ALIGN TECHNOLOGY INC
Form 10-Q
November 05, 2007

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, 2007

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, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act.

Large accelerated filer x Accelerated filer o Non-accelerated filer 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, 2007 was 68,527,058.

ALIGN TECHNOLOGY, INC.

INDEX

PART I	FINANCIAL INFORMATION	3
ITEM 1	FINANCIAL STATEMENTS (UNAUDITED):	3
	CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS	3
	CONDENSED CONSOLIDATED BALANCE SHEETS	4
	CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS	5
	NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS	6
ITEM 2.	MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS	16
ITEM 3.	QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK	25
ITEM 4.	CONTROLS AND PROCEDURES	25
PART II	OTHER INFORMATION	26
ITEM 1.	LEGAL PROCEEDINGS	26
ITEM 1A.	RISK FACTORS	30
ITEM 2.	UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS	40
ITEM 3.	DEFAULTS UPON SENIOR SECURITIES	40
ITEM 4.	SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS	40
ITEM 5.	OTHER INFORMATION	40
ITEM 6.	EXHIBITS	41
SIGNATURES		42

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

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,		Nine Months Ended September 30,	
	2007	2006	2007	2006
Revenues	$ 71,451	$ 49,034	$ 211,815	$ 151,163
Cost of revenues	18,132	16,789	55,908	47,578
Gross profit	53,319	32,245	155,907	103,585
Operating expenses:				
Sales and marketing	24,226	19,165	71,729	59,872
General and administrative	13,949	19,238	38,014	49,656
Research and development	6,749	4,807	19,117	13,526
Patients First Program			(1,796)	
Total operating expenses	44,924	43,210	127,064	123,054
Profit (loss) from operations	8,395	(10,965)	28,843	(19,469)
Interest and other income, net	1,108	854	2,243	2,393
Profit (loss) before provision for income taxes	9,503	(10,111)	31,086	(17,076)
Provision for income taxes	(43)	(209)	(1,030)	(618)
Net profit (loss)	$ 9,460	$ (10,320)	$ 30,056	$ (17,694)
Net profit (loss) per share:				
Basic	$ 0.14	$ (0.16)	$ 0.45	$ (0.28)
Diluted	$ 0.13	$ (0.16)	$ 0.42	$ (0.28)
Shares used in computing net profit (loss) per share:				
Basic	67,970	63,230	66,709	62,907
Diluted	72,230	63,230	71,058	62,907

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

ALIGN TECHNOLOGY, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands, except per share data)

(unaudited)

	September 30, 2007	December 31, 2006
ASSETS		
Current assets:		
Cash and cash equivalents	$ 87,969	$ 55,113
Restricted cash	20	93
Marketable securities	22,022	8,931
Accounts receivable, net of allowance for doubtful accounts of $612 and $844 at September 30, 2007 and December 31, 2006, respectively	46,002	33,635
Inventories, net	3,542	3,090
Prepaid expenses and other current assets	7,592	7,227
Total current assets	167,147	108,089
Property and equipment, net	26,014	26,904
Goodwill	478	478
Intangible assets, net	11,324	13,824
Other assets	1,931	2,263
Total assets	$ 206,894	$ 151,558
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Line of credit	$	$ 11,500
Accounts payable	6,344	5,034
Accrued liabilities	36,706	40,307
Deferred revenues	12,942	10,942
Total current liabilities	55,992	67,783
Other long-term liabilities	195	219
Total liabilities	56,187	68,002
Commitments and contingencies (Note 8)		
Stockholders equity:		
Preferred stock: $0.0001 par value; Authorized: 5,000 shares; Issued and outstanding: none at September 30, 2007 and December 31, 2006		
Common stock: $0.0001 par value; Authorized: 200,000 shares; Issued: 68,523 and 64,899 shares at September 30, 2007 and December 31, 2006, respectively; Outstanding: 68,481 and 64,859 shares at September 30, 2007 and December 31, 2006, respectively	7	6
Additional paid-in capital	445,478	408,921
Accumulated other comprehensive income	540	3
Accumulated deficit	(295,318)	(325,374)
Total stockholders equity	150,707	83,556
Total liabilities and stockholders equity	$ 206,894	$ 151,558

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

ALIGN TECHNOLOGY, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

(unaudited)

	Nine Months Ended September 30,	
	2007	**2006**
Cash Flows from Operating Activities:		
Net profit (loss)	$ 30,056	$ (17,694)
Adjustments to reconcile net profit (loss) to net cash provided by (used in) operating activities:		
Depreciation and amortization	7,838	6,777
Amortization of intangibles	2,500	286
Stock-based compensation expense	8,775	6,748
Loss (gain) on retirement and disposal of fixed assets	23	(135)
Income tax benefits from exercise of stock options	(339)	
Changes in assets and liabilities:		
Accounts receivable	(12,006)	(3,302)
Inventories	(468)	265
Prepaid expenses and other current assets	(304)	(317)
Accounts payable	432	5,281
Accrued and other long-term liabilities	(2,763)	2,426
Deferred revenues	2,039	(4,604)
Net cash provided by (used in) operating activities	35,783	(4,269)
Cash Flows from Investing Activities:		
Purchase of property and equipment	(6,305)	(7,477)
Proceeds from sale of property and equipment		367
Restricted cash	74	(11)
Purchases of marketable securities	(31,651)	(16,331)
Maturities of marketable securities	18,555	4,430
Other assets	363	171
Net cash used in investing activities	(18,964)	(18,851)
Cash Flows from Financing Activities:		
Proceeds from issuance of common stock	27,821	7,935
Proceeds from line of credit		15,000
Payments on line of credit	(11,500)	
Income tax benefit from exercise of stock options	339	
Employees taxes withheld and paid for restricted stock	(377)	
Net cash provided by financing activities	16,283	22,935
Effect of foreign exchange rate changes on cash and cash equivalents	(246)	
Net increase (decrease) in cash and cash equivalents	32,856	(185)
Cash and cash equivalents at beginning of period	55,113	74,219
Cash and cash equivalents at end of period	$ 87,969	$ 74,034

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

ALIGN TECHNOLOGY, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(unaudited)

Note 1. Summary of Significant Accounting Policies

Basis of presentation

The accompanying unaudited Condensed Consolidated Financial Statements have been prepared by Align Technology, Inc. (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, 2007, its results of operations for the three and nine months ended September 30, 2007 and 2006, and its cash flows for the nine months ended September 30, 2007 and 2006. The Consolidated Condensed Balance Sheet as of December 31, 2006 is derived from the December 31, 2006 audited financial statements. Certain prior period amounts have been reclassified to conform with 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, 2007 are not necessarily indicative of the results that may be expected for the year ending December 31, 2007, 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 fiscal year ended December 31, 2006.

The preparation of financial statements in accordance with U.S. generally accepted accounting principles 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.

Foreign Currency

The Company follows Statement of Financial Accounting Standards No. 52, Foreign Currency Translation (FAS 52) for both the translation and remeasurement of balance sheet and income statement items into U.S. dollars. The Company analyzes the functional currency for each of its international subsidiaries on an annual basis, or more often if necessary, to determine if a significant change in facts and circumstances indicate that the primary economic currency has changed. Prior to January 1, 2007, all of Align s subsidiaries use the U.S. dollar as its functional currency.

During the first quarter of 2007**,** the Company analyzed the various economic factors of its international subsidiaries in accordance with FAS 52 and determined that there had been a significant change in facts and circumstances to warrant a change in the functional currency for some of its European subsidiaries from U.S. dollars to the local currency. Effective January 1, 2007, the adjustment from translating certain European subsidiaries financial statements from the local currency in to U. S. dollars was recorded as a separate component of accumulated other

comprehensive income in the shareholders equity section of its Condensed Consolidated Balance Sheet. This foreign currency translation adjustment reflects the translation of its balance sheet at period end exchange rates, and its income statement at an average exchange rate in effect during each period. As of September 30, 2007, the Company had $542,000 in its accumulated other comprehensive income in stockholders equity related to the translation of its foreign subsidiaries financial statements. *See Note 12 Comprehensive Income (Loss) of the Notes to Condensed Consolidated Financial Statements for additional disclosures.*

Align s other international entities operate in a U.S. dollar functional environment, and therefore, the foreign currency assets and liabilities are remeasured into U.S. dollars at current exchange rates except for non monetary assets and liabilities which are remeasured at historical exchange rates. Revenues and expenses are generally remeasured at an average exchange rate in effect during each period. Gains or losses from foreign currency remeasurement are included in consolidated net profit (loss).

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. An uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained. Additionally, FIN 48 provides guidance on de-recognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. The adoption of FIN 48 had no impact on the Company s consolidated financial position, results of operations or cash flows for the three and nine month periods ended September 30, 2007.

Recent Accounting Pronouncements

In February 2007, the 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 and is required to be adopted by the Company in the first quarter of 2008. The Company is currently evaluating the potential impact, if any, of the adoption of FAS 159 on its consolidated financial position, results of operations and cash flows.

In September 2006, the FASB issued FAS Statement No. 157, *Fair Value Measurements* (FAS 157), which defines fair value, establishes a framework for measuring fair value under generally accepted accounting principles, and expands disclosures about fair value measurements. FAS 157 applies to other accounting pronouncements that require or permit fair value measurements. The new guidance is effective for financial statements issued for fiscal years beginning after November 15, 2007, and for interim periods within those fiscal years and is required to be adopted by the Company in the first quarter of 2008. The Company is currently evaluating the potential impact, if any, of the adoption of FAS 157 on its consolidated financial position, results of operations and cash flows.

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

Note 2. Patients First Program

On October 13, 2006, the Company entered into a formal agreement with OrthoClear, Inc., OrthoClear Holdings, Inc., and OrthoClear Pakistan Pvt. Ltd. (OrthoClear), together with certain individuals associated with OrthoClear (the OrthoClear Agreement) to end all pending litigation between the parties. As part of the OrthoClear Agreement, 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, the Company committed to make treatment available to these patients at no additional cost under the Patients First Program . Therefore, Align received no revenue for the

program, while incurring significant expense. In the fourth quarter of 2006, the Company recorded a $8.3 million charge for the anticipated costs of completing the Patients First Program in accordance with FASB Statement No. 5, Accounting for Contingencies (FAS 5). This estimated amount was based on the number of OrthoClear cases registered under the Patients First Program as of December 31, 2006. In accordance with the Patients First Program terms and conditions, those registered cases were required to submit treatment forms by the deadline of March 30, 2007. In the first quarter of 2007, the Company reduced its Patients First Program accrual by $1.8 million to reflect a reduction of the Company s initial estimate to the number of cases actually received by the case submission deadline. During the nine months ended September 30, 2007, the Company shipped virtually all Patients First Program cases. The

accrued Patients First Program balance as of September 30, 2007 was $1.4 million, and principally consists of estimated future warranty and case refinement costs.

Note 3. Marketable Securities

The Company s marketable securities as of September 30, 2007 and December 31, 2006 are as follows (in thousands):

September 30, 2007	Amortized Costs	Gross Unrealized Gains	Gross Unrealized Loss	Fair Value
U.S. Government notes and bonds	$ 5,107	$ 6	$	$ 5,113
Corporate bonds	5,969		(2)	5,967
Commercial paper and asset-backed securities	10,947		(5)	10,942
	$ 22,023	$ 6	$ (7)	$ 22,022

December 31, 2006	Amortized Costs	Gross Unrealized Gains	Gross Unrealized Loss	Fair Value
U.S. Government notes and bonds	$ 4,880	$ 2	$	$ 4,882
Corporate bonds	2,951			2,951
Commercial paper	1,098			1,098
Total	$ 8,929	$ 2	$	$ 8,931

For the three and nine months ended September 30, 2007, $52,000 in losses were realized on the sale of marketable securities. For the three and nine months ended September 30, 2006, no losses were realized on the sale of marketable securities.

Note 4. Balance Sheet Components

Inventories are comprised of (in thousands):

	September 30, 2007	December 31, 2006
Raw materials	$ 2,401	$ 2,021
Work in process	644	763
Finished goods	497	306
	$ 3,542	$ 3,090

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, 2007	December 31, 2006
Accrued payroll and benefits	$ 18,951	$ 17,768
Accrued sales rebate	3,899	3,895
Accrued Patients First Program costs	1,370	6,800
Accrued sales and marketing expense	2,817	2,235
Accrued warranty	2,382	2,094
Other	7,287	7,515
Total accrued liabilities	$ 36,706	$ 40,307

Note 5. Intangible Assets

The following is a summary of the Company s purchased intangible assets as of September 30, 2007 and December 31, 2006 (in thousands):

		September 30, 2007			December 31, 2006		
	Estimated Useful Life (in years)	Gross Carrying Value	Accumulated Amortization	Net Carrying Value	Gross Carrying Value	Accumulated Amortization	Net Carrying Value
Non-compete agreements	5	$ 14,000	$ 2,712	$ 11,288	$ 14,000	$ 612	$ 13,388
Consultant relationships	3	980	980		980	626	354
Patent	5	180	144	36	180	117	63
Other	3	55	55		55	36	19
Total		$ 15,215	$ 3,891	$ 11,324	$ 15,215	$ 1,391	$ 13,824

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

Consultant relationships and other intangible assets represent the fair value of intangible assets acquired as the result of the acquisition of General Orthodontics, LLC (GO) in 2005. Upon the integration of GO, Align included GO s consulting services in its clinical education and training programs under the name of Invisalign Consulting Services (ICS). During the second quarter of 2007, the Company announced the discontinuation of ICS, and the net carrying values of the consultant relationships and other intangible assets related to ICS were fully amortized.

The Company performs an impairment test whenever events or changes in circumstances indicate that the carrying value of such assets may not be recoverable. Examples of such events or circumstances include significant underperformance relative to historical or projected future operating results, significant changes in the manner of use of acquired assets or the strategy for its business, significant negative industry or economic trends, and/or a significant decline in the Company s stock price for a sustained period. Impairments are recognized based on the difference between the fair value of the asset and its carrying value, and fair value is generally measured based on discounted cash flow analyses. There were no impairments of intangible assets during the periods presented.

The total estimated annual future amortization expense for these intangible assets as of September 30, 2007 is as follows (in thousands):

Fiscal Year	
2007	$ 709
2008	2,827
2009	2,800
2010	2,800
2011 and thereafter	2,188
Total	$ 11,324

Note 6. 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. In May 2006, Danaher Corporation acquired Sybron Dental Specialties. 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. Oral argument took place on April 3, 2006. Following oral argument, 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. 6,544,611 to be invalid as obvious. The CAFC s decision reverses the California District Court summary judgment order of validity.

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

Although, the Company had previously entered into a settlement agreement (the Settlement Agreement) with Ormco and AOA pursuant to which Ormco and AOA were required to pay into escrow, pending the completion of the appeals process as discussed above, $884,000 to resolve the issues of past damages, willfulness and attorneys fees for the adjudged infringement of two of the Company s patents (the Align Patents) through the manufacture and sale of Ormco s and AOA s Red, White & Blue appliances. The Company s receipt of the payments out of escrow was contingent upon the Court, in a final, non-appealable judgment, finding that Ormco or AOA infringes at least one of the claims in the Align Patents. As discussed above, the CAFC has now issued a final, non-appealable judgment of invalidity with respect to each asserted claim of the Align Patents, and therefore, all funds in the escrow account will be returned to Ormco and AOA.

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 the Company is awaiting rulings from the Court. The initial case management conference and all discovery has been stayed pending the Court s decision on the motion for class certification.

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 7. Credit Facilities

On March 7, 2007, the Company renegotiated and amended its existing credit facility with Comerica Bank. The amendment, among other things, reduced financial covenants to require only a quick ratio covenant. Effective January 1, 2008, the amendment will also increase the available borrowings under the existing revolving line of credit from $20 million to $25 million. The amended credit facility matures on December 31, 2008 at which point all outstanding borrowings under this credit facility must be repaid. During the first half of 2007, the Company repaid $11.5 million of its outstanding borrowing on this credit facility. As of September 30, 2007, there were no outstanding borrowings against this credit facility. The Company is in compliance with the financial covenant of this credit facility.

The Company is in compliance with the financial covenant of this credit facility.

Note 8. Commitments and Contingencies

Operating leases

On August 3, 2007, the Company entered into an amendment to the lease agreement of its European Headquarters located in Amsterdam, The Netherlands. The original lease agreement was amended to expand its Amsterdam facility to approximately 16,000 square feet of office space and will expire June 2012, with an option to renew for an additional five year term.

As of September 30, 2007, minimum future lease payments for non-cancelable leases are as follow (in thousands):

Years Ending December 31,		
2007	$	881
2008		2,616
2009		1,584
2010		979
2011		519
Thereafter		319
Total	$	6,898

Product Warranty

The Company warrants its products against material defects until the Invisalign case is completed. The Company accrues for estimated warranty in costs of goods sold 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 repair costs. Actual warranty costs could differ from the estimated amounts. The Company regularly reviews the accrued balances and updates these balances based on historical warranty cost trends. Actual warranty costs incurred have not materially differed from those accrued.

The following table reflects the change in the Company s warranty accrual during the nine months ended September 30, 2007 and 2006, respectively (in thousands):

	Nine Months Ended September 30,			
		2007		**2006**
Balance at beginning of period	$	2,094	$	1,998
Charged to cost of sales		1,814		2,093
Actual warranty expenses		(1,526)		(2,054)
Balance at end of period	$	2,382	$	2,037

Note 9. Stock-based Compensation

Summary of stock-based compensation expense

The Company accounts for stock based compensation in accordance with Statement of Financial Accounting Standards No. 123 (Revised 2004), Share-based Payment (FAS 123R) which requires the measurement and recognition of compensation expense for all share-based payment awards made to our employees and directors and employee stock purchases related to the Employee Stock Purchase Plan (the Purchase Plan) based on estimated fair values over the requisite service period.

Stock-based compensation expense recognized in the Consolidated Statements of Operations for the three and nine months ended September 30, 2007 and 2006 is based on awards ultimately expected to vest and has been reduced for estimated forfeitures. FAS123R requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Forfeitures were estimated based on historical experience.

The following table summarizes stock-based compensation expense related to all of the Company s stock-based awards and employee stock purchases under FAS 123R for the three and nine months ended September 30, 2007 and 2006:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(In thousands)	**2007**	**2006**	**2007**	**2006**
Cost of revenues	$ 259	$ 186	$ 703	$ 515
Sales and marketing	1,301	714	3,056	2,125
General and administrative	1,403	1,015	3,934	3,132
Research and development	425	362	1,082	976
Total stock-based compensation	$ 3,388	$ 2,277	$ 8,775	$ 6,748

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,	
	2007	**2006**	**2007**	**2006**
Stock Options:				
Expected term (in years)	4.3	5.0	4.6	5.0
Expected volatility	56.8%	74.0%	70.7%	77.0%
Risk-free interest rate	4.60%	4.86%	4.68%	4.67%
Expected dividend				
Weighted average fair value at grant date	$ 12.41	$ 4.42	$ 10.97	$ 5.33
Employee Stock Purchase Plan:				
Expected term (in years)	1.23	1.25	1.24	1.26
Expected volatility	54.6%	45.5%	55.8%	48.2%
Risk-free interest rate	4.76%	5.08%	4.83%	4.97%
Expected dividend				
Weighted average fair value at grant date	$ 10.24	$ 2.49	$ 9.42	$ 2.69

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 option. Options are to be granted at an exercise price not less than the fair market value of the underlying shares at the date of grant.

Options

Stock option activity for the nine months ended September 30, 2007 under the stock incentive plans is set forth below:

	Total Shares			In-the-money Shares		
	Number of Shares (in thousands)	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Number of Shares (in thousands)	Weighted Average Exercise Price	Aggregate Intrinsic Value (in thousands)
Outstanding as of December 31, 2006	9,178	$ 8.86				
Granted	1,145	18.42				
Cancelled or expired	(382)	10.54				
Exercised	(2,913)	8.44				
Outstanding as of September 30, 2007	7,028	$ 10.50	7.26	6,996	$ 10.43	$ 104,260
Vested and expected to vest at September 30, 2007	6,730	$ 10.44	7.19	6,701	$ 10.37	$ 100,240
Exercisable at September 30, 2007	4,437	$ 9.32	6.36	4,437	$ 9.32	$ 71,045

The aggregate intrinsic value in the table above represents the total pretax intrinsic value (the difference between Align s closing stock price on the last trading day of third quarter of 2007 of $25.33 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, 2007. This amount changes based on the fair market value of Align s stock.

The total intrinsic value of stock options exercised for three and nine months ended September 30, 2007 was $17.6 million and $41.8 million, respectively. Total intrinsic value of stock options exercised for the three and nine months ended September 30, 2006, was $0.4 million and $1.2 million, respectively. As of September 30, 2007, Align expects to recognize $16.1 million of total unamortized compensation cost related to stock options over a weighted average period of 2.5 years. The Company has recognized tax benefits from exercised options for the nine months ended September 30, 2007 of approximately $0.3 million. 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 that generally vest over 4 years with 25% vesting on the one year anniversary of the date of grant and 6.25% vesting quarterly thereafter. The fair value of each award is based on the Company s closing stock price on the date of grant. During the nine months ended September 30, 2007, the total fair value of vested restricted stock unit awards was $1.3 million. A summary of the nonvested shares for the three and nine months ended September 30, 2007 is as follows:

	Number of Shares (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, 2006	419	$	8.71			
Granted	355		18.66			
Vested and released	(148)		9.24			
Forfeited	(40)		13.03			
Nonvested as of September 30, 2007	586	$	14.31	1.46	$	14,837

The aggregate intrinsic value in the table above represents the total pretax intrinsic value (calculated by using Align s closing stock price on the last trading day of third quarter of 2007 of $25.33 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, 2007. This amount changes based on the fair market value of Align s stock.

The total intrinsic value of restricted stock awards vested and released for three and nine months ended September 30, 2007 was $0.9 million and $3.0 million, respectively. There were no restricted stock awards vested during the three and nine month periods ended September 30, 2006. As of September 30, 2007, the total unamortized compensation cost related to restricted stock units was $6.9 million, which Align expects to recognize over a weighted average period of 2.9 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, 2007, Align expects to recognize $2.8 million of total unamortized compensation cost related to employee stock purchases over a weighted average period of 0.9 years.

Note 10. Accounting for Income Taxes

The Company has unrecognized tax benefits of approximately $3.3 million as of January 1, 2007. Included in the unrecognized tax benefits are $0.4 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 a decrease in retained earnings of $2.9 million, except that the decrease 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 three and nine month periods ended September 30, 2007.

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 2002.

Note 11. Net Profit (Loss) Per Share

Basic net profit (loss) per share is computed using the weighted average number of shares of common stock during the period. Diluted net profit (loss) 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 the Purchase Plan.

The following table sets forth the computation of basic and diluted net profit (loss) per share attributable to common

stock (in thousands, except per share amounts):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2007	2006	2007	2006

Net profit (loss)	$ 9,460	$ (10,320)	$ 30,056	$ (17,694)
Weighted-average common shares outstanding, basic	67,970	63,230	66,709	62,907
Effect of potential dilutive common shares	4,260		4,349	
Total shares, diluted	72,230	63,230	71,058	62,907
Basic net profit (loss) per share	$ 0.14	$ (0.16)	$ 0.45	$ (0.28)
Diluted net profit (loss) per share	$ 0.13	$ (0.16)	$ 0.42	$ (0.28)

For the three and nine months ended September 30, 2007, stock options and restricted stock units totaling 1.0 million and 0.9 million were excluded from diluted net loss per share because of their anti-dilutive effect. For the three and nine months ended September 30, 2006, stock options and restricted stock units totaling 9.6 million and 7.5 million, respectively, were excluded from diluted net loss per share because of their anti-dilutive effect.

Note 12. Comprehensive Income (Loss)

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2007	2006	2007	2006
Net profit (loss)	$ 9,460	$ (10,320)	$ 30,056	$ (17,694)
Other comprehensive income:				
Foreign currency translation adjustments	369		542	
Unrealized gain/(loss) on available-for-sale securities	5	11	(5)	(3)
Comprehensive income (loss)	$ 9,834	$ (10,309)	$ 30,593	$ (17,697)

Note 13. 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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2007	2006	2007	2006
Revenues:				
Domestic	$ 59,671	$ 41,058	$ 178,734	$ 127,545
Europe	11,196	6,472	31,002	19,628
Other International	584	1,504	2,079	3,990
Total revenues	$ 71,451	$ 49,034	$ 211,815	$ 151,163

	As of September 30, 2007	As of December 31, 2006
Long-lived assets:		
Domestic	$ 37,272	$ 40,745
Europe	815	745
Other International	1,660	1,979
Total long-lived assets	$ 39,747	$ 43,469

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

In addition to historical information, this Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. These statements include, among other things, statements concerning our expectations regarding the benefits of new products, product features, and software enhancements, including ClinAdvisor, and the expected impact these new products and product enhancements will have on doctor utilization and our market share, our expectations regarding product mix and Invisalign Express, our expectations regarding the existence and impact of seasonality, our expectation that our utilization rate will improve over time, our expectations regarding our average selling prices and gross margins in 2007, our expectations regarding the anticipated benefit of increased collaboration between orthodontists and general practitioner dentists (GPs) and the impact this collaboration will have on sales of Invisalign and on our revenue, our expectation that the percentage of revenue generated by general practitioner dentists will represent an increasingly larger percentage of our revenue, our intention to continue the integration of Invisalign into the curriculums of additional universities, our expectations regarding the benefit of increased consumer marketing programs, our expectations regarding case shipment volume in the fourth quarter and full year 2007, our expectation regarding the anticipated level of our operating expenses in 2007, as well as other statements regarding our future operations, financial condition and prospects and business strategies. These statements may contain words such as expects, anticipates, intends, plans, believes, estimates, or other words indicating future results. These forward-looking statements are subject to certain risks and uncertainties that could cause actual results to differ materially from those reflected in the forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in Item 2 Management s Discussion and Analysis of Financial Condition and Results of Operations , and in particular, the risks discussed below in Part II, Item 1A Risk Factors and in other documents we file with the Securities and Exchange Commission (SEC) . 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, founded in April 1997, designs, manufactures and markets Invisalign, 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. Invisalign is appropriate for treating adults and teens with mature dentition. We received the United States Food and Drug Administration (FDA) clearance to market Invisalign in 1998, and we began commercial operations and sales of full Invisalign treatment in July 1999.

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 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, minor crowding and spacing or as a pre-cursor to restorative or cosmetic treatment such as veneers.

A number of factors, the most important of which are set forth below, may affect our results during the remainder of 2007 and beyond.

Driving Utilization Growth. One of our key objectives is to continue to increase utilization, or the adoption of and frequency of use, of the Invisalign system (which includes full Invisalign treatment and Invisalign Express) by new and existing customers. We believe that a key lever for increasing utilization in the future is product performance. As a result, we are committed to investing in delivering new products, enhancing the user experience and introducing new product features to our existing products. Specifically, much of our research and development effort is aimed at developing and deploying GP-specific and Ortho-specific product platforms

described more fully under *Continued Product Leadership* below. Although we expect that over the long term our utilization rates will improve, we expect that period over period comparisons of our utilization rates will fluctuate. Factors that may cause these fluctuations include an increase in the number of newly certified/trained doctors in one period compared to another period and the impact of seasonality, specifically, during summer vacation/holiday periods in the United States and Europe. For the quarters ended September 30, 2007 and September 30, 2006 our utilization rates are as follows:

	Three Months Ended September 30,	
Doctor Utilization Rates*	**2007**	**2006**
U.S. Orthodontists	4.92	4.71
U.S. GPs	2.59	2.49
International	3.13	2.72
Total Utilization Rate	3.20	3.04

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

Continued Product Leadership. As stated above, in an effort to improve the user experience for our customers and increase utilization over time, we are currently in the process of developing and deploying GP-specific and Ortho-specific product platforms to improve the overall user experience for our doctors. In the second half of 2006, we announced a phased rollout of ClinAdvisor, a new suite of software tools designed to make Invisalign case selection and submission processes more efficient for doctors. ClinAdvisor is designed to help newly certified and less experienced doctors learn how to assess and select appropriate cases given their experience and skill level. Based on results obtained during the integration of this tool into our Certification Level 1 training program and on additional customer feedback, we are working to enhance and improve the features of this product. We intend to fully integrate an upgraded version of ClinAdvisor into our Certification training program during 2008. We also expect to extend the product features and functionality of the GP platform and release it to an increasing number of practices. In addition, we plan to introduce further software enhancements directed at our orthodontists that will provide these doctors with a robust set of tools for greater predictability, wider applicability and more control. We are also continuing to focus our research and development efforts on a next generation aligner material as well as a compliance indicator which will help doctors and patients understand if the patients have worn their aligners for enough time to effectively move their teeth. We expect these efforts to extend at least through 2008. By investing in developing these new products and continually enhancing our existing products, we expect to increase adoption and utilization by our doctors.

- *Expansion of our Customer Base*. We generate the vast majority of our revenues from the sales of the Invisalign system to orthodontists and GPs in the United States and Canada, our domestic market. For the nine months ended September 30, 2007 and 2006, our Invisalign revenues as a percentage of total net revenue are as follows:

	Nine Months Ended September 30,	
Revenues By Channel	**2007**	**2006**
Domestic Invisalign:		
Ortho revenues	32.5%	33.8%
GP revenues	47.7%	45.9%
Total domestic Invisalign revenues	80.2%	79.7%
International Invisalign revenues	15.3%	14.9%
Other revenues	4.5%	5.4%

Total revenues	100.0%	100.0%

As specialists, orthodontists are a critical part of our business, and we expect that orthodontists will continue to treat the majority of complex cases and continue to drive research for expanding Invisalign applications. However, there exists a significantly greater number of GPs in North America than orthodontists. As the primary provider of

dental care, GPs have access to a greater number of patients than orthodontists, and possess a unique opportunity to educate these patients on the benefits of oral care and introduce them to Invisalign. GPs also have the ability to refer appropriate cases to orthodontists and may choose to treat less complex cases themselves. Largely due to the fact that there are significantly more GPs than orthodontists, we expect that an increasingly larger percentage of our revenues will be generated by GPs. By increasing adoption and utilization rates among our existing GP customers, the overall market for Invisalign will increase, as patients who would not have otherwise sought orthodontic treatment are introduced to Invisalign by their GPs.

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. We have also integrated the Invisalign technique into the curriculums of 38 university programs, including Harvard University, Columbia University, Temple University and the University of Texas at San Antonio. We expect additional dental schools to integrate the Invisalign technique into their curriculums in the future.

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. In the third quarter of 2007, this seasonal trend caused and will likely continue to cause, fluctuations in our quarterly results, including fluctuations in sequential revenue growth rates. Late in the third quarter of 2007 we experienced lower case receipts than expected. As a result of these lower case receipts, we expect case shipments in the fourth quarter to be flat to slightly lower on a sequential basis.

Product Mix. During the first nine months of 2007, we experienced a decline in the number of Invisalign Express cases compared to the same period of 2006. We expect that for the remainder of 2007 Invisalign Express cases as a percentage of our revenues will remain consistent with the first nine months of 2007. We believe that this shift in product mix began in the fourth quarter of 2006 after we removed the cancellation fees on full Invisalign cases prior to ClinCheck approval and clarified clinical protocols surrounding what is an appropriate Invisalign Express case. For the nine months ended September 30, 2007 and 2006, our Invisalign revenues as a percentage of total net revenue are as follows:

	Nine Months Ended September 30,	
Revenues By Product	**2007**	**2006**
Domestic Invisalign:		
Full revenues	72.4%	65.1%
Express revenues	7.8%	14.6%
Total domestic Invisalign revenues	80.2%	79.7%
International Invisalign revenues	15.3%	14.9%
Other revenues	4.5%	5.4%
Total revenues	100.0%	100.0%

Increase Demand at the Consumer Level. In 2007, we increased our overall marketing spend in both the United States and Europe with a focus on programs designed to raise the profile of Invisalign and drive more consumers to our most experienced doctors. We anticipate that this increased consumer awareness of Invisalign will increase the market for our product.

Growth of International Markets. We will focus our efforts towards increasing adoption of Invisalign by dental professionals in our key international markets, Europe and Japan. We continually evaluate cost effective ways to support our customers in smaller and less strategic markets. During the first nine months of 2007, we transitioned the sales of our product in part of the Asia-Pacific and Latin America 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. In the first nine months of 2007, our international channel represented approximately 15% of our total net revenue primarily as a result of growth in Europe. We expect our

international revenue to continue to increase in absolute dollars, and we expect international revenue as a percentage of total net revenue will be comparable in the foreseeable future.

- *Reliance on International Manufacturing Operations.* Our manufacturing efficiency has been and will 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, which are transmitted electronically back to the U.S. 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, including our relationship with IMS. In addition, we currently are and will continue to be dependant on IMS s and our ability to hire and retain employees generally, as well as hire and retain employees with the necessary skills to perform the more technical aspects of our operations. If our management and/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 in the manufacturing backlog, if for these or other reasons we do not have sufficient number of trained dental technicians in Costa Rica to create the ClinCheck treatment forms 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*.

Results of Operation

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, 2007 and 2006 are as follows (in millions):

	Three Months Ended September 30,				Nine Months Ended September 30,			
Net Revenues	**2007**	**2006**	**Net Change**	**% Change**	**2007**	**2006**	**Net Change**	**% Change**
Domestic Invisalign:								
Ortho full	$ 20.1	$ 13.6	$ 6.5	47.6%	$ 62.0	$ 43.0	$ 19.0	44.3%
Ortho Express	2.4	2.6	(0.2)	(9.6)%	6.9	8.2	(1.3)	(15.9)%
Total Ortho revenues	22.5	16.2	6.3	38.5%	68.9	51.2	17.7	34.6%
GP full	31.5	18.4	13.1	71.5%	91.4	55.5	35.9	64.6%
GP Express	3.3	4.3	(1.0)	(23.3)%	9.6	13.9	(4.3)	(30.5)%
Total GP revenues	34.8	22.7	12.1	53.4%	101.0	69.4	31.6	45.6%
International Invisalign	11.6	7.3	4.3	58.6%	32.3	22.5	9.8	43.5%
Total Invisalign revenues	68.9	46.2	22.7	49.0%	202.2	143.1	59.1	41.4%

Other revenues	2.6	2.8	(0.2)	(7.5)%	9.6	8.1	1.5	18.2%
Total revenues	$ 71.5	$ 49.0	$ 22.5	45.7%	$ 211.8	$ 151.2	$ 60.6	40.1%

Case volume data which represents Invisalign case shipment by channel, for the three and nine months ended September 30, 2007 and 2006 are as follows (in thousands):

	Three Months Ended September 30,				Nine Months Ended September 30,			
Case Volume	**2007**	**2006**	**Net Change**	**% Change**	**2007**	**2006**	**Net Change**	**% Change**
Domestic Invisalign:								
Ortho full	15.2	9.6	5.6	58.7%	46.2	30.2	16.0	53.1%
Ortho Express	3.1	3.4	(0.3)	(8.1)%	9.3	10.9	(1.6)	(14.9)%
Total Ortho volume	18.3	13.0	5.3	41.1%	55.5	41.1	14.4	35.0%
GP full	21.9	12.5	9.4	74.8%	63.2	37.8	25.4	67.1%
GP Express	4.6	5.8	(1.2)	(20.4)%	13.4	18.4	(5.0)	(27.5)%
Total GP volume	26.5	18.3	8.2	44.7%	76.6	56.2	20.4	36.1%
International Invisalign	7.3	4.4	2.9	63.9%	20.0	13.7	6.3	46.3%
Total Invisalign volume	52.1	35.7	16.4	45.8%	152.1	111.0	41.1	37.0%

Our total net revenues increased for the three and nine months ended September 30, 2007 compared to the same periods in 2006 as result of an overall increase in case volume and a favorable product mix shift towards full Invisalign. This product mix shift towards full Invisalign in our domestic market began in the fourth quarter of 2006 after we removed the cancellation fees on full Invisalign cases prior to ClinCheck approval and clarified clinical protocols surrounding what is an appropriate Invisalign Express case. The revenue increases in domestic orthodontic and international channels during the three and nine month periods ended September 30, 2007 were partially offset by a slight decrease in average selling price related to the higher participation in our volume based discount programs.

Other revenues, consisting of training and sales of ancillary products increased during the nine months ended September 30, 2007 compared to the nine months ended September 30, 2006 as a result of an increase in training revenues reflecting an increase in number of doctors trained partially offset a decrease in ancillary revenues.

For fiscal year 2007, we expect our total net revenues will increase compared to 2006 primarily due to case volume increases in our domestic orthodontic and GP channels, as well as in our international markets. We expect our average selling price to be slightly higher in 2007 compared to 2006.

Cost of revenues:

	Three Months Ended September 30,			Nine Months Ended September 30,		
(In millions)	**2007**	**2006**	**Change**	**2007**	**2006**	**Change**
Cost of revenues	$ 18.1	$ 16.8	$ 1.3	$ 55.9	$ 47.6	$ 8.3
% of Revenues	25.4%	34.2%		26.4%	31.5%	
Gross profit	$ 53.3	$ 32.2	$ 20.1	$ 155.9	$ 103.6	$ 52.3
% of Revenues	74.6%	65.8%		73.6%	68.5%	

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

Gross margin improved during the three and nine months ended September 30, 2007 compared to the same periods in 2006 primarily a result of increased case volumes combined with improved operating efficiencies.

For the fiscal year 2007, we anticipate that our gross margin will be higher compared to 2006 primarily due to the impacts of the expected increase in case volume and operating efficiencies, including a full year effect of the relocation of our SLA mold operations to Juarez, Mexico completed in the first quarter of 2006.

Sales and marketing:

(In millions)	Three Months Ended September 30, 2007	2006	Change	Nine Months Ended September 30, 2007	2006	Change
Sales and marketing	$ 24.2	$ 19.2	$ 5.0	$ 71.7	$ 59.9	$ 11.8
% of Revenues	33.9%	39.1%		33.9%	39.6%	

Sales and marketing expense includes sales force compensation (combined with travel related costs and expenses for professional marketing programs), conducting workshops and market surveys, advertising, dental professional trade show attendance and stock-based compensation expense.

Our sales and marketing expense increased during the three and nine months ended September 30, 2007 compared to the same periods in 2006 as a result of increased media advertising and product research related expenses of $4.2 million and $6.8 million, respectively. Payroll related expenses increased $0.3 million and $2.1 million for the three and nine months ended September 30, 2007, respectively, as a result of higher commissions and incentive compensation, driven by increased sales volume, as well as additional headcount. Additionally, stock-based compensation expense increased $0.6 million and $0.9 million, respectively, in the three and nine months ended September 30, 2007 compared to the same periods in 2006.

For fiscal year 2007, we expect sales and marketing expense to be higher than 2006, as we expand our sales force, increase our investment in media programs and provide clinical education.

General and administrative:

(In millions)	Three Months Ended September 30, 2007	2006	Change	Nine Months Ended September 30, 2007	2006	Change
General and administrative	$ 13.9	$ 19.2	$ (5.3)	$ 38.0	$ 49.7	$ (11.7)
% of Revenues	19.5%	39.2%		17.9%	32.8%	

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

General and administrative expense decreased during the three and nine months ended September 30, 2007 compared to same periods in 2006 reflecting a $8.2 million and a $19.1 million decline, respectively, in external legal fees following the settlement of the OrthoClear litigation. Our legal expense for the nine months ended September 30, 2007 included a $1.6 million credit for an insurance reimbursement of legal costs also associated with the OrthoClear litigation we received in the second quarter of 2007. These decreases were partially offset by higher payroll related expenses of $1.9 million and $4.6 million, respectively, for the three and nine months ended September 30, 2007 as a result of increased

headcount and incentive compensation. Additionally, amortization expense increased $0.8 million and $2.5 million, respectively, in the three and nine months of 2007 compared to the same periods in 2006 related to the amortization of the non-compete agreements we received in connection with the OrthoClear settlement during the fourth quarter of 2006.

For fiscal year 2007, we expect that general and administrative expense will decrease from 2006 primarily as a result of the significant reduction in legal and other expenses following the litigation settlement with OrthoClear in the fourth quarter of 2006.

Research and development:

	Three Months Ended September 30,			Nine Months Ended September 30,		
(In millions)	**2007**	**2006**	**Change**	**2007**	**2006**	**Change**
Research and development	$ 6.7	$ 4.8	$ 1.9	$ 19.1	$ 13.5	$ 5.6
% of Revenues	9.4%	9.8%		9.0%	8.9%	

Research and development expense includes the personnel costs associated with software engineering, the cost of designing, developing and testing our products, conducting clinical and post-marketing trials and stock-based compensation expense. We expense our research and development costs as they are incurred.

Research and development expense increased during the three and nine months ended September 30, 2007 compared to the same periods of 2006 predominantly from increases in payroll related expenses of $0.8 million and $3.0 million, respectively, resulting from additional headcount and higher incentive compensation. Additionally, outside service costs increased by $0.5 million and $1.4 million, respectively, for the three and nine months ended September 30, 2007.

For fiscal year 2007, we expect research and development spending to increase from fiscal 2006 as we continue to invest in research and development efforts to bring new products to market, conduct clinical research and focus on product improvement initiatives.

Patients First Program:

	Three Months Ended September 30,			Nine Months Ended September 30,		
(In millions)	**2007**	**2006**	**Change**	**2007**	**2006**	**Change**
Patients First Program	$	$	$	$ (1,796)	$	$ (1,796)
% of Revenues	%	%		%	%	

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 . We received no revenue for the program, and incurred significant expense to complete these cases. In the fourth quarter of 2006, we recorded an $8.3 million charge for the anticipated costs of completing this program in accordance with FASB Statement No. 5, Accounting for Contingencies (FAS 5). This estimated amount was based on the number of OrthoClear cases registered under the Patients First Program as of December 31, 2006. In accordance with the Patients First Program terms and conditions, those registered cases were required to submit treatment forms by the deadline of March 30, 2007. 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. During the nine months ended September 30, 2007, the Company shipped virtually all Patients First Program cases.

Interest and other, net:

	Three Months Ended September 30,			Nine Months Ended September 30,		
(In millions)	**2007**	**2006**	**Change**	**2007**	**2006**	**Change**
Interest income	$ 1.2	$ 0.8	$ 0.4	$ 2.8	$ 2.3	$ 0.5
Interest expense				(0.3)		(0.3)
Other income (expense), net	$ (0.1)	0.1	$ (0.2)	(0.3)	0.1	(0.4)
Total interest and other, net	$ 1.1	$ 0.9	$ 0.2	$ 2.2	$ 2.4	$ (0.2)

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

Interest income for the three and nine months ended September 30, 2007 increased compared to the three and nine months ended September 30, 2006 due to higher average cash, cash equivalents and marketable securities balances in 2007. The increase in interest expense in the nine months ended September 30, 2007 was attributable to interest expense related to the outstanding balance on our line of credit during the first half of 2007, whereas there were no outstanding borrowings against our line of credit during the first nine months of 2006.

Other income (expense) decreased in the three and nine months ended September 30, 2007 compared to the same periods in 2006 reflecting the decrease in foreign currency translation gains. In January 2007, we began to record the

adjustments from translating certain European subsidiaries financial statements from the local currency into U. S. dollars as a separate component of shareholders equity on our Condensed Consolidated Balance Sheet.

Income tax provision:

(In millions)	Three Months Ended September 30, 2007	2006	Change	Nine Months Ended September 30, 2007	2006	Change
Provision for income taxes	$	$ 0.2	$ (0.2)	$ 1.0	$ 0.6	$ 0.4

We recorded an income tax provision of $43,000 and $1.0 million for the three and nine months ended September 30, 2007, respectively, representing effective tax rates of 0.5% and 3.3%, respectively. Our effective tax rate for the remainder of 2007 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 recorded an income tax provision of $0.2 million and $0.6 million for the three and nine months ended September 30, 2006, respectively, representing effective tax rates of -2.1% and -3.6%, respectively. The provision for income taxes for the three and nine months ended September 30, 2006 consisted primarily of statutory taxes incurred in our foreign jurisdictions.

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 the Company's 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 in the future we determine that we would be able to realize our deferred tax assets in excess of the net amount recorded, we would record an adjustment to the deferred tax asset and valuation allowance, increasing income in the period such determination was made.

Liquidity and Capital Resources

We fund our operations from cash generated from sales of our product, the proceeds of the sale of our common stock and an occasional borrowing under available credit facilities. As of September 30, 2007 and December 31, 2006 we had the following cash, cash equivalents and marketable securities (in thousands):

	September 30, 2007	December 31, 2006
Cash and cash equivalents	$ 87,969	$ 55,113
Restricted cash	20	93
Marketable securities, short-term	22,022	8,931
Total cash, cash equivalents and marketable securities	$ 110,011	$ 64,137

Net cash provided by operating activities for the nine months ended September 30, 2007 resulted primarily from our operating income of $30.0 million adjusted for non-cash items such as depreciation, amortization 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. Net cash used in operating activities for the nine months ended September 30, 2006 resulted primarily from an operating loss of $17.7 million adjusted for non-cash items, such as depreciation, amortization and stock-based compensation totaling $13.7 million. Additionally, $3.3 million increase in accounts receivable and a $4.6 million reduction in deferred revenue also contributed to the decrease of cash flow. These decreases were partially offset by a $5.3 million increase in accounts payable and a $2.4 million increase in accrued liabilities.

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. Net cash used in investing activities for the nine months ended September 30, 2006, principally consisted of $11.9 million of net purchases of marketable securities and $7.5 million used for the purchase of capital assets.

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. For the nine months ended September 30, 2006, net cash provided by financing activities consisted of $15.0 million in proceeds from the line of credit

and $7.9 million in proceeds from the issuance of common stock, primarily from exercises of employee stock options.

Net proceeds from the issuance of common stock related to the exercise of employee stock options have historically been a significant component of our liquidity. However, in 2006, we began granting RSUs which, unlike stock options, do not generate cash from exercise. 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 payroll withholding taxes which taxes will be paid by us on their behalf. During the first nine months of 2007, we paid $377,000 for executive officers payroll taxes as a result of RSUs vested during the period.

On March 7, 2007, we renegotiated and amended our existing credit facility with Comerica Bank. The amendment, among other things, reduced financial covenants to require only a quick ratio covenant. Effective January 1, 2008, the amendment will automatically increase the available borrowings under the existing revolving line of credit from $20 million to $25 million. The amended credit facility matures on December 31, 2008 at which point all outstanding borrowings under this credit facility must be repaid. During the first nine months of 2007, we repaid $11.5 million of our outstanding borrowing on this credit facility. As of September 30, 2007, we have no outstanding borrowings under this credit facility. We are in compliance with the financial covenant of this credit facility.

Contractual Obligations

Our contractual obligations as of September 30, 2007 were as follows (in thousands):

			For the year ending December 31,				
	Total	**2007**	**2008**	**2009**	**2010**	**2011**	**Thereafter**
Operating lease obligations	$ 6,898	$ 881	$ 2,616	$ 1,584	$ 979	$ 519	$ 319
Computer support services	1,877	194	760	740	183		
Total	$ 8,775	$ 1,075	$ 3,376	$ 2,324	$ 1,162	$ 519	$ 319

The principal changes to our contractual obligations from those disclosed in our Annual Report on Form 10-K for fiscal year ended December 31, 2006 are as follows:

During the first half of 2007, we repaid $11.5 million of our outstanding borrowing on this credit facility. *See Note 7 Credit Facilities of the Notes to Condensed Consolidated Financial Statements for additional information.*

Also during the first half of 2007, we engaged a new vendor to provide computer support services.

In August 2007, we amended the lease agreement for our European Headquarters located in Amsterdam, the Netherlands. *See Note 8 Commitment and Contingencies of the Notes to Condensed Consolidated Financial Statements for additional information*

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, 2006.

Recognition of revenues;

- Stock-based compensation;
- Long-lived assets, including finite lived purchased intangible assets;
- Patients First Program;
- Warranty expense; and
- Deferred tax valuation allowance.

There have been no significant changes in our critical accounting policies during the three and nine months ended September 30, 2007 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, 2006.

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

Quantitative Disclosures

For quantitative and qualitative disclosures about market risk affecting us, see Item 7A, Quantitative and Qualitative Disclosures About Market Risk, of our Annual Report on Form 10-K for the fiscal year ended December 31, 2006, which is incorporated herein by reference. Our exposure to market risk has not changed materially since December 31, 2006.

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 Form10-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, 2007 to provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our Chief Executive Officer and our Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure, and that such information is recorded, processed, summarized and reported within the time periods specified in the SEC rules and forms.

Changes in internal control over financial reporting.

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

PART II OTHER INFORMATION.

ITEM 1. LEGAL PROCEEDINGS

Ormco

On January 6, 2003, Ormco Corporation (Ormco) 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. In May 2006, Danaher Corporation acquired Sybron Dental Specialties. 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 (5,477,432, 5,683,243, 6,244,861 and 6,616,644). 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 (5,477,432, 5,683,243, 6,244,861 and 6,616,644). 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. The motions were heard by the Court on February 7, 2005. 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

noticed an appeal to the Federal Circuit from the Permanent Injunction.

There have been two appeals. After the Permanent Injunction was entered, Ormco and AOA appealed that injunction and the orders of the District Court on summary judgment on which the injunction was based. Oral argument took place on April 3, 2006. Following oral argument, 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. 6,544,611 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 seventy-one 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 order in which the appliances are to be worn and use of the appliances in intervals of 2-20 days.

The 6,544,611 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 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 has denied Ormco s petition for rehearing with respect to the porting of the Federal Circuit s opinion that affirmed the District Court s ruling of non-infringement and non-enablement of the 86 claims.

On our cross-appeal, the CAFC affirmed the District Court s finding that six claims in our 6,398,548 patent (claims 1-3 and 11-13) are invalid. These six 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. The majority of the claims in the 6,398,548 patent, including claims that address methods of fabricating aligners, digital data sets or computer-generated models to fabricate appliances, are unaffected by the second appeal and the CAFC s ruling.

Although we previously entered into a settlement agreement (the Settlement Agreement) with Ormco and AOA pursuant to which Ormco and AOA were required to pay into escrow, pending the completion of the appeals process as discussed above, $884,000 to resolve the issues of past damages, willfulness and attorneys fees for the adjudged infringement of two of our patents (the Align Patents) through the manufacture and sale of Ormco s and AOA s Red, White & Blue appliances. Our receipt of the payments out of escrow was contingent upon the Court, in a final, non-appealable judgment, finding that Ormco or AOA infringes at least one of the claims in the Align Patents. As discussed above, the CAFC has now issued a final, non-appealable judgment of invalidity with respect to each asserted claim of the Align Patents, and therefore all funds in the escrow account will be returned to Ormco and AOA.

Other matters

USPTO

Ex Parte Requests:

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 as follows:

U.S. Patent No.	Request for Reexamination Granted?	Initial Office Actions Received?	Status
5,975,893	Yes	Yes	On January 26, 2006, a first office action was issued rejecting all claims of U.S. Patent No. 5,975,893 (the 893 patent). We responded to this initial office action. A Final Office Action was issued by the USPTO on June 23, 2006 rejecting the pending claims of Align s response. On August 23, 2006, we filed an amendment and on February 14, 2007 we filed a supplementary amendment each in response to this Final Office Action, which included claims discussed in an interview with the Examiners. On June 27, 2007, we field a supplemental amendment per examiner s recommendations which corrected certain informalities noted by the examiners in a May 22, 2007 interview. We have received a Notice of Intent to Issue a Reexam Certificate dated September 18, 2007.
6,398,548	Yes	Yes	We filed a preliminary amendment and a supplementary preliminary amendment on July 16, 2006 and February 14, 2007, respectively. On June 28, 2007, we filed a supplemental amendment per examiner s recommendations based on a May 22, 2007 interview. A Reexam Certificate was issued on October 31, 2007.
6,309,215	Yes	Yes	On July 27, 2006, after submitting amendments, affidavits, declarations or other documents as evidence of patentability, we received an action entitled Notice of Intent to Issue Ex Parte Reexamination Certificate with respect to U.S. Patent No. 6,309,215 (the 215 patent). With this Notice, the USPTO has closed prosecution on the merits in reexamination and affirmed the patentability of all of our claims pending in reexamination in the 215 patent. While the 215 patent entered the reexamination proceedings with 16 claims, 26 additional claims were added in the reexamination by us and the 215 patent leaves the proceedings as a valid and enforceable patent with 42 claims. An Exparte Reexamination Certificate was issued on March 20, 2007.
6,705,863	Yes	Yes	We filed a preliminary amendment and a supplementary preliminary amendment on May 26, 2006 and February 14, 2007, respectively. On June 28, 2007, we filed a supplemental amendment per examiner s recommendations based on a May 22, 2007 interview. We have received a Notice of Intent to Issue a Reexam Certificate dated September 26, 2007.
6,217,325	Yes	Yes	On July 25, 2006, we received an Office Action in U.S. Patent No. 6,217,325 (the 325 patent) confirming the patentability of 32 claims. While the 325 patent entered the reexamination proceedings with 26 claims, 15 additional claims were added by us in the reexamination. On September 25, 2006, we filed an amendment in response to the final Office Action with respect to the claims that were not allowed. On June 27, 2007, we filed a supplemental amendment per examiner s recommendations based on a May 22, 2007 interview. We have received a Notice of Intent to Issue Reexam Certificate dated October 1, 2007.
6,722,880	No	N/A	On December 23, 2005, in a non-appealable, final Order, the USPTO denied the request for re-examination with respect to all twenty-one claims of U.S. Patent No. 6,722,880 (the 880 patent). Accordingly, the validity of all twenty-one claims of the 880 patent stand reaffirmed by

			the USPTO. On January 23, 2006, a Petition Seeking Review of Denial of Request for Re-examination of the 880 patent was filed by the same San Francisco, California law firm. The Petition was denied and the denial of the request for Reexamination is final.
6,318,994	Yes	Yes	The USPTO has granted the requests for reexamination of the U.S. Patent No. 6,318,994. On February 15, 2007 we filed a preliminary amendment. We had an interview on this case on May 22, 2007. We are awaiting an initial Office Action. A Reexam Certificate was issued on October 17, 2007.

Inter Parte Requests made by OrthoClear

As part of the OrthoClear Agreement, OrthoClear agreed to take no further action with respect to the Inter Parte Requests.

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.
6,685,469	Yes	Yes	The USPTO has granted the requests for reexamination of U.S. Patent of U.S. Patent No. 6,685,469. We received on May 14, 2007 an initial Office Action. We filed a response to this office action on July 16, 2007. We have received an Action Closing Prosecution dated September 24, 2007.

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 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 Align). 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. The initial case management conference and all discovery has been stayed pending the Court s decision on the motion for class certification.

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.

ITEM 1A. RISK FACTORS

If we fail to grow our revenue while controlling our expenses, the market price of our common stock may decline.

You should consider our business and prospects in light of the risks, expenses and difficulties encountered by a company in an early stage of operations. Consistent with a company in an early stage of operations, we continue to incur significant operating expenses to:

develop new software and increase the automation of our manufacturing processes;

execute our consumer marketing campaign and dental professional marketing efforts;

increase the capacity of our business enterprise systems and manufacturing operations;

execute clinical research and education plans;

develop technological improvements to our products and new product development;

continue our international sales and marketing efforts;

protect our intellectual property, including trade secrets; and

undertake quality assurance and improvement initiatives.

For instance, in an effort to raise the profile of Invisalign and match prospective patients with our most experienced dental professionals, we have in the past utilized consumer marketing campaigns involving television, radio and print media. Marketing programs of this nature are expensive and may have limited success, if any, and may not result in revenue generation commensurate with their costs.

While we achieved profitability in the first nine months of fiscal 2007, we experienced a net loss in each quarter of 2006. If we are to continue to achieve 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 the first nine months of 2007, 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 our commercial sales. These fluctuations could cause our stock price to decline. Some of the factors that could cause our operating results to fluctuate include:

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 due to the introduction of Invisalign Express, a lower-cost alternative for treating less complex cases;

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

success of marketing programs from quarter to quarter;

unanticipated delays in production caused by insufficient capacity;

any disruptions in the manufacturing process, including as a result of unexpected turnover in the labor force or the introduction of new production processes or as a result of 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 ongoing litigation;

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

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. For instance, although we entered into a definitive agreement in October 2006 with OrthoClear whereby, among other things, OrthoClear agreed to discontinue all design, manufacture, marketing and sales of removable dental aligners worldwide, we experienced increased pricing pressure in 2005 and 2006 as a result of the commercial launch of OrthoClear s product. Partly in response to this increased competition, in the fourth quarter of 2005, we changed our pricing structure and reduced our list price for full Invisalign treatment to $1,495 and expanded our volume based discount program to all doctors. These programs were in effect in 2006, and had an adverse impact on our revenues, gross margins and net profit (loss). 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, we may be unable to adjust spending quickly enough to offset any shortfall in revenues. Therefore, our operating results for a given period may be adversely affected. 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 Invisalign for the vast majority of our revenues, and any decline in sales of Invisalign or average selling prices would adversely affect revenue, gross margin and net profits.

We expect that revenues from the sale of Invisalign 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 and GPs do not collaborate as we expect, 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.

Dental professionals 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. In addition, because Invisalign has only been in clinical testing since July 1997 and commercially available only since July 1999, orthodontists and GPs may be reluctant to adopt it until more historical clinical results are available. Also, 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.

Our success depends upon the acceptance of Invisalign by a substantially larger number of dental professionals as well as potential consumers to whom we are now actively marketing. Invisalign represents a significant change from traditional orthodontic treatment, and consumers may be reluctant to accept it or may not find it preferable to conventional treatment. In addition, consumers may not comply with recommended treatment guidelines for Invisalign, which could compromise the effectiveness of their 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, reliability, improved treatment, aesthetics, greater comfort and hygiene compared to conventional 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. Adoption by consumers may also be affected by general macroeconomic conditions in North America and internationally, which fluctuate and could be affected by unstable global economic, political or other conditions.

The orthodontists and GPs may choose not to collaborate and referrals between orthodontists and GPs may not increase at the rate that we anticipate or at all.

Our success depends in part upon improving the collaboration and referral relationships between orthodontists and GP dentists. As specialists, orthodontists are a critical part of our business, and we expect that orthodontists will continue to treat the majority of complex cases and continue to drive research for expanding Invisalign applications. We expect, however, that the percentage of revenues generated by GPs will increase, largely due to the fact that there are significantly more GPs than orthodontists. As the primary provider of dental care, GPs have access to a greater number of patients than orthodontists, possess a unique opportunity to educate these patients and introduce them to Invisalign, have the ability to refer appropriate cases to orthodontists and, in certain instances, may choose to treat less complex cases themselves. If this collaboration and increase in referrals does not occur or occurs more slowly than we anticipate, our operating results could be harmed.

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. As a result of these programs, the blended average selling price for our products declined in 2006 compared to 2005. Additionally in Europe, we introduced new pricing initiatives in the first quarter of 2006 which resulted in a lower average selling price in 2006. Although our blended average selling prices increased in 2007 compared to 2006 primarily as a result of a product mix shift towards full Invisalign and an increasing number of lower volume GP dentists, who did not attain volume discount levels, if we are to introduce any similar discount programs in the future or if participation in these programs increases, our revenue, gross margin and net profits (losses) may 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. In the first quarter of 2006, we completed the process of relocating our SLA mold fabrication operations from our Santa Clara, California facility to our third party shelter services provider, IMS, located in Juarez, Mexico. IMS also fabricates 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 Costa Rica and Moscow, Russia. 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;

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;

fluctuations in currency exchange rates; 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 sufficient number of technicians in advance of such demand, the delivery time of our product 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 forms that form 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 forms 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 revenue 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 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. If IMS fails to deliver its components or if we 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 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. Finding a substitute manufacturer may be expensive, time-consuming or impossible.

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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 a product called Red, White and Blue, which is manufactured and distributed by Ormco Orthodontics, a division of Sybron Dental Specialties. In May 2006, Danaher Corporation purchased Sybron Dental Specialties. Prior to OrthoClear agreeing, pursuant to the terms of an agreement entered into in October 2006, to discontinue all design, manufacture, marketing and sales of removable dental aligners worldwide, our Invisalign system competed directly with an aligner product manufactured by them. In addition, manufacturers of traditional braces, such as 3M Company, Sybron Dental Specialties and Dentsply International 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. 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 recently resulted in 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 revenue, volume growth, net profit and stock price. For instance, in the fourth quarter of 2005, in order to encourage continued use of our products, we extended our volume based discount program to all of our doctors. In addition, in the second half of 2005, we introduced Invisalign Express, a lower-cost solution for less complex cases as well as a new pricing initiative which had the effect of reducing our average selling price per case. These programs have adversely affected our revenues, gross margin and net profit. 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, revenue and operating results.

In addition, our data center operations are located in our headquarters in Santa Clara, California. We are in the process of moving our data center operations and changing our data center infrastructure. We expect the move to be completed over the next two years. We may experience technical difficulties in connection with these changes. If we experience a system failure or disruption for any reason, including in connection with changes in our data center location or infrastructure, the performance of our website would be harmed and our service could shut down.

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

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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, 2007, we had 95 issued U.S. patents, 140 pending U.S. patent applications, and numerous foreign issued patents, as well as 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 of 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). Although in October 2006, we entered into an agreement with OrthoClear whereby OrthoClear and Align agreed, among other things, to dismiss all pending lawsuits against each other, including the patent infringement action against OrthoClear, 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 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 would have an adverse effect on our stock price.

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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, obtain regulatory approval or clearance of, manufacture and market new products. In the second half of 2005, we launched Invisalign Express a lower-cost aligner system to be used for less complex cases. We recently completed the launch of ClinAdvisor, a new suite of software tools to assist doctors in the selection of appropriate cases given their experience and skill level. In addition, we plan to introduce a further series of software enhancements that will evolve Invisalign into distinct suites of software tools for the orthodontist and GP. 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, price, safety, efficacy, reliability, marketing and sales efforts, the availability of third-party reimbursement of procedures using our new products, the existence of competing products and general economic conditions affecting purchasing patterns. 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 new products or enhanced versions of existing products and achieve market acceptance of new products and new applications could have a material adverse effect on our operating results and could cause our revenues to decline.

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 will 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.

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, we are committed to purchase all of our resin from a single-source and our scanning and stereolithography equipment are provided by single suppliers. 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 these items, our business and growth prospects may be harmed.

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We have experienced rapid growth, and our failure to manage this growth could harm our business.

We have expanded rapidly since we commenced commercial sales in 1999. Our headcount increased from approximately 50 employees as of December 31, 1999 to 1,254 employees as of September 30, 2007. This expansion will continue to place significant demands on our management and other resources and will require us to continue to develop and improve our operational, financial and other internal controls, both in the U.S. and internationally. In particular, growth increases the challenges involved in a number of areas, including recruiting and retaining sufficiently skilled personnel, providing adequate training and supervision to maintain our high quality standards, and preserving our culture and values. Our inability to effectively manage growth could harm our business.

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 domestic and international markets. As of September 30, 2007 our North America sales organization consisted of 141 people of which 118 were direct sales representatives and 23 were sales administration and regional sales management. Internationally, we have approximately 30 people engaged in sales and sales support as of September 30, 2007. 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 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 reestablish 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.

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. We and IMS, our third party shelter services provider have

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not yet been subject to an FDA inspection, and we cannot assure you we or IMS will successfully pass such an inspection in the future. 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 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.

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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 domestic market will adopt Invisalign in sufficient numbers or as rapidly as we anticipate. In addition, sales of our products outside the U.S. are subject to foreign regulatory requirements that vary widely from country to country. The time required to obtain clearances or approvals required by other countries may be longer than that required for FDA clearance or approval, and requirements for such approvals may differ from FDA requirements. We may be unable to obtain regulatory approvals in one or more of the other countries in which we do business or in which we may do business in the future. We may also incur significant costs in attempting to obtain and maintain foreign regulatory approvals. If we experience delays in receipt of approvals to market our products outside of the U.S., or if we fail to receive these approvals, we may be unable to market our products or enhancements in international markets in a timely manner, if at all.

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

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

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

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

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

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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.

We have made use of 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.

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

Not applicable.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

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

None.

ITEM 5. OTHER INFORMATION

On October 10, 2007, the Compensation Committee of our Board of Directors approved an amendment to the form of restricted stock unit (RSU) agreement to change the standard RSU vesting schedule. Accordingly, each RSU award granted after October, 10, 2007 will fully vest over a period of four years from the date of grant, with 25% vesting on each annual anniversary of the vesting commencement date. This new vesting schedule replaces the existing RSU vesting schedule whereby 25% of the RSU award vested on the one year anniversary of the date of grant and 1/12th of the remaining shares vested each quarter thereafter, for full vesting after 4 years of service. However, those RSU awards granted prior to this amendment will continue vesting under the previous vesting schedule. A copy of the amended form of RSU Agreement is attached to this Form 10-Q as Exhibit 10.1a, 10.1b and 10.1c.

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ITEM 6. EXHIBITS

(a) Exhibits:

Exhibit Number	Description	Filing	Date	Exhibit Number	Filed herewith
10.1a	Form of Restricted Stock Unit Award Agreement (Officers Form)				*
10.1b	Form of Restricted Stock Unit Award Agreement (CEO Form)				*
10.1c	Form of Restricted Stock Unit Award Agreement (General Form)				*
10.2	Separation & General Release Agreement with Michael Henry dated July 23, 2007	Form 10-Q	08/03/2007	10.3	
10.3	Offer letter between the Company and Afsaneh Azadeh, VP Information Technology and Chief Information Officer				*
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 contracts or compensatory arrangements.

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, 2007

ALIGN TECHNOLOGY, INC.

By: /s/ THOMAS M. PRESCOTT
Thomas M. Prescott
President and Chief Executive Officer

By: /s/ ELDON M. BULLINGTON
Eldon M. Bullington
Vice President of Finance and Chief Financial Officer

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