

ALIGN TECHNOLOGY INC
Form 10-Q
August 05, 2010
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended 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)

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Delaware
(State or other jurisdiction of
incorporation or organization)

94-3267295
(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.

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

Table of Contents**PART I FINANCIAL INFORMATION****ITEM 1 FINANCIAL STATEMENTS****ALIGN TECHNOLOGY, INC.****CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS****(in thousands, except per share data)****(unaudited)**

	Three Months Ended 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

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Diluted	77,607	67,373	77,644	66,941
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- (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.

Table of Contents**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.

Table of Contents**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.

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ALIGN TECHNOLOGY, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(unaudited)

Note 1. Summary of Significant Accounting Policies

Basis of presentation

The accompanying unaudited Condensed Consolidated Financial Statements have been prepared by Align Technology, Inc. (we or our) in accordance with the rules and regulations of the Securities and Exchange Commission (SEC) and contain all adjustments, including normal recurring adjustments, necessary to present fairly our financial position as of 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.

Table of Contents**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):

	Amortized Cost	Gross Unrealized Gains	Fair Value
June 30, 2010			
U.S. government notes and bonds	\$ 8,994	\$ 4	\$ 8,998
December 31, 2009			
U.S. government notes and bonds	\$ 18,972	\$ 6	\$ 18,978
Corporate bonds	1,000		1,000
Total	\$ 19,972	\$ 6	\$ 19,978

As of 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

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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.

Table of Contents**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):

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	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.

Table of Contents**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

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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.

Table of Contents**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

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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.

Table of Contents**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

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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		Six Months Ended	
	June 30,		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

Table of Contents**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:

	Number of Shares Underlying Stock Options (in thousands)	Total Shares Underlying Stock Options		
		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.

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

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	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.

Table of Contents**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,		As of December 31,	
	2010	2009	2009	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.

Table of Contents**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 1 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.

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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

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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.

Table of Contents**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):

Net revenues	Three Months Ended June 30,				Six Months Ended June 30,			
	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):

Invisalign case volume	Three Months Ended June 30,				Six Months Ended June 30,			
	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):

Net revenues	Three Months Ended June 30,				Six Months Ended June 30,			
	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%

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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.

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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,			
	2010	2009	Net Change	% Change	2010	2009	Net Change	% Change
Invisalign case volume								
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.

Table of Contents**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.

Table of Contents**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.

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

Liquidity and Capital Resources

We fund our operations from product sales and proceeds from the sale of common stock. As of 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.

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There were no other material changes to our contractual obligations outside the ordinary course of business from those disclosed in our Annual Report on Form 10-K for the year ended December 31, 2009.

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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.

Table of Contents**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.

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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.

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

In response to challenges in our business, including increased competition, we have in the past reduced the list price of our products. We also provide volume based discount programs to our doctors. In addition, we sell a number of products at different list prices. If we introduce any price reductions, 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;

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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.

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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;

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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;

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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