ALIGN TECHNOLOGY INC
Form 10-Q
November 05, 2008
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

x	**QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
	For the quarterly period ended September 30, 2008
	OR
o	**TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
	For the transition period from to

Commission file number: 0-32259

Align Technology, Inc.

(Exact name of registrant as specified in its charter)

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

881 Martin Avenue

Santa Clara, California 95050

(Address of principal executive offices) (Zip Code)

(408) 470-1000

(Registrant s telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No o

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

Large accelerated filer x	Accelerated filer o	Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company o

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

The number of shares outstanding of the registrant s Common Stock, $0.0001 par value, as of October 31, 2008 was 67,040,827.

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ALIGN TECHNOLOGY, INC.

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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.

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PART I FINANCIAL INFORMATION

ITEM 1 FINANCIAL STATEMENTS

ALIGN TECHNOLOGY, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per share data)
(unaudited)

	Three Months Ended September 30, 2008	Three Months Ended September 30, 2007	Nine Months Ended September 30, 2008	Nine Months Ended September 30, 2007
Net revenues	$ 75,173	$ 71,451	$ 229,851	$ 211,815
Cost of revenues	18,766	18,132	58,617	55,908
Gross profit	56,407	53,319	171,234	155,907
Operating expenses:				
Sales and marketing	28,214	24,226	88,737	71,729
General and administrative	14,395	13,949	45,905	38,014
Research and development	5,918	6,749	20,214	19,117
Patients First Program				(1,796)
Restructuring	2,189		2,189	
Total operating expenses	50,716	44,924	157,045	127,064
Profit from operations	5,691	8,395	14,189	28,843
Interest and other income, net	264	1,108	1,673	2,243
Net profit before provision for income taxes	5,955	9,503	15,862	31,086
Provision for income taxes	(798)	(43)	(1,371)	(1,030)
Net profit	$ 5,157	$ 9,460	$ 14,491	$ 30,056
Net profit per share:				
Basic	$ 0.08	$ 0.14	$ 0.21	$ 0.45
Diluted	$ 0.08	$ 0.13	$ 0.21	$ 0.42
Shares used in computing net profit per share:				
Basic	67,367	67,970	68,330	66,709
Diluted	68,704	72,230	69,906	71,058

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

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ALIGN TECHNOLOGY, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands, except per share data)
(unaudited)

	September 30, 2008	December 31, 2007
ASSETS		
Current assets:		
Cash and cash equivalents	$ 79,756	$ 89,140
Marketable securities, short-term	34,499	38,771
Accounts receivable, net of allowance for doubtful accounts of $715 and $760, respectively	48,872	44,850
Inventories, net	3,015	2,910
Prepaid expenses and other current assets	7,412	8,846
Total current assets	173,554	184,517
Property and equipment, net	29,568	25,320
Goodwill	478	478
Intangible assets, net	8,488	10,615
Other assets	4,432	1,831
Total assets	$ 216,520	$ 222,761
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 7,485	$ 9,222
Accrued liabilities	33,877	39,875
Deferred revenues	15,380	12,362
Total current liabilities	56,742	61,459
Other long-term liabilities	124	148
Total liabilities	56,866	61,607
Commitments and contingencies (Note 7)		
Stockholders equity:		
Preferred stock, $0.0001 par value (5,000 shares authorized; none issued)		
Common stock, $0.0001 par value (200,000 shares authorized; 67,035 and 68,682 shares issued, respectively; 67,035 and 68,642 shares outstanding, respectively)	7	7
Additional paid-in capital	445,926	450,140
Accumulated other comprehensive income, net	447	657
Accumulated deficit	(286,726)	(289,650)
Total stockholders equity	159,654	161,154
Total liabilities and stockholders equity	$ 216,520	$ 222,761

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

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ALIGN TECHNOLOGY, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)
(unaudited)

	Nine Months Ended September 30, 2008	2007
Cash Flows from Operating Activities:		
Net profit	$ 14,491	$ 30,056
Adjustments to reconcile net profit to net cash provided by operating activities:		
Depreciation and amortization	7,365	7,838
Amortization of intangibles	2,127	2,500
Stock-based compensation expense	13,176	8,775
Loss on retirement and disposal of fixed assets	206	23
Excess tax benefit from share-based payment arrangements	(188)	(339)
Non-cash restructuring charges	411	
Changes in assets and liabilities:		
Accounts receivable	(4,093)	(12,006)
Inventories	(109)	(468)
Prepaid expenses and other current assets	1,491	(304)
Accounts payable	(733)	432
Accrued and other long-term liabilities	(6,269)	(2,763)
Deferred revenues	3,116	2,039
Net cash provided by operating activities	30,991	35,783
Cash Flows from Investing Activities:		
Purchase of property and equipment	(12,361)	(6,305)
Proceeds from sale of equipment	189	
Restricted cash		74
Purchases of marketable securities	(65,094)	(31,651)
Maturities of marketable securities	66,463	18,555
Other assets	272	363
Net cash used in investing activities	(10,531)	(18,964)
Cash Flows from Financing Activities:		
Proceeds from issuance of common stock	10,222	27,821
Payments on line of credit		(11,500)
Payments on capital leases	(271)	
Repurchased shares of common stock	(39,432)	
Excess tax benefit from share-based payment arrangements	188	339
Employees taxes paid upon the vesting of restricted stock units	(347)	(377)
Net cash provided by (used in) financing activities	(29,640)	16,283
Effect of foreign exchange rate changes on cash and cash equivalents	(204)	(246)
Net increase (decrease) in cash and cash equivalents	(9,384)	32,856
Cash and cash equivalents at beginning of period	89,140	55,113
Cash and cash equivalents at end of period	$ 79,756	$ 87,969

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

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ALIGN TECHNOLOGY, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(unaudited)

Note 1. Summary of Significant Accounting Policies

Basis of presentation

The accompanying unaudited Condensed Consolidated Financial Statements have been prepared by Align Technology, Inc. (the Company or Align) in accordance with the rules and regulations of the Securities and Exchange Commission (SEC) and contain all adjustments, including normal recurring adjustments, necessary to present fairly Align s financial position as of September 30, 2008, its results of operations for the three and nine months ended September 30, 2008 and 2007, and its cash flows for the nine months ended September 30, 2008 and 2007. The Condensed Consolidated Balance Sheet as of December 31, 2007 was derived from the December 31, 2007 audited financial statements. Certain prior period amounts have been reclassified to conform with the current period presentation. These reclassifications had no impact on previously reported net earnings and financial position.

The results of operations for the three and nine months ended September 30, 2008 are not necessarily indicative of the results that may be expected for the year ending December 31, 2008, and the Company makes no representations related thereto. The information included in this Quarterly Report on Form 10-Q should be read in conjunction with Management s Discussion and Analysis of Financial Condition and Results of Operations, Quantitative and Qualitative Disclosures About Market Risk and the Consolidated Financial Statements and notes thereto included in Items 7, 7A and 8, respectively, of the Company s Annual Report on Form 10-K for the year ended December 31, 2007.

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

Recent Accounting Pronouncements

In September 2006, the FASB issued FAS No. 157, Fair Value Measurements (FAS 157) which provides guidance for using fair value to measure assets and liabilities. It also responds to investors requests for expanded information about the extent to which companies measure assets and liabilities at fair value, the information used to measure fair value, and the effect of fair value measurements on earnings. FAS 157 applies whenever other standards require (or permit) assets or liabilities to be measured at fair value, and does not expand the use of fair value in any new circumstances. FAS 157, as originally issued, was effective for fiscal years beginning after November 15, 2007. In February 2008, the FASB issued FASB Staff Position No. FSP 157-2, Effective Date of FASB Statement No. 157 (FSP 157-2), to partially defer FASB Statement No. 157, Fair Value Measurements (FAS 157). FSP 157-2 defers the effective date of FAS 157 for nonfinancial assets and nonfinancial liabilities, except those that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually), to fiscal years, and interim periods within those fiscal years, beginning after November 15, 2008. The Company adopted FAS 157 effective January 1, 2008, and the adoption of FAS 157 had no material impact to its consolidated financial position or results of operations.

In February 2007, the Financial Accounting Standards Board (FASB) issued FAS No. 159, The Fair Value Option for Financial Assets and Financial Liabilities Including an amendment of FASB Statement No. 115 (FAS 159). FAS 159 expands the use of fair value accounting but does not affect existing standards which require assets or liabilities to be carried at fair value. Under FAS 159, a company may elect to use fair value to measure accounts and loans receivable, available-for-sale and held-to-maturity securities, equity method investments, accounts payable, guarantees and issued debt. Other eligible items include firm commitments for financial instruments that otherwise would not be recognized at inception and non-cash warranty obligations where a warrantor is permitted to pay a third party to provide the warranty goods or services. If the use of fair value is elected, any upfront costs and fees related to the item must be recognized in earnings and cannot be deferred, e.g., debt issue costs. The fair value election is irrevocable and generally made on an instrument-by-instrument basis, even if a company has similar instruments that it elects not to measure based on fair value. At the adoption date, unrealized gains and losses on existing items for which fair value has been elected are reported as a cumulative adjustment to beginning retained earnings. Subsequent to the adoption of FAS 159, changes in fair value are recognized in earnings. FAS 159 is effective for fiscal years beginning after November 15, 2007. The Company adopted FAS 159 effective January 1, 2008, and the adoption of FAS 159 had no material impact to its consolidated financial position, results of operations or cash flows.

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In December 2007, the FASB issued FAS No. 141 (revised 2007), Business Combinations (FAS 141R). FAS 141R establishes principles and requirements for how the acquirer in a business combination recognizes and measures in its financial statements the fair value of identifiable assets acquired, the liabilities assumed and any noncontrolling interest in the acquiree at the acquisition date. FAS 141R determines what information to disclose to enable users of the financial statements to evaluate the nature and financial effects of the business combination. FAS 141R applies prospectively and is effective for fiscal years beginning on or after December 15, 2008. The Company is currently evaluating the potential impact, if any, of the adoption of FAS 141R on its consolidated financial position, results of operations and cash flows.

In December 2007, the FASB issued FAS No.160, Noncontrolling Interests in Consolidated Financial Statements (FAS 160), an amendment of Accounting Research Bulletin No. 51, Consolidated Financial Statements (ARB 51). FAS 160 changes the accounting and reporting for minority interests, which will be recharacterized as noncontrolling interests and classified as a component of equity. This new consolidation method significantly changes the accounting for transactions with minority interest holders. FAS 160 is effective for fiscal years beginning after December 15, 2008. The Company plans to adopt FAS 160 beginning in the first quarter of 2009. The Company is evaluating the impact the adoption of FAS 160 will have on its consolidated financial position and results of operations.

In March 2008, the FASB issued FAS No. 161, Disclosures about Derivative Instruments and Hedging Activities an amendment of FASB Statement No. 133 (FAS 161). FAS 161 requires disclosures of how and why an entity uses derivative instruments, how derivative instruments and related hedged items are accounted for and how derivative instruments and related hedged items affect an entity s financial position, financial performance, and cash flows. FAS 161 is effective for fiscal years beginning after November 15, 2008, with early adoption permitted. The Company is currently evaluating the impact of the pending adoption of FAS 161 on its consolidated financial statements.

In April 2008, the FASB issued FSP SFAS No. 142-3, Determination of the Useful Life of Intangible Assets. FSP SFAS 142-3 amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under SFAS No. 142, Goodwill and Other Intangible Assets. FSP SFAS No. 142-3 is effective for fiscal years beginning after December 15, 2008. The guidance for determining the useful life of an intangible asset must be applied prospectively to intangible assets acquired after the effective date. The Company is currently evaluating the impact of the pending adoption of FSP SFAS No. 142-3 on its consolidated financial statements.

In May 2008, the FASB issued FAS No. 162, The Hierarchy of Generally Accepted Accounting Principles (FAS 162). FAS 162 identifies the sources of accounting principles and the framework for selecting the principles used in the preparation of financial statements of nongovernmental entities that are presented in conformity with generally accepted accounting principles (the GAAP hierarchy). FAS 162 will become effective November 15, 2008. The Company does not expect the adoption of FAS 162 to have a material effect on its consolidated financial position and results of operations.

In May 2008, the FASB issued FSP Accounting Principles Board (APB) 14-1 Accounting for Convertible Debt Instruments That May Be Settled in Cash upon Conversion (Including Partial Cash Settlement) (FSP APB 14-1). FSP APB 14-1 requires the issuer of certain convertible debt instruments that may be settled in cash (or other assets) on conversion to separately account for the liability (debt) and equity (conversion option) components of the instrument in a manner that reflects the issuer s non-convertible debt borrowing rate. FSP APB 14-1 is effective for fiscal years beginning after December 15, 2008 on a retroactive basis and will be adopted by the Company in the first quarter of 2009. The Company is currently evaluating the potential impact, if any, of the adoption of FSP APB 14-1 on its consolidated results of operations and financial condition.

In August, 2008, the U.S. Securities and Exchange Commission (SEC) announced that they will issue for comment a proposed roadmap regarding the potential use by U.S. issuers of financial statements prepared in accordance with International Financial Reporting Standards (IFRS). IFRS is a comprehensive series of accounting standards published by the International Accounting Standards Board (IASB). Under the proposed roadmap, the Company could be required in fiscal 2014 to prepare financial statements in accordance with IFRS, and the SEC will make a determination in 2011 regarding the mandatory adoption of IFRS. The Company will assess the impact that this potential change would have on its consolidated financial statements and will monitor the development of the potential implementation of IFRS.

In October, 2008, the FASB issued FASB Staff Position (FSP) FAS 157-3, Determining the Fair Value of a Financial Asset When the Market for That Asset Is Not Active (FSP 157-3). FSP 157-3 clarifies the application of FAS 157 and provides an example to illustrate key considerations in determining the fair value of a financial asset when the market for that financial asset is not active. FSP 157-3 is effective upon issuance, including prior periods for which financial statements have not been issued. Revisions resulting from a change in the valuation technique or its application should be accounted for as a

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change in accounting estimate following the guidance in FAS Statement No. 154, Accounting Changes and Error Corrections (FAS 154). However, the disclosure provisions in FAS 154 for a change in accounting estimate are not required for revisions resulting from a change in valuation technique or its application. The adoption of FSP 157-3 did not have a material effect on the Company s financial position and results of operations.

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

Note 2. Marketable Securities and Fair Value Measurements

The Company s short-term marketable securities as of September 30, 2008 and December 31, 2007 are as follows (in thousands):

September 30, 2008	Amortized Costs	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. government notes and bonds	$ 9,968	$ 23	$	$ 9,991
Corporate bonds and certificates of deposit	8,957	3	(66)	8,894
Agency bonds and discount notes	10,849	4	(15)	10,838
Commercial paper	4,779	0	(3)	4,776
Total	$ 34,553	$ 30	$ (84)	$ 34,499

December 31, 2007	Amortized Costs	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. government notes and bonds	$ 4,081	$ 6	$	$ 4,087
Corporate bonds	6,983			6,983
Commercial paper and asset-backed securities	27,754		(53)	27,701
Total	$ 38,818	$ 6	$ (53)	$ 38,771

The Company s long-term marketable securities as of September 30, 2008 are as follows (in thousands):

September 30, 2008	Amortized Costs	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Corporate bonds and certificates of deposit	$ 1,000	$	$ (3)	$ 997
Commercial paper	1,896		(24)	1,872
Total	$ 2,896	$	$ (27)	$ 2,869

The long-term marketable securities are included in Other assets in the condensed consolidated balance sheets. As of December 31, 2007, the Company did not hold any long-term marketable securities.

For the three and nine months ended September 30, 2008 and 2007, no significant losses were realized on the sale of marketable securities.

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Fair Value Measurements

The following table summarizes the Company s financial assets measured at fair value on a recurring basis in accordance with FAS 157 as of September 30, 2008 (in thousands):

Description	Balance as of September 30, 2008	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)
Cash equivalents:			
Money market funds	$ 27,126	$ 27,126	$
U.S. government debt securities	7,497	7,497	
Agency bonds and discount notes	4,990		4,990
Corporate bonds and certificates of deposit	8,966		8,966
Commercial paper	19,970		19,970
Short-term investments:			
Corporate bonds and certificates of deposit	8,894		8,894
U.S. government debt securities	9,991	9,991	
Agency bonds and discount notes	10,838		10,838
Commercial paper	4,776		4,776
Long-term investments:			
Corporate bonds and certificates of deposit	1,871		1,871
Agency bonds and discount notes	998		998
	$ 105,917	$ 44,614	$ 61,303

The Company s financial assets and liabilities are valued using market prices on both active markets (Level 1) and less active markets (Level 2). Level 1 instrument valuations are obtained from real-time quotes for transactions in active exchange markets involving identical assets. Level 2 instrument valuations are obtained from readily-available pricing sources for comparable instruments. As of September 30, 2008, the Company did not have any assets or liabilities without observable market values that would require a high level of judgment to determine fair value (Level 3 assets).

Note 3. Balance Sheet Components

Inventories, net are comprised of (in thousands):

	September 30, 2008	December 31, 2007
Raw materials	$ 1,799	$ 1,983
Work in process	853	631
Finished goods	363	296
	$ 3,015	$ 2,910

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):

	September 30, 2008	December 31, 2007
Accrued payroll and benefits	$ 17,107	$ 22,165
Accrued sales and marketing expenses	2,612	2,910
Accrued sales rebate	2,443	3,724
Accrued warranty	2,095	2,035
Accrued Patients First Program costs	183	996
Other	9,437	8,045
Total accrued liabilities	$ 33,877	$ 39,875

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Note 4. Intangible Assets

The following is a summary of the Company s purchased intangible assets as of September 30, 2008 and December 31, 2007 (in thousands):

		Spetember 30, 2008			December 31, 2007		
	Estimated Usefil Life (in years)	**Gross Carrying Value**	**Accumulated Amortization**	**Net Carrying Value**	**Gross Carrying Value**	**Accumulated Amortization**	**Net Carrying Value**
Non-compete agreements	5	$ 14,000	$ 5,512	$ 8,488	$ 14,000	$ 3,412	$ 10,588
Patent	5	180	180		180	153	27
Total		$ 14,180	$ 5,692	$ 8,488	$ 14,180	$ 3,565	$ 10,615

These intangible assets are being amortized on a straight-line basis over the expected useful life of five years. The Company performs an impairment test whenever events or changes in circumstances indicate that the carrying value of such assets may not be recoverable. Examples of such events or circumstances include significant under-performance 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, or a significant decline in the Company s stock price for a sustained period. Impairments are recognized based on the difference between the fair value of the asset and its carrying value, and fair value is generally measured based on discounted cash flow analyses. There were no impairments of intangible assets during the periods presented.

The total estimated annual future amortization expense for these intangible assets as of September 30, 2008 is as follows (in thousands):

Fiscal Year	
2008 (remaining 3 months)	$ 700
2009	2,800
2010	2,800
2011	2,188
Total	$ 8,488

Note 5. Legal Proceedings

Ormco

On January 6, 2003, Ormco Corporation (Ormco) filed suit against the Company in the United States District Court for the Central District, Orange County Division, asserting infringement of certain patents. Ormco is a division of Sybron Dental Specialties (a Danaher Corporation subsidiary). The complaint sought unspecified monetary damages and injunctive relief. On February 18, 2003, the Company answered the complaint and asserted counterclaims seeking a declaration by the Court of invalidity and non-infringement of the asserted patents. In addition, the Company counterclaimed for infringement of one of its patents, seeking unspecified monetary damages and injunctive relief. Ormco filed a reply to its counterclaims on March 10, 2003 and asserted counterclaims against the Company seeking a declaration by the Court of invalidity and non-infringement of the patent. The Company amended its counterclaim to add Allesee Orthodontic Appliances, Inc. (AOA), a wholly-owned subsidiary of Ormco, as a counterdefendant in regard to its counterclaim of infringement of the patent.

There have been two appeals. After the permanent injunction was entered, Ormco and AOA appealed that injunction and the orders of the District Court on summary judgment on which the injunction was based. In April 2006, the U.S. Court of Appeals for the Federal Circuit (CAFC) issued a ruling declaring two out of a total of 71 claims in the Company s US Patent No. 6,398,548 and four out of a total of ten claims in US Patent No. 6,554,611 to be invalid as obvious. The CAFC s decision reversed the California District Court summary judgment order of validity.

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The second appeal was from the final judgment. Ormco appealed the ruling of the District Court that 92 claims in four of its patents are not infringed by the Company and that the asserted claims are invalid. Align appealed the ruling of the District Court that certain claims of its 6,398,548 patent which were found to be infringed by Ormco s and AOA s Red, White & Blue appliances were invalid. The CAFC issued a ruling on August 24, 2007, affirming the District Court s ruling that 86 out of 92 claims in the four asserted Ormco patents are invalid and not infringed by Align. The CAFC reversed the District Court s non-infringement rulings on six claims in Ormco s 6,616,444 patent, which will be returned to the District Court for a determination of validity and infringement of those claims. The Court denied Ormco s petition for rehearing with respect to the portion of the Federal Circuit s opinion that affirmed the District Court s ruling of non-infringement and non-enablement of the 86 claims. On Align s cross-appeal, the CAFC affirmed the District Court s finding that six claims in the 6,398,548 patent are invalid.

Ormco filed a petition for review with the U.S. Supreme Court with respect to the portion of the CAFC s opinion that affirmed the District Court s ruling of non-infringement and non-enablement of Ormco s 86 claims. The Supreme Court denied Ormco s petition, and the case on the six claims in Ormco s 444 patent has been returned to the District Court for further proceedings.

The District Court issued orders construing the claim terms at issue and granting Align s motion to amend its answer and counterclaim to assert inequitable conduct. The parties are currently conducting discovery. Trial on liability issues is scheduled for June 2, 2009.

Class Action

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

On July 3, 2007, the Company filed an answer to the complaint and asserted 17 affirmative defenses. On July 20, 2007, the Company filed a motion for summary judgment on the Third Cause of Action (the only cause of action alleged against Align). On August 24, 2007, Weber filed a motion for class certification. On October 1, 2007, the Company filed an opposition to the motion for class certification and it is currently awaiting rulings from the Court. OrthoClear has filed a motion to dismiss. The initial case management conference and all discovery has been stayed pending the Court s decision on the motion for class certification, OrthoClear s motion to dismiss and the Company s motion for summary judgment.

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

Note 6. **Credit Facilities**

Effective January 1, 2008, the available borrowings under the revolving line of credit is $25 million. This credit facility matures on December 31, 2008. As of September 30, 2008, there were no outstanding borrowings against this credit facility, and the Company is in compliance with the financial covenant.

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Note 7. Commitments and Contingencies

As of September 30, 2008, minimum future lease payments for non-cancelable leases are as follow (in thousands):

Years Ending December 31,		
2008	$	850
2009		2,904
2010		2,176
2011		1,684
2012 and thereafter		2,333
Total	$	9,947

Lease Guarantee

On July 31, 2008, the Company entered into an agreement in favor and for the benefit of Elamex de Juarez, S.A. DE C.V., landlord to International Manufacturing Solutions Operaciones, S.R.L. (IMS), Align s third party shelter services provider, to guarantee IMS lease payments for its facility located in Juarez, Mexico. The current lease for this facility expires in July 2013. Pursuant to the guarantee, the Company is obligated to pay Elamex de Juarez, S.A. DE C.V. for any rental payments in default by IMS.

In connection with the above guarantee issued by the Company and as of September 30, 2008, the Company is contingently liable for future payments of approximately $1.8 million, which will decrease as IMS pays the monthly rent of approximately $30,000. During the three months ended September 30, 2008, there have been no rental payment defaults by IMS. The fair value of the guarantee is not considered material, therefore the Company has not recorded any amounts in its financial statements related to this guarantee as of September 30, 2008.

Product Warranty

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

The following table reflects the change in the Company s warranty accrual during the nine months ended September 30, 2008 and 2007, respectively (in thousands):

	Nine Months Ended September 30	
	2008	2007
Balance at beginning of period	$ 2,035	$ 2,094
Charged to cost of revenues	1,910	1,814
Actual warranty expenses	(1,850)	(1,526)
Balance at end of period	$ 2,095	$ 2,382

Note 8. Stock-based Compensation

Summary of stock-based compensation expense

Stock-based compensation expense recognized in the Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2008 and 2007 is based on options ultimately expected to vest and has been reduced for estimated forfeitures. FAS 123R requires forfeitures to be estimated at the time of grant and revised, if necessary, in

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subsequent periods if actual forfeitures differ from those estimates. Forfeitures were estimated based on historical experience. The following table summarizes stock-based compensation expense related to all of the Company s stock-based options and employee stock purchases under FAS 123R for the three and nine months ended September 30, 2008 and 2007:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(In thousands)	2008	2007	2008	2007
Cost of revenues	$ 437	$ 259	$ 1,298	$ 703
Sales and marketing	1,390	1,301	4,069	3,056
General and administrative	2,009	1,403	6,122	3,934
Research and development	554	425	1,687	1,082
Total stock-based compensation expense	$ 4,390	$ 3,388	$ 13,176	$ 8,775

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
Stock Options:				
Expected term (in years)	4.4	4.3	4.4	4.6
Expected volatility	60.2%	56.8%	59.8%	70.7%
Risk-free interest rate	3.1%	4.6%	2.8%	4.7%
Expected dividend				
Weighted average fair value at grant date	$ 5.49	$ 12.41	$ 6.46	$ 10.97
Employee Stock Purchase Plan:				
Expected term (in years)	1.2	1.2	1.2	1.2
Expected volatility	64.7%	54.6%	67.2%	55.8%
Risk-free interest rate	2.2%	4.8%	2.2%	4.8%
Expected dividend				
Weighted average fair value at grant date	$ 4.49	$ 10.24	$ 4.89	$ 9.42

Stock Incentive Plans

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

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Options

Stock option activity for the nine months ended September 30, 2008 under the stock incentive plans is set forth below:

	Total Shares Underlying Stock Options			In-The-Money Options		
	Number of Shares Underlying Stock Options (in thousands)	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Number of Shares Underlying Stock Options (in thousands)	Weighted Average Exercise Price	Aggregate Intrinsic Value (in thousands)
Outstanding as of December 31, 2007	7,133	$ 10.99				
Granted	2,104	12.92				
Cancelled or expired	(615)	14.63				
Exercised	(820)	6.54				
Outstanding as of September 30, 2008	7,802	$ 11.69	7.1	3,534	$ 6.86	$ 14,031
Vested and expected to vest at September 30, 2008	7,565	$ 11.63	7.1	3,511	$ 6.85	$ 13,962
Exercisable at September 30, 2008	4,390	$ 10.55	5.8	2,908	$ 6.67	$ 12,092

The aggregate intrinsic value in the table above represents the total pre-tax intrinsic value (the difference between Align s closing stock price on the last trading day of the third quarter of 2008 of $10.83 and the number of in-the-money options multiplied by the respective exercise price) that would have been received by the option holders had all option holders exercised their options on September 30, 2008. This amount changes based on the fair market value of Align s stock.

The total intrinsic value of stock options exercised for the three and nine months ended September 30, 2008 was $1.3 million and $10.3 million, respectively. The total intrinsic value of stock options exercised for the three and nine months ended September 30, 2007 was $17.6 million and $41.8 million, respectively. As of September 30, 2008, Align expects to recognize $22.0 million of total unamortized compensation cost related to stock options over a weighted average period of 2.6 years. The Company has recognized tax benefits from exercised options for the nine months ended September 30, 2008 of approximately $188,000. The tax benefits associated with these option exercises reduced income taxes payable with the offset credited to additional paid-in capital.

Restricted Stock Units

The Company grants restricted stock units (RSUs) that generally vest over 4 years. Prior to October 2007, 25% of the grant vested on the one year anniversary of the date of grant and 6.25% vested quarterly thereafter. In October 2007, the Compensation Committee of the Board of Directors approved to change the vesting for prospective grants of RSUs to 25% annually. The fair value of each award is based on the Company s closing stock price on the date of grant. A summary of the nonvested shares for the nine months ended September 30, 2008 is as follows:

	Number of Shares Underlying RSUs (in thousands)	Weighted Average Grant Date Fair Value	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Nonvested as of December 31, 2007	651	$ 15.78		
Granted	668	12.85		
Vested and released	(197)	12.70		
Forfeited	(113)	16.86		
Nonvested as of September 30, 2008	1,009	$ 14.32	2.7	$ 10,922

The aggregate intrinsic value in the table above represents the total pre-tax intrinsic value (calculated by using Align s closing stock price on the last trading day of the third quarter of 2008 of $10.83 multiplied by the number of nonvested restricted stock units) that would have been received by the award holders had all restricted stock units been vested and released on September 30, 2008. This amount changes based on the fair market value of Align s stock.

The total intrinsic value of restricted stock units vested and released for the three and nine months ended September 30, 2008 was $0.6 million and $2.5 million, respectively. The total intrinsic value of restricted stock units vested and released

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for the three and nine months ended September 30, 2007 was $0.9 million and $3.0 million, respectively. As of September 30, 2008, the total unamortized compensation cost related to restricted stock units was $12.3 million, which Align expects to recognize over a weighted average period of 2.7 years.

Employee Stock Purchase Plan

Align s Employee Stock Purchase Plan (the Purchase Plan) consists of overlapping twenty-four month offering periods with four six-month purchase periods in each offering period. Employees purchase shares at 85% of the fair market value of the common stock at either the beginning of the purchase period or the end of the purchase period, whichever price is lower. The Company accounts for the Purchase Plan as a compensatory plan and has valued the shares in accordance with FAS 123R. The fair value of the option component of the Purchase Plan shares was estimated at the date of grant using the Black-Scholes option pricing model.

As of September 30, 2008, Align expects to recognize $3.7 million of total unamortized compensation cost related to employee stock purchases over a weighted average period of 0.9 years.

Note 9. Accounting for Income Taxes

On January 1, 2007, the Company adopted the provision of Financial Accounting Standards Board (FASB) Interpretation No. 48, Accounting for Uncertain Income Taxes An Interpretation of FASB Statement No. 109 (FIN 48). FIN 48 clarifies the accounting for uncertainty in income taxes recognized in an entity s financial statements in accordance with FASB Statement No. 109, Accounting for Income Taxes (FAS 109) and prescribes a recognition threshold and measurement attributes for financial statement disclosure of tax positions taken or expected to be taken on a tax return. Under FIN 48, the impact of an uncertain income tax position on the income tax return must be recognized at the largest amount that is more-likely-than-not to be sustained upon audit by the relevant taxing authority.

The Company has unrecognized tax benefits of approximately $2.8 million as of December 31, 2007. Included in the unrecognized tax benefits are $0.3 million of uncertain tax positions that would impact the Company s effective tax rate if recognized. The application of FIN 48 would have resulted in an increase of the accumulated deficit by $2.9 million, except that the increase was fully offset by the application of a valuation allowance. In accordance with FIN 48, the Company recognizes interest and penalties related to unrecognized tax benefits as a component of income taxes. Interest and penalties are immaterial at the date of adoption and are included in the unrecognized tax benefits. There was no change to the Company s unrecognized tax benefits for the nine month period ended September 30, 2008 nor does the Company expect a material change for the twelve month period ending December 31, 2008.

The Company is subject to taxation in the U.S. and various states and foreign jurisdictions. All the Company s tax years will be open to examination by the U.S. federal and most state tax authorities due to the Company s net operating loss and overall credit carryforward position. With few exceptions, the Company is no longer subject to examination by foreign tax authorities for years before 2003.

Note 10. Net Profit Per Share

Basic net profit per share is computed using the weighted average number of shares of common stock during the period. Diluted net profit per share is computed using the weighted average number of shares of common stock, adjusted for the dilutive effect of potential common stock. Potential common stock, computed using the treasury stock method, includes options, restricted stock units, and the dilutive component of Purchase Plan shares.

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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 September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
Net profit	$ 5,157	$ 9,460	$ 14,491	$ 30,056
Weighted-average common shares outstanding, basic	67,367	67,970	68,330	66,709
Effect of potential dilutive common shares	1,337	4,260	1,576	4,349
Total shares, diluted	68,704	72,230	69,906	71,058
Basic net profit per share	$ 0.08	$ 0.14	$ 0.21	$ 0.45
Diluted net profit per share	$ 0.08	$ 0.13	$ 0.21	$ 0.42

For the three and nine months ended September 30, 2008, stock options and restricted stock units totaling 5.0 million and 4.5 million, respectively, were excluded from diluted net profit per share because of their anti-dilutive effect. For the three and nine months ended September 30, 2007, stock options and restricted stock units totaling 1.0 million and 0.9 million, respectively, were excluded from diluted net profit per share because of their anti-dilutive effect.

Note 11. Comprehensive Income

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

	Three Months Ended Sept 30,		Nine Months Ended Sept 30,	
	2008	2007	2008	2007
Net profit	$ 5,157	$ 9,460	$ 14,491	$ 30,056
Foreign currency translation adjustments	(429)	369	(176)	542
Unrealized gain/(loss) on available-for-sale securities	(43)	5	(34)	(5)
Comprehensive income	$ 4,685	$ 9,834	$ 14,281	$ 30,593

Note 12. Segments and Geographical Information

Segment

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

Geographical Information

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
Net revenues:				
North America	$ 59,627	$ 59,671	$ 182,910	$ 178,734
Europe	15,056	11,196	45,522	31,002
Other international	490	584	1,419	2,079
Total net revenues	$ 75,173	$ 71,451	$ 229,851	$ 211,815

	As of September 30, 2008	As of December 31, 2007
Long-lived assets:		
North America	$ 40,608	$ 35,632
Europe	991	1,081
Other international	1,367	1,531
Total long-lived assets	$ 42,966	$ 38,244

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Note 13. Common Stock Repurchase Program

In April 2008, the Company s Board of Directors approved a common stock repurchase program authorizing management to repurchase up to $50 million of the Company s outstanding common stock. Purchases under the program were made, from time to time, in the open market. During the three months ended September 30, 2008, the Company purchased approximately 930,000 shares of common stock at an average price of $12.62 per share for an aggregate purchase price of $11.7 million, including commissions. The common stock repurchases reduced additional paid-in capital by $8.3 million and increased accumulated deficit by $3.4 million.

During the nine months ended September 30, 2008, the Company repurchased approximately 3.1 million shares of common stock at an average price of $12.64 per share for an aggregate purchase price of $39.4 million, including commissions. The common stock repurchases reduced additional paid-in capital by $27.9 million and increased accumulated deficit by $11.4 million. The remaining authorized amount of stock repurchases under this program is $10.7 million, excluding commissions. All repurchased shares will be retired.

Note 14. Restructuring

In July 2008, the Company announced a restructuring plan to reduce overall spending by reducing its full time headcount, implementing the phased-consolidation of the Company s order acquisition operations from its corporate headquarters in Santa Clara, California to Juarez, Mexico and slowing planned headcount growth. The Company anticipates completing the phased-consolidation by the end of 2008, at which time, the headcount in the United States will be transitioned out.

For the three months ended September 30, 2008, the Company incurred approximately $2.2 million in restructuring expenses which includes $0.4 million related to the acceleration of stock option vesting and $1.8 million related to severance and termination benefits, of which $1.4 million was paid during the quarter. The Company expects to incur additional expense of $0.5 million during the fourth quarter of 2008 relating to this restructuring plan.

Note 15. Subsequent Events

In October 2008, the Company announced an additional restructuring plan to increase efficiencies across the organization and lower its overall cost structure. The restructuring plan includes a total reduction of 110 full time headcount in Santa Clara, California, of which 45 positions will be eliminated by January 2009. The remaining positions are expected to be eliminated between February and July 2009 as the Company creates a new shared services organization in its existing Costa Rica facility that will consolidate customer care, accounts receivable, credit and collections, and customer event registration organizations, which are currently located in Santa Clara, California. The Company anticipates completing the creation of the shared services organization in Costa Rica by the end of July 2009. These actions will result in a restructuring charge of approximately $5.0 million, of which $3.5 million will be recognized in the fourth quarter of 2008 and the remainder over the first half of 2009.

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

In addition to historical information, this quarterly report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. These statements include, among other things, statements concerning our expectations regarding Invisalign Assist, Invisalign Teen and Vivera including the expected impact these 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, the anticipated amount of cost-savings due to the July and October restructurings, the expected amount and timing of the charges to be incurred in connection with these measures, our expectations regarding the relocation of several customer facing organizations from our Santa Clara, California facility to our facility in Costa Rica, including the timing of such relocation, our expectation that our utilization rate will improve over time, our expectations regarding our average selling prices and gross profits in 2008, our expectations regarding the benefit of increased consumer marketing programs, our expectations in 2008 regarding case shipment volume, the anticipated level of our operating expenses, and the number of doctors trained, statements regarding our stock repurchase program which could be delayed indefinitely by conditions in the stock or debt markets, our need to conserve capital resources for use in our operations 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 7 Management s Discussion and Analysis of Financial Condition and Results of Operations , and in particular, the risks discussed below in Part II, Item 1A Risk Factors . We undertake no obligation to revise or update these forward-looking statements. Given these risks and uncertainties, readers are cautioned not to place undue reliance on such forward-looking statements.

The following discussion and analysis of our financial condition and results of operations should be read together with our Condensed Consolidated Financial Statements and related notes included elsewhere in this Quarterly Report on Form 10-Q.

Overview

Align Technology, Inc., founded in April 1997, designs, manufactures and markets the Invisalign system, a proprietary method for treating malocclusion, or the misalignment of teeth. Invisalign corrects malocclusion using a series of clear, nearly invisible, removable appliances that gently move teeth to a desired final position. Because it does not rely on the use of metal or ceramic brackets and wires, Invisalign significantly reduces the aesthetic and other limitations associated with 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.

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

A number of factors, the most important of which are set forth below, may affect our results during the remainder of 2008 and beyond.

• *Product innovation New products and enhancements to existing products.* We believe that product performance and innovation is a cornerstone to our future long-term growth by driving and sustaining product adoption and enhancing the user experience and thereby increasing utilization growth. Currently, the Invisalign system is a single system used by both GPs and orthodontists. We are committed to delivering new products and introducing new product features to better meet the needs of our two customers orthodontists and GPs each with distinct and separate needs. Orthodontists want a more robust set of tools for greater predictability, wider applicability and more flexibility in the use of the Invisalign system. On the other hand, typical GPs want

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greater ease of use, more efficient and simplified diagnostic tools, guidance through the case set-up process, minimal treatment intervention and self-help tools designed to simplify treatment of cases of mild to moderate malocclusion. Based on this knowledge, in July 2008 we announced the release of Invisalign Teen, and in October 2008, we announced the release of Invisalign Assist.

With the introduction of Invisalign Teen in July, our Invisalign product family now includes a product designed to meet the specific needs of the non-adult comprehensive or teen market. Invisalign Teen includes features such as an aligner wear indicator to help gauge patient compliance and specially engineered aligner features to address the natural eruption of key teeth and root control issues common in teen patients. Predominantly marketed to orthodontists who treat the vast majority of malocclusion in teen patients, these features make it easier and more efficient for orthodontists to treat those younger patients. The launch of a teen-specific product makes the Invisalign system more applicable to an orthodontist s patient base, which we believe will increase our penetration into and our share of the teen treatment market. **We expect that orthodontists will adopt Invisalign Teen slowly, after they experience multiple successful treatment outcomes. As a result, we anticipate that Invisalign Teen volume may increase gradually and will not constitute a significant portion of our total product mix in the near-term.**

Invisalign Assist is the first phase of our GP-specific product platform and is intended to help newly-certified and low volume Invisalign GPs accelerate the adoption and frequency of use of Invisalign into their practice. Invisalign Assist includes new software and clinical protocols that make it easier for doctors to select appropriate cases for their experience level or treatment approach. In addition, GPs can plan and submit cases efficiently, manage appointments with suggested tasks, and receive batch shipments of aligners based on treatment progress. We believe Invisalign Assist will help GPs increase their confidence in prescribing Invisalign treatment by delivering more predictable results.

We believe continuing to introduce new products and product features as well as enhancing the user experience will keep us at the forefront of the market and increase demand for Invisalign. The recent launch of Invisalign Teen and Invisalign Assist and other future products will rely on new features, tools and delivery options to meet specific clinical demands while providing a family of end-to-end solutions for our customers. Enhanced product performance and innovation should continue to drive the adoption and frequency of use (what we call utilization). Although we believe new product introduction to be a cornerstone to our future long-term growth, we expect that adoption of these new products will increase gradually over a number of years. *See Part II, Item 1A Risk Factors for risks related to our ability to develop and successfully introduce new products.*

- *Increase customer adoption and utilization.* By increasing adoption through the expansion of our customer base and then increasing utilization by offering new products and feature enhancements to meet the needs of orthodontists and GPs, we believe the overall market for Invisalign and our share of that market will increase. Although we expect that over the long-term our utilization rates will gradually improve, we expect that period over period comparisons of our utilization rates will fluctuate. Our quarterly utilization rates from the second quarter of 2006 through the third quarter of 2008 are as follows:

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- *Utilization rates = # of cases shipped / # of doctors cases were shipped to*

- *Training new orthodontists and general practitioners.* Expanding our customer base through training is a key part of our strategy. Through September 30, 2008, we have trained 31,300 GPs and 8,600 orthodontists in the United States and 13,670 doctors internationally. We expect to train approximately 7,000 GPs and orthodontists worldwide in 2008. In addition, by educating dental students and orthodontic residents on the benefits of the Invisalign technique, we believe they will be more likely to use this technology in their future practices and offer Invisalign as a treatment option. Currently, we have incorporated the Invisalign technique into the curriculum of 38 university programs.

- *Focus on education and customer support.* In order to build long-term relationships with our customers and increase utilization, we focus on providing ongoing training, support and services. In early 2008, we announced the introduction of the Aligntech Institute program brand (*www.aligntechinstitute.com*), which is a new interactive website that will provide clinical education and practice development training. These clinical education and practice development training opportunities will include instructor-led certification classes, seminars and workshops, conference calls, web-based videos, case studies, and other clinical resources. Many of these courses and resources are eligible for continuing education (CE) credits. By participating in these events, we believe that our customers will emerge with a better understanding of the product and its applicability, and with a greater aptitude for starting and finishing Invisalign cases successfully. Our VIP portal (Virtual Invisalign Practice) provides our trained doctors and their staff access to thousands of Invisalign cases and best practices as well as up-to-date support information, programs and marketing materials for continuous support and information access.

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- *Stimulate demand for Invisalign treatment Increasing our patient base.* Marketing to the consumer and creating demand is one of our key strategic objectives to driving long-term growth. Our market research indicates that the vast majority of people with malocclusion who desire treatment do not elect traditional treatment because of its many limitations, such as compromised aesthetics and oral discomfort. By communicating the benefits of Invisalign to both dental professionals and consumers, we intend to increase the number of patients who seek Invisalign treatment annually. We launched our new TV advertising campaign in the first quarter of 2008 in the United States and increased our focus on other programs, such as digital online media, designed to raise the profile of Invisalign and drive more consumers to our most experienced doctors. In addition, we incurred and will continue to incur additional costs in the United States related to bringing new products to market, such as Invisalign Teen and Invisalign Assist. We also initiated similar consumer marketing efforts, but on a smaller scale, in key European countries. Despite the continuing challenges in the U.S. economy and weak consumer spending, we believe that consumer demand creation is critical to our long-term growth. As a result, we will continue to invest in efforts to increase consumer awareness of Invisalign.

- *Impact of new products on deferred revenue.* Over the past twelve months, we launched three new products: Vivera retainers in November 2007, Invisalign Teen in July 2008, and Invisalign Assist in October 2008. As a result of and depending upon customer adoption of these new products, we expect our mix of products to begin shifting gradually as we exit 2008 and move into 2009. Key features of these new products include staged delivery of retainers with Vivera, up to six free replacement aligners with Invisalign Teen and staged delivery of aligners with Invisalign Assist. As a result of these features, these new products will have a significantly higher amount of deferred revenue as a percentage of their average selling prices compared to our current products.

The Vivera retainer subscription includes four shipments per year, and revenue is deferred upon the first shipment and then recognized ratably over the one year subscription period. Revenue for the six replacement aligners included in Invisalign Teen will be deferred based on their fair market value until the earlier of replacement aligners being used or until the case is completed. Invisalign Assist will be deferred upon the first staged shipment and will be recognized upon shipment of the final staged shipment. In addition, included in the price of full Invisalign treatment, we offer case refinement, which is a finishing tool used to adjust a patient s teeth to the desired final position. Both Invisalign Teen and Invisalign Assist include a deferral for case refinement. As these new products increase as a percentage of our total case volume, deferred revenue on our balance sheet will increase.

- *Growth of international markets.* We will continue to focus our efforts towards increasing adoption of Invisalign by dental professionals in our key international markets, Europe and Japan. We expect our

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international revenues to continue to increase in absolute dollars and as a percentage of total net revenues in the foreseeable future. We continually evaluate cost effective ways to support our customers in smaller and less strategic markets. During 2007, we transitioned the sales of our product in part of the Asia-Pacific and Latin American regions to a distributor model. We will consider selling through distributors in other smaller or less strategic markets as well as consider expanding directly into additional countries on a case-by-case basis.

- *Reliance on international manufacturing operations.* Our manufacturing efficiency has been and will continue to be an important factor in our future profitability. Currently, two of our key production steps are performed in operations located outside of the U.S. At our facility in Costa Rica, dental technicians use a sophisticated, internally developed computer-modeling program to prepare electronic treatment plans. These electronic treatment plans form the basis of ClinCheck and are used to manufacture aligner molds. In addition, we use International Manufacturing Solutions Operaciones, S.R.L. (IMS), a third party based in Juarez, Mexico, for the fabrication and packaging of aligners. Our success will depend in part on the efforts and abilities of management to effectively manage these international operations. In addition, we currently are and will continue to be dependent on IMS s and our ability to hire and retain employees, as well as hire and retain employees with the necessary skills to perform the more technical aspects of our operations. If our management or IMS fail in any of these respects, we could experience production delays and lost or delayed revenue. In addition, even if we have case submissions, we may not have a sufficient number of trained dental technicians in Costa Rica to create the ClinCheck treatments, or if IMS is unable to ship our product to our customers on a timely basis, our revenue will be delayed or lost, which will cause our operating results to fluctuate. *See Part II, Item 1A Risk Factors for risks related to our international operations.*

- *Stock Repurchase Program.* On April 29, 2008, we announced that our Board of Directors had approved a stock repurchase program of up to $50 million. During the three months ended September 30, 2008, we repurchased 930,000 shares of our common stock at an average price of $12.62 per share for an aggregate purchase price of $11.7 million, including commissions. For the nine months ended September 30, 2008, we repurchased 3.1 million shares of our common stock at an average price of $12.64 per share for an aggregate purchase price of $39.4 million, including commissions. The remaining authorized amount of stock repurchases under this program is $10.7 million, excluding commission.

- *Seasonal Fluctuations.* Seasonal fluctuations in the number of doctors in their offices and available to take appointments have affected, and are likely to continue to affect, our business. Specifically, our customers often take vacation or are on holiday during the summer months and therefore tend to start fewer cases. These seasonal trends have caused and will likely continue to cause, fluctuations in our quarterly results, including fluctuations in sequential revenue growth rates.

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

- *July Restructuring*. In July 2008, we announced a restructuring plan to reduce our overall company spending by reducing our full time headcount, implementing a phased-consolidation of order acquisition operations from our corporate headquarters in Santa Clara, California to Juarez, Mexico and slowing planned headcount growth. We anticipate completing the phased-consolidation by the end of 2008, at which time, the headcount in the United States will be transitioned out. For the three months ended September 30, 2008, we incurred approximately $2.2 million in restructuring expenses and we expect to incur additional expense of $0.5 million during the fourth quarter of 2008 relating to this restructuring plan. We expect savings of $10.0 to $12.0 million in 2009, a significant portion of which is related to a substantial reduction of planned hiring in 2009.

- *October Restructuring.* In October 2008, we announced an additional restructuring plan to increase efficiencies across the organization and lower our overall cost structure. The restructuring plan includes a total reduction of 110 full time headcount in Santa Clara, California, of which 45 positions will be eliminated between now and January 2009. The remaining positions are expected to be eliminated between February and July 2009 as we create a new shared services organization in our existing Costa Rica facility that will consolidate customer care, accounts receivable, credit and collections, and customer event registration organizations, which are currently

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located in Santa Clara, California. We anticipate staging the relocation to Costa Rica in an attempt to minimize disruptions to customer service levels and expect the relocation to be completed by the end of July 2009. These actions will result in a restructuring charge of approximately $5.0 million, of which $3.5 million will be recognized in the fourth quarter of 2008 and the remainder over the first half of 2009. We expect annualized savings of $12 to $15 million in 2009, which consists primarily of headcount reduction and reductions in discretionary spending. This cost savings does not include any amounts related to slowing of planned hiring. *See Part II, Item 1A Risk Factors for risks related to the October restructuring, including the phased-relocation of our customer facing operations to Costa Rica* .

- *Review of our investment portfolio and policies.* Our cash equivalent and short-term investment portfolio as of the date of this Form 10-Q consisted of US government notes and bonds, corporate bonds and certificates of deposits, agency bonds and discount notes and commercial paper. We follow an established investment policy and set of guidelines to monitor, manage and limit our exposure to interest rate, liquidity credit risk. The policy sets forth credit quality standards and limits our exposure to any one issuer, as well as our maximum exposure to various asset classes. As a result of current adverse financial market conditions, investments in some financial instruments, such as structured investment vehicles, sub-prime mortgage-backed securities and collateralized debt obligations, may pose risks arising from liquidity and credit concerns. As of the date of this Form 10-Q, we had no direct holdings in these categories of investments and our indirect exposure to these financial instruments through our holdings in money market mutual funds was immaterial. As of the date of this Form 10-Q, we had no impairment charge associated with our short-term investment portfolio relating to such adverse financial market conditions. Although we believe our current investment portfolio has very little risk of impairment, we cannot predict future market conditions or market liquidity and can provide no assurance that our investment portfolio will remain unimpaired. *See Part II, Item 1A Risk Factors for risks related to global financial and securities markets.*

Our short-term marketable securities as of September 30, 2008 are as follows (in thousands):

September 30, 2008	**Amortized Costs**	**Gross Unrealized Gains**	**Gross Unrealized Losses**	**Fair Value**
U.S. government notes and bonds	$ 9,968	$ 23	$	$ 9,991
Corporate bonds and certificates of deposit	8,957	3	(66)	8,894
Agency bonds and discount notes	10,849	4	(15)	10,838
Commercial paper	4,779	0	(3)	4,776
Total	$ 34,553	$ 30	$ (84)	$ 34,499

Our long-term marketable securities as of September 30, 2008 are as follows (in thousands):

September 30, 2008	**Amortized Costs**	**Gross Unrealized Gains**	**Gross Unrealized Losses**	**Fair Value**
Corporate bonds and certificates of deposit	$ 1,000	$	$ (3)	$ 997
Commercial paper	1,896		(24)	1,872
Total	$ 2,896	$	$ (27)	$ 2,869

- *Tax Valuation Allowance.* We have recorded a valuation allowance to fully reserve our net deferred tax assets. We continually monitor our position to determine whether it is more likely than not that we will be able to utilize most of our net operating loss carryforwards prior to their expiration and other deferred tax assets as they reverse. As we exit the fourth quarter of 2008, we will again review and determine whether circumstances require us to release this valuation allowance. If the tax valuation allowance is released, we will record a one-time income tax benefit of approximately $60 million to $70 million on our statement of operations.

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• *Stock-based compensation.* We implemented Statement of Financial Accounting Standards No. 123 (Revised 2004), Share-based Payment (FAS 123R) in 2006, and we expect stock-based compensation to increase until at least 2010, which corresponds to our standard 4 year vesting term. Thereafter, new grants will be expensed over the vesting period, however, this expense may be offset by fully vested grants that are no longer expensed. For the three and nine months ended September 30, 2008 and 2007, stock-based compensation expense recognized in accordance with FAS 123R is as follows (in thousands):

	Three Months Ended September 30, 2008		Three Months Ended September 30, 2007		Nine Months Ended September 30, 2008		Nine Months Ended September 30, 2007	
	Stock-based Compensation	**% of net revenues**	**Stock-based Compensation**	**% of net reveues**	**Stock-based Compensation**	**% of net revenues**	**Stock-based Compensation**	**% of net revenues**
Cost of revenues	$ 437	0.6%	$ 259	0.3%	$ 1,298	0.6%	$ 703	0.3%
Sales and marketing	1,390	1.8%	1,301	1.8%	4,069	1.8%	3,056	1.4%
General and administrative	2,009	2.7%	1,403	2.0%	6,122	2.6%	3,934	1.9%
Research and development	554	0.7%	425	0.6%	1,687	0.7%	1,082	0.5%
Total stock-based compensation expense	$ 4,390	5.8%	$ 3,388	4.7%	$ 13,176	5.7%	$ 8,775	4.1%

Results of Operations

Net revenues:

Invisalign product revenues by channel and other revenues, which represented training and sales of ancillary products, for the three and nine months ended September 30, 2008 and 2007 are as follows (in millions):

	Three Months Ended September 30,				Nine Months Ended September 30,			
Net revenues	**2008**	**2007**	**Net Change**	**% Change**	**2008**	**2007**	**Net Change**	**% Change**
North America:								
Ortho	$ 22.3	$ 22.5	$ (0.2)	-0.9%	$ 68.3	$ 68.9	$ (0.6)	-0.9%
GP	35.2	34.8	0.4	1.1%	106.6	101.0	5.6	5.5%
Total North American Invisalign	57.5	57.3	0.2	0.3%	174.9	169.9	5.0	2.9%
International Invisalign	15.1	11.6	3.5	30.2%	45.7	32.3	13.4	41.5%
Total Invisalign revenues	72.6	68.9	3.7	5.4%	220.6	202.2	18.4	9.1%
Other revenues	2.6	2.6	0.0	0.0%	9.3	9.6	(0.3)	-3.1%
Total net revenues	$ 75.2	$ 71.5	$ 3.7	5.2%	$ 229.9	$ 211.8	$ 18.1	8.5%

Case volume data which represents Invisalign case shipments by channel, for the three and nine months ended September 30, 2008 and 2007 are as follows (in thousands):

	Three Months Ended September 30,				Nine Months Ended September 30,			
Invisalign case volume	**2008**	**2007**	**Net Change**	**% Change**	**2008**	**2007**	**Net Change**	**% Change**
North America:								
Ortho	18.0	18.3	(0.3)	-1.8%	53.6	55.5	(1.9)	-3.4%
GP	25.7	26.5	(0.8)	-3.0%	78.7	76.6	2.1	2.7%
Total North American Invisalign	43.7	44.8	(1.1)	-2.5%	132.3	132.1	0.2	0.2%
International Invisalign	9.1	7.3	1.8	24.7%	27.1	20.0	7.1	35.5%
Total Invisalign case volume	52.8	52.1	0.7	1.3%	159.4	152.1	7.3	4.8%

For the three month period ended September 30, 2008 compared to the same period in 2007, overall net revenues improved as a result of increased International Invisalign revenues which benefited from increased case volume and

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favorable exchange rates against the U.S. dollar. Our North American Invisalign revenues were higher during the third quarter of 2008 compared to the same period in 2007 due to increased average selling prices, resulting from fewer volume rebates, related to a reduction in Ortho and GP case volume.

For the nine month period ended September 30, 2008 compared to the same period in 2007, overall net revenues improved as a result of increased case volume in International Invisalign and higher average selling prices primarily due to favorable exchange rates against the U.S. dollar. Our North American Invisalign revenues were higher during the first nine months of 2008 compared to the same period in 2007 reflecting increased average selling prices as a result of fewer volume rebates.

For 2008, we expect our total net revenues to increase compared to 2007 resulting from increased case volume. We expect our average selling price to be slightly higher in 2008 compared to 2007. As a result of and depending upon customer adoption of Invisalign Teen, which we launched in July 2008 and Invisalign Assist, which we launched in October 2008, we expect our product mix to begin shifting gradually as we exit 2008 and move into 2009. These new products will have a significantly higher amount of deferred revenue as a percentage of their average selling price, compared to our current products. As these new products increase as a percentage of our total case volume in the latter part of 2008, deferred revenue on our balance sheet will increase.

Cost of revenues and gross profit:

	Three Months Ended September 30,			Nine Months Ended September 30,		
(In millions)	**2008**	**2007**	**Change**	**2008**	**2007**	**Change**
Cost of revenues	$ 18.8	$ 18.1	$ 0.7	$ 58.6	$ 55.9	$ 2.7
% of net revenues	25.0%	25.4%		25.5%	26.4%	
Gross profit	$ 56.4	$ 53.3	$ 3.1	$ 171.2	$ 155.9	$ 15.3
Gross profit%	75.0%	74.6%		74.5%	73.6%	

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

For the three month period ended September 30, 2008 compared to the same period in 2007, overall gross profit reflects an increase in average selling price combined with a slightly higher case volume over our relatively fixed cost structure, which resulted in a decrease in our per unit standard cost. The improvement in gross profit for the nine months ended September 2008 was primarily driven by an increase in case volume compared to the same period in 2007. Additionally, cost reductions resulting from improved operating efficiencies contributed to the increase in gross profit for both periods.

We anticipate our gross profit in 2008 to be higher than 2007 due to increased case volume, higher average selling prices and improved operating efficiencies partially offset by increases in fuel surcharges.

Sales and marketing:

	Three Months Ended September 30,			Nine Months Ended September 30,		
(In millions)	**2008**	**2007**	**Change**	**2008**	**2007**	**Change**
Sales and marketing	$ 28.2	$ 24.2	$ 4.0	$ 88.7	$ 71.7	$ 17.0
% of net revenues	37.5%	33.9%		38.6%	33.9%	

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.

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Our sales and marketing expenses increased during the three months ended September 30, 2008 compared to the same period in 2007 primarily due to higher payroll-related expenses, including stock-based compensation and commissions, of $2.4 million, as a result of increased headcount. We also incurred higher costs relating to new product development and media of $2.0 million, which was partially offset by a $0.6 million decrease in advertising and promotions for the three months ended September 30, 2008.

Sales and marketing expenses increased for the nine months ended September 30, 2008 compared to the same period in 2007 due to higher payroll-related expenses, including stock-based compensation and commissions, of $7.0 million as a result of increased headcount. We also incurred higher expenditures for new product development costs of $5.5 million and media costs of $3.5 million for the nine months ended September 30, 2008.

For 2008, we expect sales and marketing expense, including stock-based compensation, to be higher than in 2007 as a result of the expansion of the North American sales force in the fourth quarter of 2007 and our international sales force in 2008. In addition, we have higher marketing spending in the United States and Europe with a focus on consumer advertising, including television and print media. We have incurred and will continue to incur additional costs in the United States related to bringing new products to market, such as Invisalign Teen and Invisalign Assist.

General and administrative:

	Three Months Ended September 30,			Nine Months Ended September 30,		
(In millions)	**2008**	**2007**	**Change**	**2008**	**2007**	**Change**
General and administrative	$ 14.4	$ 13.9	$ 0.5	$ 45.9	$ 38.0	$ 7.9
% of net revenues	19.1%	19.5%		20.0%	17.9%	

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

General and administrative expenses increased during the three months ended September 30, 2008 compared to the same period in 2007 primarily due to higher stock-based compensation expense.

General and administrative expenses increased during the nine months ended September 30, 2008 compared to the same period in 2007 primarily due to higher payroll-related expenses of $4.5 million resulting from additional headcount and increased stock-based compensation expense of $2.2 million. In addition, legal and other professional fees were also higher by $3.0 million compared to the same period in 2007 primarily due to a $1.6 million credit in 2007 from insurance reimbursement we received associated with the OrthoClear litigation.

For 2008, we expect general and administrative expense, including stock-based compensation, to be higher than 2007 due to increased headcount and other compensation expenses and higher professional and legal fees.

Research and development:

	Three Months Ended September 30,			Nine Months Ended September 30,		
(In millions)	**2008**	**2007**	**Change**	**2008**	**2007**	**Change**
Research and development	$ 5.9	$ 6.7	$ (0.8)	$ 20.2	$ 19.1	$ 1.1
% of net revenues	7.8%	9.4%		8.8%	9.0%	

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

Research and development expenses were lower during the three months ended September 30, 2008 compared to the same period in 2007 primarily due to decreases in outside services of $0.4 million and payroll-related expenses which includes stock-based compensation.

Research and development expenses increased during the nine months ended September 30, 2008 compared to the same period in 2007 primarily due to higher payroll-related expenses, including stock-based compensation, of $2.3 million as a result of increased headcount in the first six months of 2008, partially offset by a decrease in consulting fees of $1.2 million.

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For 2008, we expect research and development expense to be comparable to 2007.

Patients First Program:

	Three Months Ended September 30,			Nine Months Ended September 30,		
(In millions)	**2008**	**2007**	**Change**	**2008**	**2007**	**Change**
Patients First Program	$	$	$	$	$ (1.8)	$ 1.8
% of net revenues	%	%		%	-0.8%	

As part of the OrthoClear Agreement in October 2006, OrthoClear agreed to stop the importation of aligners into the United States and discontinue all aligner business operations worldwide. As a result, most OrthoClear patients were unable to complete their orthodontic treatment with OrthoClear. In an attempt to help minimize treatment disruptions for the OrthoClear patients and their doctors, we committed to make treatment available to these patients at no additional cost under the Patients First Program . In the fourth quarter of 2006, we recorded an $8.3 million charge for the anticipated costs of completing this program. Subsequently, in the first quarter of 2007, we reduced our Patients First Program accrual by $1.8 million to reflect a reduction of our initial estimate to the number of cases actually received by the case submission deadline. We shipped all Patients First Program cases by June 30, 2007.

Restructuring:

	Three Months Ended September 30,			Nine Months Ended September 30,		
(In millions)	**2008**	**2007**	**Change**	**2008**	**2007**	**Change**
Restructuring	$ 2.2	$	$ 2.2	$ 2.2	$	$ 2.2
% of net revenues	2.9%	%		1.0%	%	

In July 2008, we announced a restructuring plan to reduce our overall company spending by reducing our full time headcount, implementing a phased-consolidation of order acquisition operations from our corporate headquarters in Santa Clara, California to Juarez, Mexico and by slowing our planned headcount growth. We anticipate completing the phased-consolidation by the end of 2008, at which time, the headcount in the United States will be transitioned out.

For the three months ended September 30, 2008, we incurred approximately $2.2 million in restructuring expenses which includes $0.4 million related to the acceleration of stock option vesting and $1.8 million related to severance and termination benefits, of which $1.4 million was paid during the quarter. We expect to incur additional expense of $0.5 million during the fourth quarter of 2008 relating to this restructuring plan.

Interest and other income, net:

(In millions)	Three Months Ended September 30, 2008	Three Months Ended September 30, 2007	Change	Nine Months Ended September 30, 2008	Nine Months Ended September 30, 2007	Change
Interest income	$ 0.7	$ 1.2	$ (0.5)	$ 2.6	$ 2.8	$ (0.2)
Interest expense					(0.3)	0.3
Other income (expense), net	(0.4)	(0.1)	(0.3)	(0.9)	(0.3)	(0.6)
Total interest and other, net	$ 0.3	$ 1.1	$ (0.8)	$ 1.7	$ 2.2	$ (0.5)

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

Interest income, net for the three months ended September 30, 2008 decreased compared to the three months ended September 30, 2007 primarily due to lower average cash, cash equivalents and marketable securities balances resulting from

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the $11.7 million stock repurchase in the third quarter of 2008 and lower interest rates.

Interest income, net for the nine months ended September 30, 2008 decreased compared to the nine months ended September 30, 2007 primarily due to lower average cash, cash equivalents and marketable securities balances resulting from the $39.4 million stock repurchase and lower interest rates. In addition, we also incurred interest expense on the outstanding balance of our line of credit in the first nine months of 2007. We repaid the outstanding balance of our credit facility during the first nine months of 2007. We had no outstanding borrowings as of September 30, 2008.

Other income (expense), net decreased in the three and nine months ended September 30, 2008 compared to the same periods in 2007 reflecting the decreases in foreign currency translation gains.

Income tax provision:

	Three Months Ended September 30,			Nine Months Ended September 30,		
(In millions)	**2008**	**2007**	**Change**	**2008**	**2007**	**Change**
Provision for income taxes	$ 0.8	$	$ 0.8	$ 1.4	$ 1.0	$ 0.4

We recorded an income tax provision of $0.8 million and $43,000 for the three months ended September 30, 2008 and 2007, respectively, representing effective tax rates of 13.4% and 0.5%. We recorded an income tax provision of $1.4 million and $1.0 million for the nine months ended September 30, 2008 and 2007, respectively, representing effective tax rates of 8.6% and 3.3%. Our effective tax rate for the remainder of 2008 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 exercise 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 tax benefit from deferred tax assets. We have historically experienced operating losses and have significant net operating loss and tax credit carryforwards. We have considered our future taxable income and tax planning strategies in assessing our valuation allowance. Future taxable income is based upon our estimates, and actual results may significantly differ from these estimates. If it is determined that the valuation allowance should be released, it will result in a significant one-time benefit to our statement of operations of approximately $60 million to $70 million.

Liquidity and Capital Resources

We fund our operations from product sales, the proceeds from the sale of our common stock, and from occasional borrowings under our available credit facility. As of September 30, 2008 and December 31, 2007 we had the following cash and cash equivalents, and short-term marketable securities (in thousands):

		September 30, 2008		December 31, 2007
Cash and cash equivalents	$	79,756	$	89,140
Marketable securities, short-term		34,499		38,771
Total	$	114,255	$	127,911

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

Net cash provided by operating activities was $35.8 million for the nine months ended September 30, 2007 resulted primarily from our net profit of $30.0 million adjusted for non-cash items such as depreciation, amortization of intangibles and stock-based compensation totaling $18.8 million. These increases in cash flows from operating activities were partially offset by a $12.0 million increase in accounts receivable.

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Net cash used in investing activities was $10.5 million for the nine months ended September 30, 2008, largely consisted of $12.4 million used for the purchase of property and equipment and offset by $1.4 million of net maturities of marketable securities. Net cash used in investing activities for the nine months ended September 30, 2007, largely consisted of $13.1million of net purchases of marketable securities and $6.3 million used for the purchase of capital assets.

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

Net cash used in financing activities was $29.6 million for the nine months ended September 30, 2008, which resulted primarily from our $39.4 million stock repurchase offset by $10.2 million in proceeds from the issuance of our common stock, primarily from exercises of employee stock options. Net cash provided by financing activities for the nine months ended September 30, 2007 consisted of $27.8 million in proceeds from the issuance of common stock, primarily from exercises of employee stock options. This increase was partially offset by the repayment of $11.5 million against the outstanding balance on our line of credit.

Net proceeds from the issuance of our common stock related to the exercise of employee stock options have historically been a significant component of our liquidity. In 2006, we began granting restricted stock units (RSUs) which, unlike stock options, do not generate cash from exercises. As a result, we will likely generate less cash from the proceeds of the sale of our common stock in future periods. In addition, because RSUs are taxable to the individuals when they vest, the number of shares we issue to each of our executive officers will be net of applicable withholding taxes which will be paid by us on their behalf. During the first nine months of 2008, we paid $0.3 million of taxes related to RSUs that vested during the period for executive officers.

Effective January 1, 2008, the available borrowings under the revolving line of credit is $25 million. This credit facility matures on December 31, 2008. During the first nine months of 2007, we repaid $11.5 million of our outstanding borrowing on this credit facility. As of September 30, 2008, we have no outstanding borrowings and we are in compliance with the financial covenant of this credit facility. We intend to renew the line of credit, although there is no assurance that the bank will offer a renewal or, if the renewal is offered, that it will be on favorable terms.

On April 29, 2008, we announced that our Board of Directors had approved a stock repurchase program of up to $50 million. For the nine months ended September 30, 2008, the Company repurchased 3.1 million shares of common stock at an average price of $12.64 per share for an aggregate purchase price of $39.4 million including commissions. The remaining authorized amount of stock repurchases under this program is $10.7 million.

In July, 2008, we entered into an agreement in favor and for the benefit of Elamex de Juarez, S.A. DE C.V., landlord to IMS, our third party shelter services provider, to guarantee IMS s lease payments for its facility located in Juarez, Mexico. The current lease for the facility expires in July 2013. Pursuant to the guarantee, we are obligated to pay Elamex de Juarez, S.A. DE C.V. for any rental payments in default by IMS. As of September 30, 2008, we are contingently liable for future payments of approximately $1.8 million which will decrease monthly as IMS pays the monthly rent of approximately $30,000.

In July 2008, we announced a restructuring plan to reduce our overall company spending by reducing our full time headcount, implementing a phased-consolidation of order acquisition operations from our corporate headquarters in Santa Clara, California to Juarez, Mexico and by a slowing our planned headcount growth. We anticipate completing the phased-consolidation by the end of 2008, at which time, the headcount in the United States will be transitioned out. For the three months ended September 30, 2008, we incurred approximately $2.2 million in restructuring expenses and we expect to incur additional expense of $0.5 million during the fourth quarter of 2008 relating to this restructuring plan. We expect annualized cost savings of $10.0 to $12.0 million from this action will be realized in 2009, a significant portion of which is related to the substantial slowing in our planned hires in 2009.

In October 2008, we announced an additional restructuring plan to increase efficiencies across the organization and lower our overall cost structure. The restructuring plan includes a total reduction of 110 full time headcount in Santa Clara, California, of which 45 positions will be eliminated between now and January 2009. The remaining positions are expected to be eliminated between February and July 2009 as we create a new shared services organization in our existing Costa Rica facility that will consolidate customer care, accounts receivable, credit and collections, and customer event registration organizations, which are currently located in Santa Clara, California. We anticipate staging the relocation to Costa Rica in an attempt to minimize disruptions to customer service levels and expect the relocation to be completed by the end of July 2009.

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These actions will result in a restructuring charge of approximately $5.0 million, of which $3.5 million will be recognized in the fourth quarter of 2008 and the remainder over the first half of 2009. We expect annualized cost savings of $12.0 to $15.0 million from this action will be realized in 2009, which consists primarily of headcount reduction and reduction in discretionary spending.

Contractual Obligations

As of September 30, 2008 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, 2007.

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, 2007.

- Revenue recognition;
- Stock-based compensation expense;
- Long-lived assets, including finite lived purchased intangible assets;
- Deferred tax valuation allowance.

There have been no significant changes in our critical accounting policies during the nine months ended September 30, 2008 compared to what was previously disclosed in Item 7, *Management s Discussion and Analysis of Financial Condition and Results of Operations* included in our Annual Report on Form 10-K for the year ended December 31, 2007.

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, 2007, which is incorporated herein by reference. Our exposure to market risk has not changed materially since December 31, 2007.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of disclosure controls and procedures.

Under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, we have evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of the end of the period covered by this Quarterly Report on Form 10-Q. Based upon that evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that our disclosure controls and procedures are effective as of September 30, 2008 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,

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as appropriate, to allow timely decisions regarding required disclosure, and that such information is recorded, processed, summarized and reported within the time periods specified in the SEC rules and forms.

Changes in internal control over financial reporting.

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

PART II OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

Ormco

On January 6, 2003, Ormco Corporation (Ormco) filed suit against us in the United States District Court for the Central District, Orange County Division, asserting infringement of U.S. Patent Nos. 5,447,432, 5,683,243 and 6,244,861. Ormco is a division of Sybron Dental Specialties (a Danaher Corporation subsidiary). The complaint sought unspecified monetary damages and injunctive relief. On February 18, 2003, we answered the complaint and asserted counterclaims seeking a declaration by the Court of invalidity and non-infringement of the asserted patents. In addition, we counterclaimed for infringement of our U.S. Patent No. 6,398,548, seeking unspecified monetary damages and injunctive relief. Ormco filed a reply to our counterclaims on March 10, 2003 and asserted counterclaims against us seeking a declaration by the Court of invalidity and non-infringement of U.S. Patent No. 6,398,548. We amended our counterclaim to add Allesee Orthodontic Appliances, Inc. (AOA), a wholly-owned subsidiary of Ormco, as a counterdefendant in regard to our counterclaim of infringement of U.S. Patent No. 6,398,548. The Court then permitted Ormco to amend its Complaint and permitted us to amend our counterclaim to add an additional patent each. Ormco filed a first amended complaint for infringement of U.S. Patent No. 6,616,444 on October 15, 2003. On October 27, 2003, we filed an answer to Ormco s first amended complaint and a counterclaim for invalidity and non-infringement of U.S. Patent No. 6,616,444 and for infringement of U.S. Patent No. 6,554,611.

In connection with these claims, the Court granted five motions for summary judgment that we filed. First, on May 14, 2004, the Court granted our motion for summary judgment of non-infringement, finding that our Invisalign system does not infringe any of the asserted Ormco patents (5,447,432, 5,683,243, 6,244,861 and 6,616,444). Second, on July 2, 2004, the Court granted in part our motion for summary judgment of infringement, finding that Ormco and AOA infringe certain, but not all, claims of our patents Nos. 6,398,548 and 6,554,611 through the manufacture and sale of Red, White & Blue appliances. Third, on August 26, 2004, the Court granted our motion for summary judgment of invalidity of Ormco s asserted patents claims (5,447,432, 5,683,243, 6,244,861 and 6,616,444). As noted above, the Court earlier found that we do not infringe these patents. In addition, the Court also denied Ormco s and AOA s motion for summary judgment seeking a finding of invalidity of our asserted patent claims (6,398,548 and 6,554,611). Fourth, the Court granted our summary judgment motion that our asserted patent claims are not invalid based on the evidence currently before the Court. Although the Court granted that motion, it reopened discovery on two additional invalidity arguments Ormco and AOA asserted. Fifth, the Court also granted our summary judgment motion that our patents are not unenforceable and granted Ormco s and AOA s summary judgment motion that Ormco and AOA did not willfully infringe our patents.

On December 20, 2004, we filed a further summary judgment motion that our asserted claims are not invalid based on Ormco s and AOA s new evidence. Ormco and AOA filed a counter-summary judgment motion that our asserted claims are invalid based on this new evidence. On February 24, 2005, the Court granted our motion in part, confirming the validity of all of the asserted claims of our 6,554,611 patent and two of the asserted claims of our 6,398,548 patent. The Court also granted Ormco s and AOA s motion in part, finding certain claims of our 6,398,548 patent to be invalid in view of prior use evidence. On March 10, 2005, Ormco and AOA moved for reconsideration of the Court s ruling that Claims 10 and 17 of our U.S. Patent No. 6,398,548 are not invalid. On April 8, 2005, the Court ruled that it would adhere to its previous ruling that Claims 10 and 17 of our 6,398,548 patent are not invalid.

On March 28, 2005, we filed a motion for permanent injunction to prevent Ormco and AOA from selling the infringing Red, White & Blue system. On May 26, 2005, the Court issued a permanent injunction (the Permanent Injunction) to enjoin Ormco and AOA from further infringement of Claims 10 and 17 of our 6,398,548 patent and Claims 1-3 and 7 of our 6,554,611 patent. On May 31, 2005, Ormco and AOA filed a notice of appeal with the Federal Circuit from the Permanent Injunction.

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

The 6,398,548 patent consists of 71 claims; only claims 10 and 17 were at issue in the first appeal and CAFC ruling. These two claims are directed to a system of appliances and method of repositioning teeth from an initial to a final tooth arrangement where at least some of the appliances are marked to show order of use. These claims contain further limitations requiring instructions as to the order in which the appliances are to be worn and use of the appliances in intervals of 2-20 days.

The 6,554,611 patent consists of ten claims directed to a system for repositioning teeth that includes one or more intermediate appliances and a final appliance, provided in a single package, as well as instructions which set forth the order in which the appliances are to be worn. The CAFC s ruling pertains only to claims 1, 2, 3 and 7 in the patent.

The second appeal was from the final judgment. Ormco appealed the ruling of the District Court that 92 claims in four of its patents are not infringed by us and that the asserted claims are invalid. We appealed the ruling of the District Court that certain claims of our 6,398,548 patent which were found to be infringed by Ormco s and AOA s Red, White & Blue appliances were invalid. The CAFC issued a ruling on August 24, 2007, affirming the District Court s ruling that 86 out of 92 claims in Ormco s 5,447,432, 5,683,243, 6,244,861 and 6,616,444 patents are invalid and not infringed by us. The CAFC reversed the District Court s non-infringement and invalidity rulings on six claims in Ormco s 6,616,444 patent, which will be returned to the District Court for a determination of validity and infringement of those claims. The Court has denied Ormco s petition for rehearing with respect to the portion of the Federal Circuit s opinion that affirmed the District Court s ruling of non-infringement and non-enablement of the 86 claims.

Ormco filed a petition for review with the U.S. Supreme Court with respect to the portion of the CAFC s opinion that affirmed the District Court s ruling of non-infringement and non-enablement of Ormco s 86 claims. The Supreme Court denied Ormco s petition, and the case on the six claims in Ormco s 444 patent which were returned to the District Court for further proceedings.

The District Court issued orders construing the claim terms at issue and granting our motion to amend it answer and counterclaim to assert inequitable conduct. The parties are currently conducting discovery. Trial on liability issues is scheduled for June 2, 2009.

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Other matters

USPTO

During fiscal 2005 and 2006, requests were filed with the United States Patent and Trademark Office (USPTO) by a San Francisco, California, law firm, acting on behalf of an unnamed party, requesting Ex Parte re-examination of our patents. A Reexamination Certificate has been issued regarding the 6,309,215, 6,398,548, 6,705,863, 6,217,325, 6,722,880, 6,318,994 and 5,975,893 patents and therefore these patents are no longer in reexamination. We received an Action Closing Prosecution on the 6,685,469 patent. The status of the 6,629,840 patent is as follows:

Patent No.	**Request for Reexamination Granted?**	**Initial Office Actions Received?**	**Status**
6,629,840	Yes	Yes	In this initial Office Action dated June 13, 2006, the examiners confirmed the validity of eight of the eleven claims of U.S. Patent No. 6,629,840 (the 840 patent) without amendment and preliminarily rejected the remaining claims of the patents. The non-final initial Office Action presented us with the first opportunity to respond to the USPTO s review and interpretation of the prior art. On September 13, 2006, we submitted a response to the initial Office Action. A petition seeking a waiver was filed on February 15, 2007 and was granted on April 17, 2007, granting a single interview. The interview was held on May 22, 2007, and an Interview Summary was filed with the USPTO on June 21, 2007. We are awaiting further action by the USPTO.

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

Class Action

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

On July 3, 2007, we filed our answer to the complaint and asserted 17 affirmative defenses. On July 20, 2007, we filed a motion for summary judgment on the Third Cause of Action (the only cause of action alleged against us). On August 24, 2007, Weber filed a motion for class certification. On October 1, 2007, we filed an opposition to the motion of class certification and we are currently awaiting rulings from the Court. OrthoClear has filed a motion to dismiss. The initial case management conference and all discovery has been stayed pending the Court s decision on the motion for class certification, OrthoClear s motion to dismiss and our motion for summary judgment.

Litigating claims of the types discussed in this Quarterly Report on Form 10-Q, whether or not ultimately determined in our favor or settled by us, is costly and diverts the efforts and attention of our management and technical personnel from normal business operations. Any of these results from litigation could adversely affect our results of operations and stock price. From time to time, we have received, and may again receive, letters from third parties drawing our attention to their patent rights. While we do not believe that we infringe any such rights that have been brought to our attention, there may be other more pertinent proprietary rights of which we are presently unaware.

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ITEM 1A. RISK FACTORS

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

While we returned to profitability in 2007 and into the first nine months of 2008, we experienced a net loss in each quarter of 2006. 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 2007 and into the first nine months of 2008, we experienced negative cash flow in 2006. We cannot be certain that we will be able to achieve positive cash flow from operations, from period to period, in the future. Because our business is evolving, it is difficult to predict our future operating results or levels of growth, and we have in the past not been and may in the future not be able to sustain our historical growth rates. If we do not increase profitability or revenue growth or otherwise meet the expectations of securities analysts or investors, the market price of our common stock will likely decline.

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

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

- limited visibility into and difficulty predicting the level of activity in our customers practices from quarter to quarter;
- weakness in consumer spending as a result of the slowdown in the United States economy and certain international economies;
- changes in the timing of receipt of case product orders during a given quarter which, given our cycle time and the delay between case receipts and case shipments, could have an impact on which quarter revenue can be recognized;
- changes in product mix;
- seasonal fluctuations in the number of doctors in their offices and available to take appointments;
- success of marketing programs from quarter to quarter;
- changes in the timing of revenue recognition with the introduction of new products such as Invisalign Assist and Invisalign Teen;
- unanticipated delays in production caused by insufficient capacity;
- any disruptions in the manufacturing process, including unexpected turnover in the labor force or the introduction of new production processes or natural or other disasters beyond our control;
- the development and marketing of directly competitive products by existing and new competitors;
- aggressive price competition from competitors;

- costs and expenditures in connection with litigation;
- inaccurate forecasting of revenues, production and other operating costs; and
- investments in research and development to develop new products and enhancements to Invisalign.

To respond to these and other factors, we may need to make business decisions that could adversely affect our operating results such as modifications to our pricing policy, business structure or operations. Most of our expenses, such as employee compensation and lease payment obligations, are relatively fixed in the short term. Moreover, our expense levels are based, in part, on our expectations regarding future revenue levels. As a result, if our revenues for a particular period fall below our expectations, whether caused by changes in consumer spending, consumer preferences, weakness in the U.S. or global economies, changes in customer behavior related to advertising and prescribing our product, or other factors, we may be unable to adjust spending quickly enough to offset any shortfall in revenues. Due to these and other factors, we believe that quarter-to-quarter comparisons of our operating results may not be meaningful. You should not rely on our results for any one quarter as an indication of our future performance.

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

We expect that revenues from the sale of the Invisalign system will continue to account for the vast majority of our total revenues for the foreseeable future. Continued and widespread market acceptance of Invisalign by orthodontists, GPs and consumers is critical to our future success. If orthodontists and GPs experience a reduction in consumer demand for orthodontic services, if consumers prove unwilling to adopt Invisalign as rapidly as we anticipate or in the volume that we anticipate, if orthodontists or GPs choose to use a competitive product rather than Invisalign or if the average selling price of our product declines as it has in the past, our operating results would be harmed. Factors that could cause Invisalign not to achieve market acceptance at the rate at which we expect, as well as the risk related to declining average selling prices are described more fully below.

Orthodontists and GPs may not adopt Invisalign in sufficient numbers or as rapidly as we anticipate.

Our success depends upon increasing acceptance and frequency of use of the Invisalign system by dental professionals (what we refer to as utilization). Invisalign requires orthodontists, GPs and their staff to undergo special training and learn to interact with patients in new ways. Increasing adoption and cumulative use by orthodontists and GPs will depend on factors such as the capability, safety, efficacy, ease of use, price, quality and reliability of our products, our ability to provide effective sales support, training and service and the availability of competing products, technologies and alternative treatments. In addition, unanticipated poor clinical performance of Invisalign could result in significant adverse publicity and, consequently, reduced acceptance by dental professionals. Also increased competition from direct competitors could cause us to lose market share and reduce dental professionals efforts and commitment to expand their Invisalign practice. If adoption and utilization does not increase as we anticipate, our revenues may fail to grow as expected and our operating results may be harmed.

Consumers may not adopt Invisalign in sufficient numbers or as rapidly as we anticipate.

Invisalign represents a significant change from traditional orthodontic treatment, and consumers may be reluctant to accept it or may not find it preferable to traditional treatment We have generally received positive feedback from both orthodontists, GPs and consumers regarding Invisalign as both an alternative to braces and as a clinical method for treatment of malocclusion, but a number of dental professionals believe that Invisalign is appropriate for only a limited percentage of their patients. Market acceptance will depend in part upon the recommendations of dental professionals, as well as other factors including effectiveness, safety, ease of use, reliability, aesthetics, greater comfort and hygiene compared to traditional orthodontic products and price for Invisalign compared to competing products. Furthermore, consumers may not respond to our direct marketing campaigns or we may be unsuccessful in reaching our target audience. In addition, 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 could have a material adverse effect on our sales and operating results.

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

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

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

In response to challenges in our business, including increased competition, in November 2005, we reduced the list price of full Invisalign cases and in the third quarter of 2005 we introduced Invisalign Express, a lower-cost solution for less complex cases. In addition, in the fourth quarter of 2005, we expanded our volume based discount program to all doctors. If we are to introduce any similar price reductions or discount programs in the future or if participation in these programs increases, our revenues, gross margin and net profits (losses) may be adversely affected.

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We may experience unexpected problems and expenses associated with the phased-relocation of our customer facing organizations to Costa Rica.

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

- failure to successfully coordinate and phase the relocation of these customer facing organizations may cause our customers to experience decrease in service levels;
- the relocation may absorb significant management and key employee attention and resources that would otherwise be available for the ongoing development of our business;
- failure to retain key employees who possess specific knowledge or expertise and who we are depending upon for the timely and successful transition to Costa Rica; and
- difficulties hiring employees in Costa Rica with the necessary skills to perform these customer facing functions.

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

Our future success may depend on our ability to develop and successfully introduce new products.

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

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

A disruption in the operations of our key shipper 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.

Currently, two of 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 electronic treatment plans, which are transmitted electronically back to the U.S. These electronic files form the basis of ClinCheck and are used to manufacture aligner molds. IMS, our third party shelter services provider located in Juarez, Mexico fabricates the aligner molds, the aligners and ships the completed products to our customers. 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. We also expect to have completed the relocation of our order acquisition operations from our Santa Clara facility to Mexico by the end of 2008. In addition, in October 2008, we announced the phased-consolidation of our customer-care, accounts receivable, credit and collections and customer event registration organizations, which are currently located in Santa Clara, California, to our facility in Costa Rica. We expect this relocation to be completed by the end of July 2009. Our increasing reliance on international operations exposes us to risks and uncertainties that may affect our business or results of operation, including:

- difficulties in hiring and retaining employees generally, as well as difficulties in hiring and retaining employees with the necessary skills to perform the more technical aspects of our operations;
- difficulties in managing international operations, including our relationship with IMS, our third party shelter services provider;
- 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;
- acts of terrorism and acts of war;
- interruptions and limitations in telecommunication services;
- product or material transportation delays or disruption;
- burdens of complying with a wide variety of local country and regional laws;
- trade restrictions and changes in tariffs; and
- potential adverse tax consequences.

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

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

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

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

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

We currently rely on third parties to provide key inputs to our manufacturing process, and if our access to these inputs is diminished, our business may be harmed.

We currently outsource key portions of our manufacturing process. We rely on IMS, a third party shelter services provider located in Juarez, Mexico, to fabricate aligner molds as well as finished aligners and to ship the completed product to customers. In addition, by the end of 2008, we expect to complete the relocation of our order acquisition process to the same third party manufacturer in Mexico. If IMS fails to deliver its components or if we unexpectedly lose its services, we may be unable to deliver our products in a timely manner, and our business may be harmed. Any difficulties encountered by us or IMS with respect to hiring and retaining qualified personnel, and maintaining acceptable manufacturing standards, controls, procedures and policies could disrupt our ability to deliver our products in a timely manner.

We experience competition from manufacturers of traditional braces and expect aggressive competition from these and other companies that may introduce new technologies in the future.

Currently, our Invisalign product competes directly against products manufactured and distributed by Ormco Orthodontics, a division of Sybron Dental Specialties (a Danaher Corporation subsidiary), and traditional braces manufactured by 3M Company and Dentsply International. These manufacturers have substantially greater financial resources and manufacturing and marketing experience than we do and may, in the future, attempt to develop an orthodontic system similar to ours or combine technologies that make our product economically unattractive. Large consumer product companies may also enter the orthodontic supply market. Furthermore, we may face competition in the future from new companies that may introduce new technologies. We may be unable to compete with these competitors and one or more of these competitors may render our technology obsolete or economically unattractive. If we are unable to compete effectively with existing products or respond effectively to any products developed by new or existing competitors, our business could be harmed. Increased competition has resulted in the past and may in the future result in volume discounting and price reductions, reduced gross margins, reduced profitability and loss of market share, any of which could have a material adverse effect on our revenues, volume growth, net profit (losses) and stock price. We cannot assure you that we will be able to compete successfully against our current or future competitors or that competitive pressures will not have a material adverse effect on our business, results of operations and financial condition.

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

We rely on the efficient and uninterrupted operation of complex information technology systems. All information technology systems are vulnerable to damage or interruption from a variety of sources. As our business has grown in size and complexity, the growth has placed, and will continue to place, significant demands on our information technology systems. To effectively manage this growth, we will need to continually upgrade and enhance our information systems. In addition, experienced computer programmers and hackers may be able to penetrate our network security and misappropriate our confidential information or that of third parties, create system disruptions or cause shutdowns. Furthermore, sophisticated hardware and operating system software and applications that we either internally produce or procure from third parties may contain defects in design and manufacture, including bugs and other problems that can unexpectedly interfere with the operation of the system. The costs to eliminate or alleviate security problems, viruses and bugs could be significant, and the efforts to address these problems could result in interruptions that may have a material adverse impact on our operations, revenues and operating results.

We are currently focused on adding additional functionality into our business enterprise systems to more efficiently integrate these systems with our other system applications, such as customer facing and manufacturing tools, and intend to continue this effort for the foreseeable future. System upgrades and enhancements require significant expenditures and allocation of valuable employee resources. Delays in integration or disruptions to our business from implementation of these new or upgraded systems could have a material adverse impact on our financial condition and operating results. Furthermore, we continuously upgrade our customer facing software applications, specifically ClinCheck and VIP. Software applications frequently contain errors or defects, especially when they are first introduced or when new versions are released. The discovery of a defect or error in a new upgraded version or the failure of our primary information systems may result in the

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following consequences, among others: loss of revenue or delay in market acceptance, damage to our reputation or increased service costs, any of which could have a material adverse effect on our business, financial condition or results of operations.

Our success depends in part on our proprietary technology, and if we are unable to successfully enforce our intellectual property rights, our competitive position may be harmed. Litigating claims of this type is costly and could distract our management and cause a decline in our results of operations and stock price.

Our success will depend in part on our ability to maintain existing intellectual property and to obtain and maintain further intellectual property protection for our products, both in the U.S. and in other countries. Our inability to do so could harm our competitive position. As of September 30, 2008, we had 109 issued U.S. patents, 181 pending U.S. patent applications, and 43 issued foreign patents, and 132 pending foreign patent applications.

We intend to rely on our portfolio of issued and pending patent applications in the U.S. and in other countries to protect a large part of our intellectual property and our competitive position. However, our currently pending or future patent filings may not result in the issuance of patents. Additionally, any patents issued to us may be challenged, invalidated, held unenforceable, circumvented, or may not be sufficiently broad to prevent third parties from producing competing products similar in design to our products. During fiscal 2005 and 2006, requests were filed with the United States Patent and Trademark Office (USPTO) by a San Francisco, California law firm, acting on behalf of an unnamed party and in some instances acting on behalf of OrthoClear, requesting re-examination of a number of our patents. *See Part II, Item 1 of this Quarterly Report on Form 10-Q for a summary of the USPTO proceedings.* In addition, any protection afforded by foreign patents may be more limited than that provided under U.S. patents and intellectual property laws. We also rely on protection of our copyrights, trade secrets, know-how and proprietary information. We generally enter into confidentiality agreements with our employees, consultants and our collaborative partners upon commencement of a relationship with us. However, these agreements may not provide meaningful protection against the unauthorized use or disclosure of our trade secrets or other confidential information, and adequate remedies may not exist if unauthorized use or disclosure were to occur. Our inability to maintain the proprietary nature of our technology through patents, copyrights or trade secrets would impair our competitive advantages and could have a material adverse effect on our operating results, financial condition and future growth prospects. In particular, a failure to protect our proprietary rights might allow competitors to copy our technology, which could adversely affect our pricing and market share.

In addition, in an effort to protect our intellectual property we have in the past been and may in the future be involved in litigation. For example, we are currently involved in a patent infringement lawsuit with Ormco. In addition, during 2005 and 2006 we were involved in several lawsuits with OrthoClear, Inc. and other parties related to OrthoClear, including a patent infringement action against OrthoClear filed in the Western District of Wisconsin (Madison). We settled this lawsuit in October 2006, however, the potential effects on our business operations resulting from similar litigation that we may participate in the future, whether or not ultimately determined in our favor or settled by us, are costly and divert the efforts and attention of our management and technical personnel from normal business operations. Any of these results from our litigation could adversely affect our results of operations and stock price.

We are currently a party to various other legal proceedings and claims. Management does not believe that the ultimate outcome of these other legal proceedings and claims will have a material adverse effect on our financial position or results of operations. In addition, litigation is subject to inherent uncertainties and unfavorable rulings could occur. An unfavorable ruling could include monetary damages or, in cases where injunctive relief is sought, an injunction prohibiting us from selling our products. Any of these results from our litigation could adversely affect our results of operations and stock price. *See Part II, Item 1 of this Quarterly Report on Form 10-Q for a summary of our material pending legal proceedings.*

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

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

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reporting is effective in any future period (or if our auditors are unable to express an opinion on the effectiveness of our internal controls or conclude that our internal controls are ineffective), we could lose investor confidence in the accuracy and completeness of our financial reports, which could have an adverse effect on our stock price.

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

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

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

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

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

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

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

Our ability to sell our products and generate revenues depends upon our direct sales force within our North American and international markets. As of September 30, 2008, our North American sales organization consisted of 163 people, of which 134 were direct sales representatives and 29 were sales administration and regional sales management. Internationally, we have 36 people engaged in sales and sales support as of September 30, 2008. We do not have any long-term employment contracts with the members of our direct sales force. The loss of the services of these key personnel may harm our business. If we are unable to retain our direct sales force personnel or replace them with individuals of equivalent technical expertise and qualifications, or if we are unable to successfully instill such technical expertise or if we fail to establish strong relationships with our customers within a relatively short period of time, our revenues and our ability to maintain market share could be materially harmed. In addition, due to our large and fragmented customer base, we may not be able to provide all of our customers with product support immediately upon the launch of a new product. As a result,

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adoption of new products by our customers may be slower than anticipated and our ability to grow market share and increase our revenues may be harmed.

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

Our products are medical devices and are subject to extensive regulation in the U.S. and internationally. FDA regulations are wide ranging and govern, among other things:

- product design, development, manufacture and testing;
- product labeling;
- product storage;
- pre-market clearance or approval;
- advertising and promotion; and
- product sales and distribution.

Our failure to comply with applicable regulatory requirements could result in enforcement action by the FDA or state agencies, which may include any of the following sanctions:

- warning letters, fines, injunctions, consent decrees and civil penalties;
- repair, replacement, refunds, recall or seizure of our products;
- operating restrictions or partial suspension or total shutdown of production;
- refusing our requests for 510(k) clearance or pre-market approval of new products, new intended uses, or modifications to existing products;
- withdrawing clearance or pre-market approvals that have already been granted; and
- criminal prosecution.

If any of these events were to occur, they could harm our business. We must comply with facility registration and product listing requirements of the FDA and adhere to applicable Quality System regulations. The FDA enforces its Quality System regulations through periodic unannounced inspections. Our failure or the failure of IMS to take satisfactory corrective action in response to an adverse inspection or the failure to comply with applicable manufacturing regulations could result in enforcement action, and we may be required to find alternative manufacturers, which could be a long and costly process.

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

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

We retain confidential customer and patient information in our processing centers. Therefore, it is critical that our facilities and infrastructure remain secure and that our facilities and infrastructure are perceived by the marketplace and our customers to be secure. Despite the implementation of security measures, our infrastructure may be vulnerable to physical break-ins, computer viruses, programming errors, attacks by third parties or similar disruptive problems. If we fail to meet our clients expectations regarding the security of healthcare information, we could be liable for damages and our reputation

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could be impaired. In addition, patient care could suffer, and we could be liable if our systems fail to deliver correct information in a timely manner. Our insurance may not protect us from this risk.

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

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

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

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

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

- storage, transmission and disclosure of medical information and healthcare records;
- prohibitions against the offer, payment or receipt of remuneration to induce referrals to entities providing healthcare services or goods or to induce the order, purchase or recommendation of our products; and
- the marketing and advertising of our products.

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

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

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

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

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

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have the effect of increasing our expenses and diverting management s attention away from the operation of our business, and could harm our business.

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

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

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

In addition, the stock market in general, and the market for technology and medical device companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated to or disproportionate to the operating performance of those companies. These broad market and industry factors may seriously harm the market price of our common stock, regardless of our operating performance. In the past, class action litigation has often been brought against the issuing company following periods of volatility in the market price of a company s securities. If a securities class action suit is filed against us in the future, we would incur substantial legal fees, and our management s attention and resources would be diverted from operating our business in order to respond to the litigation.

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

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

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

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

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

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

The primary objective of most of our investment activities is to preserve principal while at the same time maximizing yields without significantly increasing risk. To achieve this objective, a majority of our marketable investments are investment grade, liquid, short-term fixed-income securities and money market instruments denominated in U.S. dollars. If the carrying value of our investments exceeds the fair value, and the decline in fair value is deemed to be other-than-

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temporary, we will be required to write down the value of our investments, which could materially harm our results of operations and financial condition. Moreover, the performance of certain securities in our investment portfolio correlates with the credit condition of the U.S. financial sector. With the current unstable credit environment, we might incur significant realized, unrealized or impairment losses associated with these investments.

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

Our board of directors has the authority to issue up to 5,000,000 shares of preferred stock and to determine the rights, preferences, privileges and restrictions of such shares without any further vote or action by our shareholders. To date, our board of directors has designated 200,000 shares as Series A participating preferred stock in connection with our shareholder rights plan. The issuance of preferred stock under certain circumstances could have the effect of delaying or preventing an acquisition of the company or otherwise adversely affecting the rights of the holders of our stock. The shareholder rights plan may have the effect of rendering more difficult or discouraging an acquisition of our company which is deemed undesirable by our board of directors. The shareholder rights plan may cause substantial dilution to a person or group attempting to acquire us on terms or in a manner not approved by our board of directors, except pursuant to an offer conditioned on the negation, purchase or redemption of the rights issued under the shareholder rights plan.

Our effective tax rate may vary significantly from period to period, and we could owe significant taxes even during periods when we experience low operating profit or operating losses.

We have negotiated tax incentives with the Costa Rica Ministry of Foreign Trade, an agency of the Government of Costa Rica. Under the incentives, all of the income we earn in Costa Rica during these eight to twelve year incentive periods is subject to reduced rates of Costa Rica income tax. The incentive tax rates will expire in various years beginning in 2010. The Costa Rica corporate income tax rate that would apply, absent the incentives, is 30% for 2008. As a result of these incentives, income taxes decreased by $2 million in 2007. In order to receive the benefit of the incentives, we must hire specified numbers of employees and maintain minimum levels of fixed asset investment in Costa Rica. If we do not fulfill these conditions for any reason, our incentive could lapse and our income in Costa Rica would be subject to taxation at higher rates, which could cause our operating results to be harmed.

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

Following is a summary of stock repurchases for the three months ended September 30, 2008 (1):

Period	Total Number of Shares Repurchased	Average Price Paid per Share	Total Number of Shares Repurchased as Part of Publicly Announced Program	Approximate Dollar Value of Shares that May Yet Be Repurchased Under the Program
August 1, 2008 to August 31, 2008 (2)	895,000	$ 12.63	895,000	$ 11,100,000
September 1, 2008 to September 30, 2008 (2)	35,000	$ 12.51	35,000	$ 10,662,000
Total	930,000	$ 12.62	930,000	

In April 2008, our Board of Directors authorized a stock repurchase program of up to $50.0 million of shares of common stock. Purchases under the program were made, from time to time, in the open market. As of September 30, 2008, we repurchased 3.1 million shares of common stock at an average price of $12.64 per share for an aggregate purchase price of $39.4 million including commissions. The remaining authorized amount of stock repurchases under this program is $10.7 million, excluding commissions. All repurchased shares will be retired.

(1) All shares were repurchased pursuant to the publicly announced repurchase program described above.

(2) The stock repurchase program has no expiration date.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

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

None.

ITEM 5. OTHER INFORMATION

None.

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ITEM 6. EXHIBITS

(a) Exhibits:

Exhibit Number	Description	Filing	Date	Exhibit Number	Filed herewith
10.1	Severance Agreement between Afsaneh Azadeh and Align Technology, Inc. date August 1, 2008.				*
31.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				*
31.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				*
32.1	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				*

Management contract or compensatory plan or arrangement

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Date: November 5, 2008	ALIGN TECHNOLOGY, INC.	
	By:	/s/ THOMAS M. PRESCOTT Thomas M. Prescott *President and Chief Executive Officer*
	By:	/s/ KENNETH B. AROLA Kenneth B. Arola *Chief Financial Officer and Vice President, Finance*

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Management contract or compensatory plan or arrangement