8	17.5%
Invisalign Teen	6.8	5.9	0.9	15.3%	14.2	9.8	4.4	44.9%
Invisalign Assist	4.0	1.2	2.8	233.3%	7.3	2.1	5.2	247.6%
Total Invisalign case volume	67.5	53.0	14.5	27.4%	131.1	103.1	28.0	27.2%

Total net revenues increased for the three and six month periods ended June 30, 2010 as compared to the same periods in 2009 primarily as a result of worldwide volume growth across all customer channels and all products in addition to the release of $14.3 million related to previously deferred revenue for Invisalign Teen replacement aligners. 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 both the three and six months ended June 30, 2010, North America revenue increased 24.8% and 25.3%, respectively, as compared to the same periods in 2009 due to case volume growth of 25.9% for both periods. The incremental revenue from the volume growth was offset slightly by higher volume-based discounts. Our International Invisalign revenue also increased for the three and six months ended June 30, 2010, as compared to the same periods in 2009, mainly due to growth in case volumes from all products.

Invisalign Teen includes up to six replacement aligners which may be ordered at any time throughout treatment. Revenue for these replacement aligners was deferred based on 100 percent of the fair value of the aligners until the replacement aligners were used or the case completed. Since the launch of Invisalign Teen nearly two years ago, we have evaluated the usage experience of the replacement aligners and now believe that there is sufficient historical experience to establish an estimated usage rate. As a result, in June 2010, we reduced deferred revenue for Invisalign Teen replacement aligners by $14.3 million to reflect the lower estimated usage for in-process cases.

Other non-case revenues, consisting of training fees and sales of ancillary products, were higher for the three and six month periods ended June 30, 2010 compared to the same periods in 2009 primarily due to increased sales of our Vivera and retainer products.

Cost of revenues and gross profit (in millions):

	Three Months Ended June 30,			Six Months Ended June 30,		
	2010	2009	Change	2010	2009	Change
Cost of revenues	$21.2	$18.3	$ 2.9	$ 41.6	$ 35.8	$ 5.8
% of net revenues	19.6%	24.1%		21.0%	24.4%	
Gross profit	$87.0	$58.0	$ 29.0	$156.7	$110.7	$ 46.0
Gross margin	80.4%	75.9%		79.0%	75.6%	

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. Through April 2009, cost of revenues also included the cost of our third party shelter service provider in Juarez, Mexico. Royalties fully amortized in the first quarter of 2010 of $0.8 million are also included in cost of revenues for the six month ended June 30, 2010.

Gross margin improved for the three and six months ended June 30, 2010 compared to the same period in 2009 primarily due to increased cost absorption due to higher production volumes and the release of teen deferred revenue of $14.3 million during second quarter of 2010 partially offset by higher volume-based discounts.

Sales and marketing (in millions):

	Three Months Ended June 30,			Six Months Ended June 30,		
	2010	2009	Change	2010	2009	Change
Sales and marketing	$28.9	$29.1	$ (0.2)	$56.9	$57.0	$ (0.1)
% of net revenues	26.7%	38.1%		28.7%	38.9%	

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 June 30, 2010 was comparable to the same period in 2009. The second quarter of 2010 reflects a decrease of $1.2 million in clinical education relating to expenses for our European summit held in June 2009. This reduction was partially offset by a $0.6 million increase in payroll and employee benefits, and a $0.3 million increase in marketing, media, and advertising expenses.

Our sales and marketing expense for the six months ended June 30, 2010 was comparable to the same period in 2009. The second quarter of 2010 reflects a decrease of $2.2 million in clinical education relating to expenses for our European summit held in June 2009. This reduction was offset by a $1.4 million increase in marketing, media, and advertising expenses, and a $0.5 million increase in other charges associated with the transition into our new building combined with additional depreciation expense.

General and administrative (in millions):

	Three Months Ended June 30,			Six Months Ended June 30,		
	2010	2009	Change	2010	2009	Change
General and administrative	$15.0	$16.5	$ (1.5)	$30.0	$30.0	$ —
% of net revenues	13.9%	21.7%		15.1%	20.5%	

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

General and administrative expense decreased in the three months ended June 30, 2010 as compared to the same period in 2009 due to $1.7 million of legal fees that were incurred during the second quarter of 2009 related to the Ormco litigation which settled in the third quarter of 2009. These costs were slightly offset by other higher legal and outside consulting fees of $0.3 million during the second quarter of 2010.

General and administrative expense was comparable for the six months ended June 30, 2010 as compared to the same period in 2009.

Research and development (in millions):

	Three Months Ended June 30,			Six Months Ended June 30		
	2010	2009	Change	2010	2009	Change
Research and development	$ 6.4	$ 5.7	$ 0.7	$12.5	$10.9	$ 1.6
% of net revenues	5.9%	7.4%		6.3%	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.

Research and development expense was slightly higher during the three months ended June 30, 2010 compared to the same period in 2009 primarily due to $0.5 million higher payroll-related and temporary contractor expenses.

Research and development expense was slightly higher during the six months ended June 30, 2010 compared to the same period in 2009 primarily due to a $1.0 million increase in payroll-related and temporary contractor expenses as well as $0.4 million in other charges associated with the transition into our new building combined with additional depreciation expense.

Restructuring (in millions):

	Three Months Ended June 30,			Six Months Ended June 30,		
	2010	2009	Change	2010	2009	Change
Restructuring	—	$ 0.4	$ (0.4)	—	$ 1.3	$ (1.3)
% of net revenues	0.0%	0.5%		0.0%	0.9%	

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 $1.3 million during the first half of 2009 of cost related to severance and termination benefits. There were no restructuring costs during the first half of 2010.

Insurance settlement (in millions):

	Three Months Ended June 30,			Six Months Ended June 30,		
	2010	2009	Change	2010	2009	Change
Insurance settlement	$(8.7)	$—	$ (8.7)	$(8.7)	$—	$ (8.7)
% of net revenues	8.0%	0.0%		4.4%	0.0%	

In June 2010, we received an $8.7 million insurance settlement over a disputed coverage under our general liability umbrella that was not previously reimbursed by our insurer related to the OrthoClear litigation.

Interest and other income, net (in millions):

	Three Months Ended June 30,			Six Months Ended June 30,		
	2010	2009	Change	2010	2009	Change
Interest income	$ 0.1	$ 0.2	$ (0.1)	$ 0.2	$ 0.4	$ (0.2)
Other income (expense), net	0.1	0.4	(0.3)	(0.6)	0.3	(0.9)
Total interest income and other (expense), net	$ 0.2	$ 0.6	$ (0.4)	$ (0.4)	$ 0.7	$ (1.1)

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

Interest income, net for the three and six months ended June 30, 2010 decreased slightly compared to the same period in 2009 primarily due to lower returns on our investments as we shifted into more conservative savings accounts and money market funds which bear lower interest rates.

Other income (expense), net for the three and six months ended June 30, 2010 decreased as compared with the same period in 2009 reflecting increases in foreign exchange losses during the first half of 2010.

Income tax (in millions):

	Three Months Ended June 30,			Six Months Ended June 30,		
	2010	2009	Change	2010	2009	Change
Provision for income taxes	$ 12.9	$ 2.3	$ 10.6	$18.1	$5.1	$ 13.0

We recorded an income tax provision of $ 12.9 million and $2.3 million for the three months ended June 30, 2010 and 2009, respectively, representing effective tax rates of 28.3% and 33.3%. We recorded an income tax provision of $18.1 million and $5.1 million for the six months ended June 30, 2010 and 2009, respectively, representing effective tax rates of 27.6% and 41.3%. 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 June 30, 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.

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 June 30, 2010 and December 31, 2009 we had the following cash and cash equivalents, and short-term marketable securities (in thousands):

	June 30, 2010	December 31, 2009
Cash and cash equivalents	$235,801	$ 166,487
Marketable securities, short-term	8,998	19,978
Total	$244,799	$ 186,465

Net cash provided by operating activities was $61.2 million for the six months ended June 30, 2010 resulting primarily from our net profit of $47.5 million adjusted for non-cash items largely from deferred income taxes, depreciation, amortization of intangibles and royalties of $25.5 million and $7.7 million of stock-based compensation expenses. These expenses were partially offset by increases in accounts receivables and prepaid expenses and other assets of $13.8 million and decreases in accrued liabilities and deferred revenue of $5.1 million.

Net cash provided by operating activities was $29.1 million for the six months ended June 30, 2009 resulting primarily from our net profit of $7.2 million adjusted by $14.9 million for non-cash items such as depreciation, amortization of intangibles and stock based compensation expense, as well as a $10.5 million increase in accounts payable and accrued liabilities due to timing of payments to our suppliers and higher deferred revenue related to our new Invisalign Teen and Invisalign Assist products. These changes were offset by a $3.5 million increase in accounts receivable, prepaids, and other assets.

Net cash provided by investing activities was $2.0 million for the six months ended June 30, 2010 primarily consisted of maturities of our marketable securities of $10.9 million, which were partially offset by property, plant, and equipment purchases of $8.8 million. There were no purchases of marketable securities during the first half of 2010 as we have shifted our investments into savings accounts and money market funds.

Net cash provided by investing activities was $2.1 million for the six months ended June 30, 2009, consisting largely of $5.1 million of proceeds from net maturities of marketable securities due to the timing of the reinvestment of proceeds from securities that matured, which were partially offset by $3.0 million for the purchase of property, plant, and equipment.

Net cash provided by financing activities was $6.4 million for the six months ended June 30, 2010 primarily resulting from $7.2 million in proceeds from the issuance of our common stock, which were partially offset by $0.8 million of taxes paid on the vesting of restricted stock units related to our employee stock plan.

Net cash provided by financing activities was $3.9 million for the six months ended June 30, 2009, which primarily resulted from $4.2 million in proceeds from the issuance of our common stock for employee stock option exercises.

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 commenced on June 28, 2010 and will continue for an initial term of seven years and two months. The lease agreement for our previous office headquarters in Santa Clara, California, expired on June 30, 2010.

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.

Revenue Recognition

In the second quarter of 2010, we established a usage rate for the six replacement aligners that are included with the Invisalign Teen product. Invisalign Teen is delivered in a single shipment except for the six replacement aligners which may be ordered at any time throughout treatment. We use vendor specific objective evidence of fair value to allocate revenue to the replacement aligners and recognize the residual revenue upon initial shipment. We deferred 100 percent of the fair value for the six replacement aligners until we collected sufficient historical evidence to establish a usage rate. This deferred revenue is subsequently recognized as the replacement aligners are shipped or when the case is completed.

Since the launch of Invisalign Teen nearly two years ago, management has evaluated the actual usage of replacement aligners and believes that there is sufficient historical evidence to establish an estimated usage rate. As a result, in June 2010, we reduced deferred revenue for Invisalign Teen replacement aligners by $14.3 million to reflect the estimated usage for in-process cases. We believe that this estimated usage is reasonable and appropriate because of the relative stability of the Invisalign Teen replacement utilization since it was first offered. Although we are not expecting any material changes, we will continue to analyze the usage of replacement aligners and may adjust the estimated usage rate as necessary.

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 June 30, 2010 to provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our Chief Executive Officer and our Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure, and that such information is recorded, processed, summarized and reported within the time periods specified in the SEC rules and forms.

Changes in internal control over financial reporting.

There was no change in our internal control over financial reporting that occurred during the period covered by this Quarterly Report on Form 10-Q that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

Weber

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 June 2, 2010, the Court granted our motion for summary judgment and dismissed us from the action.

On June 29, 2010, Weber requested that the Court enter final judgment as to Align pursuant to Federal Rule of Civil Procedure 54(b) in order to certify Align’s dismissal for immediate appeal. We filed an opposition to Weber’s request on July 19, 2010, on the grounds that Weber failed to show that exceptional circumstances warranted the entry of a final judgment where fewer than all claims or parties had been dismissed. We await the Court’s ruling on Weber’s motion.

Leiszler

On May 10, 2010, Christopher J. Leiszler filed a complaint against us in the United States District Court for the Northern District of California. The complaint alleges that we implemented unfair and fraudulent requirements for the prescription of Invisalign through the Invisalign Proficiency Requirements. Dr. Leiszler, a general practice dentist in Kansas City, Missouri, attended Invisalign training in 2008 and had started one Invisalign case since that time. His Invisalign provider status was changed in January 2010 for failing to meet the Proficiency Requirements. Dr. Leiszler purports to sue on behalf of himself and all others similarly situated. The complaint seeks a refund of the price paid to us for Invisalign training. On July 7, 2010, we filed a motion to dismiss. We intend to vigorously defend ourselves against the litigation.

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 our common stock of 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. The 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 was heard by the Court on July 9, 2010 and the Court has not yet released a ruling on the motion. We believe the lawsuit to be without merit and intend to vigorously defend ourselves.

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. 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 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 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 or changes to our 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;
- 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 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, and expects to launch further evolutions in product features and functionality, as well as customer facing systems in the near future. 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, compatibility of our computer operating systems and hardware configurations with customers, 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;
- 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 penetrate our network security and misappropriate our confidential information or that of third parties, create system disruptions or cause shutdowns. Furthermore, sophisticated hardware and operating system software and applications that we either internally develop or procure from third parties may contain defects in design and manufacture, including "bugs" and other problems that can unexpectedly interfere with the operation of the system. The costs to eliminate or alleviate security problems, viruses and bugs could be significant, and the efforts to address these problems could result in interruptions that may have a material adverse impact on our operations, revenues and operating results.

We are currently focused on adding more functionality into our business enterprise systems to more efficiently integrate these systems with our other system applications, such as customer facing and manufacturing tools, and intend to continue this effort for the foreseeable future. System upgrades and enhancements, including those upgrades and enhancements associated with the anticipated launch in the fall of 2010 of a collection of innovation that will touch every product and virtually each of our systems, 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 or the incompatibility with the computer operating system and hardware configurations of customers 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 June 30, 2010, we had 140 issued U.S. patents, 145 pending U.S. patent applications, and 74 issued foreign patents, and 111 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.

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.

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

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

If we lose our key personnel or are unable to attract and retain key personnel, we may be unable to pursue business opportunities or develop our products.

We are highly dependent on the key employees in our clinical engineering, technology development, sales and marketing personnel and management teams. The loss of the services provided by those individuals may significantly delay or prevent the achievement of our product development and other business objectives and could harm our business. Our future success will also depend on our ability to identify, recruit, train and retain additional qualified personnel, including orthodontists. Few orthodontists are accustomed to working in a manufacturing environment since they are generally trained to work in private practices, universities and other research institutions. Thus, we may be unable to attract and retain personnel with the advanced qualifications necessary for the further development of our business. Furthermore, we may not be successful in retaining our key personnel or their services. If we are unable to attract and retain key personnel, our business could be materially harmed.

If we infringe the patents or proprietary rights of other parties or are subject to a patent infringement claim, our ability to grow our business may be severely limited.

Extensive litigation over patents and other intellectual property rights is common in the medical device industry. We have been sued for infringement of third party's patents in the past and we may be the subject of patent or other litigation in the future. From time to time, we have received and may in the future receive letters from third parties drawing our attention to their patent rights. While we do not believe that we infringe upon any valid and enforceable rights that have been brought to our attention, there may be other more pertinent rights of which we are presently unaware. The defense and prosecution of intellectual property suits, interference proceedings and related legal and administrative proceedings could result in substantial expense to us and significant diversion of effort by our technical and management personnel. An adverse determination of any litigation or interference proceeding to which we may become a party could subject us to significant liabilities. An adverse determination of this nature could also put our patents at risk of being invalidated or interpreted narrowly or require us to seek licenses from third parties. Licenses may not be available on commercially reasonable terms or at all, in which event, our business would be materially adversely affected.

We maintain single supply relationships for certain of our key machines and materials technologies, and our business and operating results could be harmed if supply is restricted or ends or the price of raw materials used in our manufacturing process increases.

We are highly dependent on manufacturers of specialized scanning equipment, rapid prototyping machines, resin and other advanced materials. We maintain single supply relationships for many of these machines and materials technologies. In particular, our scanning and stereolithography equipment are provided by a single supplier. We are also committed to purchasing all of our resin and polymer, the primary raw materials used in our manufacturing process, from a single source. In addition, technology changes by our vendors could disrupt access to required manufacturing capacity or require expensive, time consuming development efforts to adapt and integrate new equipment or processes. Our growth may exceed the capacity of one or more of these manufacturers to produce the needed equipment and materials in sufficient quantities to support our growth. In the event of technology changes, delivery delays, or shortages of or increases in price for these items, our business and growth prospects may be harmed.

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 June 30, 2010, our North American sales organization consisted of 169 people, of which 134 were quota carrying sales representatives and 35 were regional sales managers and administration. Internationally, we had 43 people engaged in sales and sales support as of June 30, 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.

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.

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 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.

The market price of our common stock could be subject to wide price fluctuations in response to various factors, many of which are beyond our control. The factors include:

- quarterly variations in our results of operations and liquidity;
- changes in recommendations by the investment community or in their estimates of our revenues or operating results;
- speculation in the press or investment community concerning our business and results of operations;
- strategic actions by our competitors, such as product announcements or acquisitions;
- announcements of technological innovations or new products by us, our customers or competitors; and
- general economic market conditions.

In addition, the stock market in general, and the market for technology and medical device companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated to or disproportionate to the operating performance of those companies. These broad market and industry factors may seriously harm the market price of our common stock, regardless of our operating performance. 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 negation, purchase or redemption of the rights issued under the shareholder rights' plan.

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

Various internal and external factors may have favorable or unfavorable effects on our future effective tax rate. These factors include, but are not limited to, changes in tax laws, regulations and/or rates, changing interpretations of existing tax laws or regulations, the future levels of tax benefits of stock option deductions relating to incentive stock options and employee stock purchase plans and changes in overall levels of pretax earnings. In June 2009, the Costa Rica Ministry of Foreign Trade, an agency of the Government of Costa Rica, granted a twelve year extension of the tax incentives which were previously granted in 2002. Under these incentives, all of the income we earn in Costa Rica during these twelve year incentive periods is subject to reduced rates of Costa Rica income tax. The incentive tax rates will expire in various years beginning in 2017. The Costa Rica corporate income tax rate that would apply, absent the incentives, is 30% for 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. REMOVED AND RESERVED

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

(a) Exhibits:

Exhibit Number	Description	Filing	Date	Exhibit Number	Filed herewith
10.1	Align's Amended and Restated 2005 Incentive Plan	Form 8-K	05/20/2010	10.1	
10.2	Align's 2010 Employee Stock Purchase Plan	Form 8-K	05/20/2010	10.2	
31.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				*
31.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				*
32.1	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				*
101.INS	XBRL Instance Document				*
101.SCH	XBRL Taxonomy Extension Schema Document				*
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document				*
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document				*
101.LAB	XBRL Taxonomy Extension Label Linkbase Document				*
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document				*

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: August 5, 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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Exhibit 31.1

CERTIFICATION

I, Thomas M. Prescott, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Align Technology, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 5, 2010

/s/ THOMAS M. PRESCOTT

Thomas M. Prescott
President and Chief Executive Officer

Exhibit 31.2

CERTIFICATION

I, Kenneth B. Arola, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Align Technology, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 5, 2010

/S/ KENNETH B. AROLA

Kenneth B. Arola
Chief Financial Officer and Vice President, Finance

Exhibit 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

I, Thomas M. Prescott, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Quarterly Report of Align Technology, Inc. on Form 10-Q for the quarter ended June 30, 2010 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in such Quarterly Report on Form 10-Q fairly presents in all material respects the financial condition and results of operations of Align Technology, Inc.

By: /S/ THOMAS M. PRESCOTT
Name: **Thomas M. Prescott**
Title: **President and Chief Executive Officer**

Date: August 5, 2010

I, Kenneth B. Arola, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Quarterly Report of Align Technology, Inc. on Form 10-Q for the quarter ended June 30, 2010 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in such Quarterly Report on Form 10-Q fairly presents in all material respects the financial condition and results of operations of Align Technology, Inc.

By: /S/ KENNETH B. AROLA
Name: **Kenneth B. Arola**
Title: **Chief Financial Officer and Vice President of Finance**

Date: August 5, 2010