ALIGN TECHNOLOGY INC
Form 10-Q
May 05, 2011
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2011

OR

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

For the transition period from to

Commission file number: 0-32259

ALIGN TECHNOLOGY, INC.

(Exact name of registrant as specified in its charter)

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

2560 Orchard Parkway

San Jose, California 95131

(Address of principal executive offices)

(408) 470-1000

(Registrant s telephone number, including area code)

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No ¨

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

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

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

The number of shares outstanding of the registrant s Common Stock, $0.0001 par value, as of April 29, 2010 was 77,816,865.

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PART I FINANCIAL INFORMATION

ITEM 1 FINANCIAL STATEMENTS

ALIGN TECHNOLOGY, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per share data)

(unaudited)

	Three Months Ended March 31,	
	2011	2010
Net revenues:		
Invisalign	$ 99,437	$ 85,422
Non-case	5,419	4,668
Total net revenues	104,856	90,090
Cost of revenues		
Invisalign	20,993	18,607
Non-case	1,637	1,773
Total cost of revenues	22,630	20,380
Gross profit	82,226	69,710
Operating expenses:		
Sales and marketing	32,821	27,946
General and administrative	18,992	14,951
Research and development	9,390	6,116
Total operating expenses	61,203	49,013
Profit from operations	21,023	20,697
Interest and other income (expense), net	89	(553)
Net profit before provision for income taxes	21,112	20,144
Provision for income taxes	5,271	5,214
Net profit	$ 15,841	$ 14,930
Net profit per share:		
Basic	$ 0.21	$ 0.20
Diluted	$ 0.20	$ 0.19
Shares used in computing net profit per share:		
Basic	76,844	75,166

Diluted	79,361	77,597

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

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ALIGN TECHNOLOGY, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands, except per share data)

(unaudited)

	March 31, 2011	December 31, 2010
ASSETS		
Current assets:		
Cash and cash equivalents	$ 308,608	$ 294,664
Restricted cash	7,991	
Marketable securities, short-term	8,328	8,615
Accounts receivable, net of allowance for doubtful accounts of $485 and $735, respectively	73,904	65,430
Inventories	2,867	2,544
Prepaid expenses and other current assets	16,243	17,358
Total current assets	417,941	388,611
Marketable securities, long-term	5,615	9,089
Property and equipment, net	30,722	30,684
Goodwill	478	478
Intangible assets, net	1,488	2,188
Deferred tax asset	38,024	42,439
Other assets	2,714	3,454
Total assets	$ 496,982	$ 476,943
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 6,594	$ 7,768
Accrued liabilities	44,201	51,358
Deferred revenues	37,199	33,848
Total current liabilities	87,994	92,974
Other long-term liabilities	6,883	6,222
Total liabilities	94,877	99,196
Commitments and contingencies (Notes 5, 8 and 14)		
Stockholders equity:		
Preferred stock, $0.0001 par value (5,000 shares authorized; none issued)		
Common stock, $0.0001 par value (200,000 shares authorized; 77,189 and 74,568 issued and outstanding, respectively)	8	8
Additional paid-in capital	563,878	555,851
Accumulated other comprehensive income, net	624	134
Accumulated deficit	(162,405)	(178,246)
Total stockholders equity	402,105	377,747

Total liabilities and stockholders equity	$ 496,982	$ 476,943

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

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ALIGN TECHNOLOGY, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

(unaudited)

	Three Months Ended March 31,	
	2011	**2010**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net profit	$ 15,841	$ 14,930
Adjustments to reconcile net profit to net cash provided by operating activities:		
Deferred taxes	3,983	4,975
Depreciation and amortization	2,979	2,944
Stock-based compensation	4,279	3,473
Amortization of intangibles	700	700
Amortization of prepaid royalties		827
Benefit from doubtful accounts	(162)	(200)
Changes in assets and liabilities:		
Accounts receivable	(7,317)	(4,857)
Inventories	(312)	(319)
Prepaid expenses and other assets	207	(738)
Accounts payable	(634)	(271)
Accrued and other long-term liabilities	(5,315)	(7,927)
Deferred revenues	2,999	5,108
Net cash provided by operating activities	17,248	18,645
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	(2,825)	(4,530)
Restricted cash	(7,991)	
Maturities of marketable securities	3,767	4,988
Other assets	(177)	(246)
Net cash provided by (used in) investing activities	(7,226)	212
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock	5,068	6,016
Employees taxes paid upon the vesting of restricted stock units	(1,319)	(755)
Net cash provided by financing activities	3,749	5,261
Effect of foreign exchange rate changes on cash and cash equivalents	173	(198)
Net increase in cash and cash equivalents	13,944	23,920
Cash and cash equivalents, beginning of period	294,664	166,487
Cash and cash equivalents, end of period	$ 308,608	$ 190,407

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

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ALIGN TECHNOLOGY, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(unaudited)

Note 1. Summary of Significant Accounting Policies

Basis of presentation

The accompanying unaudited Condensed Consolidated Financial Statements have been prepared by Align Technology, Inc. (we , our , 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 our financial position as of March 31, 2011, our results of operations for the three months ended March 31, 2011 and 2010, and our cash flows for the three months ended March 31, 2011 and 2010. The Condensed Consolidated Balance Sheet as of December 31, 2010 was derived from the December 31, 2010 audited financial statements.

The results of operations for the three months ended March 31, 2011 are not necessarily indicative of the results that may be expected for the year ending December 31, 2011 or any other future period, and we make no representations related thereto. The information included in this Quarterly Report on Form 10-Q should be read in conjunction with Management s Discussion and Analysis of Financial Condition and Results of Operations, Quantitative and Qualitative Disclosures About Market Risk and the Consolidated Financial Statements and notes thereto included in Items 7, 7A and 8, respectively, in our Annual Report on Form 10-K for the year ended December 31, 2010.

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

Revenue recognition

We recognize revenue when persuasive evidence of an arrangement exists, delivery has occurred, the price is fixed or determinable, and collectability is reasonably assured. Revenues are recognized from product sales, net of discounts and rebates. Service revenues related to the training of dental professionals and staff on the Invisalign treatment process is recorded when the services are completed.

We enter into arrangements (treatment plans) that involve multiple future product deliverables. For example, included in the price of Invisalign Full, Invisalign Teen and Invisalign Assist, we offer optional case refinement, which is a finishing tool used to adjust a patient s teeth to the desired final position. Case refinement may be elected by the dental professional at any time during treatment however it is generally ordered in the last stages of orthodontic treatment. Invisalign Teen also includes six optional replacement aligners in the price of the product and may be ordered at any time throughout treatment.

Beginning January 1, 2011, we adopted revenue recognition guidance under Accounting Standards Update (ASU) 2009-13, Revenue Recognition: Multiple-Deliverable Revenue Arrangements, on a prospective basis for new or materially modified arrangements. This update amends the guidance on revenue arrangements with multiple deliverables and eliminates the use of the residual method. We use vendor specific objective evidence (VSOE) adjusted by estimated usage rates for case refinements and replacement aligners to determine the respective estimated selling price (ESP). In the absence of VSOE, we determine our best estimate of selling price, as if it is sold on a stand-alone basis, and take into consideration our pricing and discounting strategies, market conditions, as well as historical price. We regularly review our VSOE and ESP and maintain internal controls over the establishment and update of these estimates.

A deliverable constitutes a separate unit of accounting when it has stand-alone value, even if the deliverable is not sold separately. We determined that our treatment plans are comprised of four possible deliverables that represent separate units of accounting: single-batched aligners, multiple-batched aligners, case refinement and replacement aligners. We allocate revenue for each treatment plan based on each unit s relative selling price and recognize the revenue upon the delivery of each unit in the treatment plan.

The adoption of ASU 2009-13 did not have a material impact on our financial statements and is not expected to have a material impact in future periods. Although the financial statement impact was not material, the adoption of ASU 2009-13 did impact our accounting for Invisalign Assist with the progress tracking feature, in which aligners are shipped to the dental professional every nine stages (a batch). We determined that each batch has stand-alone value and therefore represents a separate unit of accounting. The estimated selling price for Invisalign Assist with progress tracking is allocated according to the estimated number of batches.

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Prior to January 1, 2011, we used VSOE as fair value to allocate revenue to the case refinement and replacement aligner deliverables. We deferred the fair value of case refinement and replacement aligner deliverables based on a breakage factor and recognized the residual revenue upon initial batch shipment. The deferred revenue was subsequently recognized as the refinement and replacement aligners were shipped. For Invisalign Assist with the progress tracking feature, we did not have independent evidence of fair value for the separate batches of aligners, so all batches of aligners were considered a single unit of accounting prior to January 1, 2011. For these treatment plans, revenue was deferred upon the first batched shipment and recognized upon the final batched shipment.

We estimate and record a provision for amounts of estimated losses on sales, if any, in the period such sales occur. We have not recorded any estimated losses for the periods presented. Provisions for discounts and rebates to customers are provided for in the same period that the related product sales are recorded based upon historical discounts and rebates.

Recent Accounting Pronouncements

In January 2011, the Financial Accounting Standards Board (FASB) has issued ASU 2011-01, Receivables (ASC 310): Deferral of the Effective Date of Disclosures about Troubled Debt Restructurings in Update No. 2010-20. The amendments in ASU 2011-01 temporarily delays the effective date of the disclosures about troubled debt restructurings in ASU 2010-20, Receivables (ASC 310): Disclosures about the Credit Quality of Financing Receivables and the Allowance for Credit Losses, for public entities. The delay is intended to allow the FASB time to complete its deliberations on what constitutes a troubled debt restructuring. The effective date of the new disclosures about troubled debt restructurings for public entities and the guidance for determining what constitutes a troubled debt restructuring will then be coordinated. Currently, that guidance is anticipated to be effective for interim and annual periods ending after June 15, 2011. We are still assessing the impact of this guidance. However, we do not believe that the adoption will have a material impact on our consolidated financial statements.

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Note 2. Marketable Securities and Fair Value Measurements

Our short-term and long-term marketable securities as of March 31, 2011 and December 31, 2010 are as follows (in thousands):

Short-term

March 31, 2011	Amortized Costs	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Corporate bonds	$ 3,606	$ 3	$ (1)	$ 3,608
Foreign bonds	703			703
Discount notes	3,000			3,000
Agency bonds	1,016	1		1,017
Total	$ 8,325	$ 4	$ (1)	$ 8,328

Long-term

March 31, 2011	Amortized Costs	Gross Unrealized Losses	Fair Value
Corporate bonds	$ 3,309	$ (6)	$ 3,303
Foreign bonds	1,292	(2)	1,290
Agency bonds	1,023	(1)	1,022
Total	$ 5,624	$ (9)	$ 5,615

Short-term

December 31, 2010	Amortized Costs	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. government notes and bonds	$ 3,012	$	$ (1)	$ 3,011
Corporate bonds and certificate of deposit	705			705
Foreign bonds	1,900			1,900
Commercial paper	2,998	1		2,999
Total	$ 8,615	$ 1	$ (1)	$ 8,615

Long-term

December 31, 2010	Amortized Costs	Gross Unrealized Losses	Fair Value
Corporate bonds	$ 5,748	$ (11)	$ 5,737
Foreign bonds	1,307	(1)	1,306

Agency bonds	2,047	(1)	2,046
Total	$ 9,102	$ (13)	$ 9,089

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For the three months ended March 31, 2011 and 2010, no significant gains or losses were realized on the sale of marketable securities.

Fair Value Measurements

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

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

Our Level 1 assets consist of money market funds. We did not hold any Level 1 liabilities as of March 31, 2011.

Level 2 Observable inputs other than quoted prices included in Level 1, such as quoted prices for similar assets or liabilities in active markets; quoted prices for identical or similar assets or liabilities in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the asset or liability.

Our Level 2 assets consist of corporate bonds, foreign bonds, agency bonds, and discount notes. We did not hold any Level 2 liabilities as of March 31, 2011.

Level 3 Unobservable inputs to the valuation methodology that are supported by little or no market activity and that are significant to the measurement of the fair value of the assets or liabilities. Level 3 assets and liabilities include those whose fair value measurements are determined using pricing models, discounted cash flow methodologies or similar valuation techniques, as well as significant management judgment or estimation.

We did not hold any Level 3 assets or liabilities as of March 31, 2011.

The following table summarizes our financial assets measured at fair value on a recurring basis as of March 31, 2011 (in thousands):

Description	Balance as of March 31, 2011	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)
Cash equivalents:			
Money market funds	$ 187,238	$ 187,238	$
Short-term investments:			
Corporate bonds	3,608		3,608
Foreign bonds	703		703
Discount notes	3,000		3,000
Agency bonds	1,017		1,017
Long-term investments:			
Corporate bonds	3,303		3,303
Foreign bonds	1,290		1,290
Agency bonds	1,022		1,022
	$ 201,181	$ 187,238	$ 13,943

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Note 3. Balance Sheet Components

Restricted cash

In January 2011, we funded approximately $8.0 million into a third party escrow account for certain class members who may elect the cash remedy as part of the proposed terms related to the Leiszler class action suit. Payments to these class members are expected to be finalized by the second quarter of 2011.

Inventories

Inventories are comprised of (in thousands):

	March 31, 2011	December 31, 2010
Raw materials	$ 1,541	$ 1,272
Work in process	1,107	1,030
Finished goods	219	242
	$ 2,867	$ 2,544

Work in process includes costs to produce the Invisalign product. Finished goods primarily represent ancillary products that support the Invisalign system.

Accrued liabilities

Accrued liabilities consist of the following (in thousands):

	March 31, 2011	December 31, 2010
Accrued payroll and benefits	$ 19,225	$ 26,551
Accrued litigation settlement	4,517	4,549
Accrued income taxes	347	1,936
Accrued sales rebate	4,865	3,826
Accrued sales tax and value added tax	2,642	2,940
Accrued warranty	2,766	2,607
Accrued sales and marketing expenses	3,297	2,955
Other	6,542	5,994
	$ 44,201	$ 51,358

Note 4. Intangible Assets

The intangible assets represent non-compete agreements received in conjunction with the October 2006 OrthoClear Agreement at gross value of $14.0 million. These assets are amortized on a straight-line basis over the expected useful life of five years. As of March 31, 2011 and December 31, 2010, the net carrying value of these non-compete agreements was $1.5 million (net of $12.5 million of accumulated amortization) and $2.2 million (net of $11.8 million of accumulated amortization), respectively.

We perform an impairment test whenever events or changes in circumstances indicate that the carrying value of such assets may not be recoverable. Examples of such events or circumstances include significant underperformance relative to historical or projected future operating results, significant changes in the manner of use of acquired assets or the strategy for its business, significant negative industry or economic trends, and/or a significant decline in our stock price for a sustained period. Impairments are recognized based on the difference between the fair

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

The total estimated annual future amortization expense for these intangible assets as of March 31, 2011 is $1.5 million.

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Note 5. Legal Proceedings

Weber

On May 18, 2007, Debra A. Weber filed a consumer class action lawsuit against us, OrthoClear, Inc. and OrthoClear Holdings, Inc. (d/b/a OrthoClear, Inc.) in Syracuse, New York, U.S. District Court. The complaint alleges two causes of action against the OrthoClear defendants and one cause of action against us for breach of contract. The cause of action against us titled Breach of Third Party Benefit Contract references our agreement to make Invisalign treatment available to OrthoClear patients, alleging that we failed to provide the promised treatment to Plaintiff or any of the class members. On June 2, 2010, the Court granted our motion for summary judgment and dismissed us from the action.

On June 29, 2010, Weber requested that the Court enter final judgment as to Align pursuant to Federal Rule of Civil Procedure 54(b) in order to certify Align s dismissal for immediate appeal. We filed an opposition to Weber s request on July 19, 2010, on the grounds that Weber failed to show that exceptional circumstances warranted the entry of a final judgment where fewer than all claims or parties had been dismissed. On August 20, 2010, the Court denied Weber s motion. On October 29, 2010, the Court dismissed the action against OrthoClear and OrthoClear Holdings Inc. with prejudice at the request of the remaining parties pursuant to a settlement. The Stipulation and Order of Dismissal with Prejudice entered by the Court provides that the settlement and dismissal does not affect any rights Weber may have to appeal dismissal of the action as against us. We believe there is no evidence to indicate that a reasonable possibility exists that a loss had been incurred as of March 31, 2011.

Securities Litigation

In August 2009, Plaintiff Charles Wozniak filed a lawsuit against us and our Chief Executive Officer and President, Thomas M. Prescott (Mr. Prescott), in District Court for the Northern District of California on behalf of a claimed class consisting of all persons or entities who purchased our common stock between January 30, 2007 and October 24, 2007. The complaint alleges that Align and Mr. Prescott violated Section 10(b) of the Securities Exchange Act of 1934 and that Mr. Prescott violated Section 20(a) of the Securities Exchange Act of 1934. Specifically, the complaint alleges that during the class period we failed to disclose that we had shifted the focus of our sales force to clearing backlog, causing a significant decrease in the number of new case starts. On November 13, 2009, the Court appointed Plumbers and Pipefitters National Pension Fund as lead plaintiff. The lead plaintiff filed an amended complaint on January 29, 2010. The amended complaint alleges that we and Mr. Prescott issued a number of purportedly false and misleading statements throughout the class period concerning the Patients First program, our production capacity, a purported backlog, and the focus of our sales force. On March 26, 2010, we and Mr. Prescott filed a motion to dismiss the amended complaint. The motion was heard by the Court on July 9, 2010 and the Court has not yet released a ruling on the motion. We believe the lawsuit to be without merit and intend to vigorously defend ourselves. We believe there is no evidence to indicate that a reasonable possibility exists that a loss had been incurred as of March 31, 2011.

Note 6. Legal Settlements

Ormco

On August 16, 2009 we entered into a Settlement Agreement with Ormco Corporation, an affiliate of Danaher Corporation that ended all pending litigation between the parties and included a payment of $7.0 million for prepaid royalties. We amortized $6.2 million of the prepaid royalties to cost of sales in fiscal year 2009 and the remaining $0.8 million in the first quarter of 2010.

Leiszler

On May 10, 2010, Christopher J. Leiszler filed a complaint against us in the United States District Court for the Northern District of California. The complaint alleges that we implemented unfair and fraudulent requirements for the prescription of Invisalign through the Invisalign Proficiency Requirements for minimum case submission and continuing education credits requirements. In January 2010 Dr. Leiszler s Invisalign provider status was suspended for failing to meet the Proficiency Requirements. Dr. Leiszler sued on behalf of himself and all others similarly situated. The complaint seeks a refund of the price paid to us for Invisalign training. On October 19, 2010, we entered into a memorandum of understanding to resolve this litigation, and on November 30, 2010, we executed a formal Stipulation of Settlement. On December 23, 2010, the Court granted preliminary approval of the proposed settlement and on April 8, 2011, granted final approval of the settlement. Pursuant to its terms, the settlement will become effective in mid-May 2011. Under terms of the settlement, class members who did not elect to receive the cash remedy prior to the Court-ordered deadline will be reinstated to prescribe Invisalign treatment after the effective date under certain circumstances (the Reinstatement Benefit). In January 2011, we deposited approximately $8.0 million into an escrow account to pay eligible class members who elect the cash remedy, as well as legal fees and other costs. We recorded a total litigation settlement charge of $4.5 million during 2010 for our estimated liability related to this settlement. We will continue to assess and evaluate the matter with our legal

counsel and update the estimated settlement charge as appropriate as new information becomes available.

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Note 7. Credit Facilities

On December 14, 2010, we renegotiated and amended our existing credit facility with Comerica Bank. Under this revolving line of credit, we have $30.0 million of available borrowings with a maturity date of December 31, 2012. The interest rate on borrowings will range from Libor plus 1.5% to 2.0% depending upon the amount of cash we maintain at Comerica Bank. This credit facility requires a quick ratio covenant and also requires us to maintain a minimum unrestricted cash balance of $10.0 million. Additionally, in the event our unrestricted cash deposited is less than $55.0 million, the unused facility fee will increase from 0.050% per quarter to 0.125% per quarter. As of March 31, 2011, we had no outstanding borrowings under this credit facility and are in compliance with the financial covenants.

Note 8. Commitments and Contingencies

Operating Leases

As of March 31, 2011, minimum future lease payments for non-cancelable leases are as follows (in thousands):

Fiscal Year	
2011 (remaining 9 months)	$ 4,850
2012	5,485
2013	4,512
2014	3,506
2015	3,206
2016 and thereafter	4,979
Total	$ 26,538

Warranty

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

The following table reflects the change in our warranty accrual during the three months ended March 31, 2011 and 2010, respectively (in thousands):

	Three Months Ended March 31,	
	2011	**2010**
Balance at beginning of period	$ 2,607	$ 2,376
Charged to cost of revenues	895	788
Actual warranty expenses	(736)	(701)
Balance at end of period	$ 2,766	$ 2,463

Note 9. Stock-based Compensation

Summary of stock-based compensation expense

Stock-based compensation expense is based on the estimated fair value of awards, net of estimated forfeitures and recognized over the requisite service period. Estimated forfeitures are based on historical experience at the time of grant and may be revised, if necessary, in subsequent

periods if actual forfeitures differ from those estimates. The stock-based compensation expense related to all of our stock-based awards and employee stock purchases for the three months ended March 31, 2011 and 2010 are as follows (in thousands):

	Three Months Ended March 31,	
	2011	2010
Cost of revenues	$ 517	$ 435
Sales and marketing	1,098	847
General and administrative	2,101	1,813
Research and development	563	378
Total stock-based compensation expense	$ 4,279	$ 3,473

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Options

Activity for the period ended March 31, 2011 under the stock option plans are set forth below (in thousands, except years and per share amounts):

	Stock Options			
	Number of Shares Underlying Stock Options	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding at of December 31, 2010	7,815	$ 12.99		
Granted	263	20.80		
Exercised	(218)	12.27		
Cancelled or expired	(18)	14.08		
Outstanding as of March 31, 2011	7,842	$ 13.27	5.51	$ 56,962
Vested and expected to vest at March 31, 2011	7,635	$ 13.19	5.48	$ 56,100
Exercisable at March 31, 2011	5,724	$ 12.48	5.08	$ 46,146

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

	Three Months Ended March 31,	
	2011	2010
Stock Options:		
Expected term (in years)	4.4	4.4
Expected volatility	61.0%	63.3%
Risk-free interest rate	1.8%	2.0%
Expected dividend		
Weighted average fair value per share at grant date	$ 10.37	$ 9.26

As of March 31, 2011, we expect to recognize $13.9 million of total unamortized compensation cost, net of estimated forfeitures, related to stock options over a weighted average period of 2.5 years.

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Restricted Stock Units

A summary of the nonvested shares for the three months ended March 31, 2011 is as follows:

	Number of Shares Underlying RSUs (in thousands)	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Nonvested as of December 31, 2010	905		
Granted	540		
Vested and released	(325)		
Forfeited	(7)		
Nonvested as of March 31, 2011	1,113	1.86	$ 22,796

As of March 31, 2011 the total unamortized compensation cost related to restricted stock units, net of estimated forfeitures, was $15.3 million, which we expect to recognize over a weighted average period of 2.9 years.

On February 18, 2011, we granted market-performance based restricted stock units (MSU) to our named executive officers. Each MSU represents the right to one share of Align s common stock and will be issued through our amended 2005 Incentive Plan. The actual number of MSUs which will be eligible to vest will be based on the performance of Align s stock price relative to the performance of the NASDAQ Composite Index over the vesting period, generally two to three years, up to 150% of the MSUs initially granted.

The following table summarizes the MSU performance as of March 31, 2011:

	Number of Shares Underlying MSUs (in thousands)	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Nonvested as of December 31, 2010*			
Granted	138		
Vested and released			
Forfeited			
Nonvested as of March 31, 2011	138	2.39	$ 2,830

* There were no MSU grants outstanding as of December 31, 2010.

The fair value of the MSUs is estimated at the grant date using a Monte Carlo simulation to that includes a factor for market conditions. The following weighted-average assumptions used in the Monte Carlo simulation were as follows:

	Three Months Ended March 31,	
	2011	2010
Expected term (in years)	3.0	N/A
Expected volatility	58.4%	N/A
Risk-free interest rate	1.3%	N/A

Expected dividend		N/A
Weighted average fair value per share at grant date	$ 22.12	N/A

As of March 31, 2011, we expect to recognize $2.4 million of total unamortized compensation cost, net of estimated forfeitures, related to MSU over a weighted average period of 2.4 years.

Employee Stock Purchase Plan

In May 2010, our shareholders approved the 2010 Employee Stock Purchase Plan (the 2010 Purchase Plan) to replace the 2001 Purchase Plan which expired on January 31, 2011. The terms and features of the 2010 Purchase Plan are substantially the same as the 2001 Purchase Plan and will continue until terminated by either the Board or its administrator. The maximum number of shares available for issuance under the 2010 Purchase Plan is 2,400,000 shares.

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

	Three Months Ended March 31,	
	2011	2010
Employee Stock Purchase Plan:		
Expected term (in years)	1.2	1.3
Expected volatility	43.0%	58.3%
Risk-free interest rate	0.4%	0.5%
Expected dividend		
Weighted average fair value at grant date	$ 7.26	$ 7.57

As of March 31, 2011, we expect to recognize $3.3 million of the total unamortized compensation cost related to employee purchases over a weighted average period of 0.7 years.

Note 10. Accounting for Income Taxes

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

During the first quarter of fiscal 2011, the amount of unrecognized tax benefits was increased by approximately $1.1 million. The total amount of unrecognized tax benefits was $12.1 million as of March 31, 2011, which would impact our effective tax rate if recognized. We are subject to taxation in the U.S. and various states and foreign jurisdictions. All of our tax years will be open to examination by the U.S. federal and most state tax authorities due to our net operating loss and overall credit carryforward position. With few exceptions, we are no longer subject to examination by foreign tax authorities for years before 2005.

Note 11. Net Profit Per Share

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

The following table sets forth the computation of basic and diluted net profit per share attributable to common stock (in thousands, except per share amounts):

	Three Months Ended March 31,	
	2011	2010
Net profit	$ 15,841	$ 14,930
Weighted-average common shares outstanding, basic	76,844	75,166
Effect of potential dilutive common shares	2,517	2,431
Total shares, diluted	79,361	77,597
Basic net profit per share	$ 0.21	$ 0.20
Diluted net profit per share	$ 0.20	$ 0.19

For the three months ended March, 2011 and 2010, stock options and restricted stock units totaling 1.5 million and 2.1 million, respectively, were excluded from diluted net profit per share because of their anti-dilutive effect.

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Note 12. Comprehensive Income

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

	Three Months Ended March 31,	
	2011	2010
Net profit	$ 15,841	$ 14,930
Foreign currency translation adjustments	483	(347)
Change in unrealized gains on available-for-sale securities	7	1
Comprehensive income	$ 16,331	$ 14,584

Note 13. Segments and Geographical Information

Segment

We report segment data based on the internal reporting that is used by management for making operating decisions and assessing performance. During all periods presented, we operated as a single business segment.

Geographical Information

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

	Three Months Ended March 31,	
	2011	2010
Net revenues:		
North America	$ 79,135	$ 68,854
Europe	24,537	20,378
Other international	1,184	858
Total net revenues	$ 104,856	$ 90,090

	As of March 31, 2011	As of December 31, 2010
Long-lived assets:		
North America	$ 76,148	$ 85,576
Europe	972	837
Other international	1,921	1,919
Total long-lived assets	$ 79,041	$ 88,332

Note 14. Subsequent Event

On March 29, 2011, we entered into an Agreement and Plan of Merger (the Merger Agreement) to acquire Cadent Holdings, Inc. (Cadent), for approximately $190 million in cash, less certain adjustments. Cadent is a leading provider of 3D digital scanning solutions for the orthodontic

and dental industry.

On April 29, 2011, we completed our acquisition of Cadent. In accordance with the terms of the Merger Agreement, we acquired all outstanding capital stock and Cadent became a wholly owned subsidiary. We are in the process of determining the preliminary allocation of purchase price to Cadent s tangible and intangible assets and liabilities assumed.

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

In addition to historical information, this annual report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. These statements include, among other things, our expectations regarding the anticipated impact of our new products and product enhancements, including Invisalign G3, will have on doctor utilization and our market share, our expectations regarding product mix and product adoption, our expectations regarding the existence and impact of seasonality, our expectations regarding the financial and strategic benefits of the Cadent Holdings, Inc. (Cadent) acquisition, our expectations to increase our investment in manufacturing capacity, our expectations regarding the continued growth of our international markets, including the expected timing of the commercial launch of Invisalign in China , the anticipated number of new doctors trained and their impact on volumes, the level of our operating expenses and gross margins, and other factors beyond our control, as well as other statements regarding our future operations, financial condition and prospects and business strategies. These statements may contain words such as expects, anticipates, intends, plans, believes, estimates, or other words indicating future results. These forward-looking statements are subject to certain risks and uncertainties that could cause actual results to differ materially from those reflected in the forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in Item 2 Management s Discussion and Analysis of Financial Condition and Results of Operations , and in particular, the risks discussed below in Part II, Item 1A Risk Factors . We undertake no obligation to revise or update these forward-looking statements. Given these risks and uncertainties, readers are cautioned not to place undue reliance on such forward-looking statements.

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

We design, manufacture and market the Invisalign system, a proprietary method for treating malocclusion, or the misalignment of teeth. Invisalign corrects malocclusion using a series of clear, nearly invisible, removable appliances that gently move teeth to a desired final position. Because it does not rely on the use of metal or ceramic brackets and wires, Invisalign significantly reduces the aesthetic and other limitations associated with metal arch wires and brackets, commonly referred to as braces. We received the United States Food and Drug Administration (FDA) clearance to market Invisalign in 1998. The Invisalign system is regulated by the FDA as a Class II medical device.

We distribute the vast majority of our products directly to our customers: the orthodontist and the general practitioner dentist, or GP. Orthodontists and GPs must complete an initial Invisalign training course in order to begin providing the Invisalign treatment solution to their patients. The Invisalign system is sold in North America, Europe, Asia Pacific, Latin America and Japan. We use a distributor model for the sale of our products in parts of the Asia Pacific, Latin American and EMEA (Europe, Middle East and Africa) regions.

Each Invisalign treatment plan is unique to the individual patient. Our Invisalign Full treatment consists of as many aligners as indicated by ClinCheck in order to achieve the doctors treatment goals. Our Invisalign Express is a dual arch orthodontic treatment for cases that meet certain predetermined clinical criteria and consist of up to ten sets of aligners. Invisalign Express treatment is intended to assist dental professionals to treat a broader range of patients by providing a lower-cost option for adult relapse cases, for minor crowding and spacing, or as a pre-cursor to restorative or cosmetic treatments such as veneers. In April 2010, we replaced Invisalign Express in international markets with the launch of Invisalign Lite. Invisalign Lite offers doctors a new option for less complex orthodontic cases, such as short-term aesthetic cases, relapsed cases and pre-restorative treatments, using up to 14 stages. Invisalign Teen is designed to meet the specific needs of the non-adult comprehensive or teen treatment market particularly younger teenagers aged 11 to 15 years. Invisalign Assist is intended to help newly-trained and lower volume Invisalign GPs accelerate the adoption and frequency of use of Invisalign into their practice. Upon completion of an Invisalign or non-Invisalign treatment, the patient may be prescribed our traditional retainer product, or our Vivera retainers, a clear aligner set designed for ongoing retention. Our goal is to establish Invisalign as the standard method for treating malocclusion ultimately driving increased product adoption by dental professionals by focusing on the four key objectives: driving product innovation and clinical effectiveness, enhancing the customer experience, generating consumer demand and expanding into international markets. Each of these four key objectives is described more fully in *Item I Business Business Strategy* of our 2010 Annual Report on Form 10-K. As we execute on our business strategy, we will continue to deliver significant evolutions in product features and functionality, as well as customer facing systems.

In addition to the successful execution of our business strategy, which is set forth in our Annual Report in Form 10-K, there are a number of other factors which may affect our results in 2011 and beyond, both of which are updated below:

Accelerate product and clinical innovation. In October 2010, we launched Invisalign G3 in North America, the most significant collection of new features and innovation in our company history touching virtually every system and product. Significant improvements and enhancements were made in to all our customer-facing systems. For instance, the Invisalign Doctor Site now consolidates all of a patient s Invisalign records and treatment tasks together in one location

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for easy access and the ClinCheck software now includes drag and drop features, additional clinical tools and a more intuitive interface. In addition, with the exception of our Vivera retainers, we introduced new and expanded features across our product line. Engineered to deliver even better clinical results, the Invisalign G3 new aligner and software features make it easier to use Invisalign with more complex and challenging cases, including Precision Cuts designed for use on patients with Class II and Class III malocclusion, new SmartForce features designed for increased predictability of certain tooth movements, and simpler, more intuitive software to streamline treatment planning and review. We believe that, in addition to an increase in the number of patients visiting dental offices throughout the first quarter as reported by our customers, and patient interest in higher value procedures, Invisalign G3 is an important contributor to the increased utilization in the first quarter of 2011 by our North American Ortho customer. Additionally, since most of our international customers are Orthodontists, we believe the international launch of Invisalign G3 beginning in May 2011 is important for continued growth both in our existing international markets and to support our expansion in new markets like China.

Investments to Increase Manufacturing Capacity. We expect capital expenditures to increase in 2011 as we invest in our manufacturing facility in Juarez, Mexico to add incremental capacity. In addition, in order to meet the increased demands from expected volumes, we expect to open an additional aligner fabrication site in Juarez, Mexico by the end of 2011. Our ability to plan, construct and equip this additional manufacturing facility is subject to significant risk and uncertainty, including delays and cost overruns. If the opening of this facility is significantly delayed for any reason, or if demand for our product in 2011 exceeds our current expectations, we may not be able to fulfill orders timely, which may negatively impact our financial results and overall business.

Number of new doctors trained. In the first quarter of 2011 we trained approximately 957 new doctors worldwide, which is fewer than the number of doctors trained compared to the fourth quarter of 2010. We planned on training fewer international doctors until after the international release of Invisalign G3 in the second quarter of 2011. As a result, we trained 165 new international doctors in the first quarter of 2011, compared to 500 in the fourth quarter of 2010. Although we will begin training more international doctors later in the year, we expect that the number of international doctors trained in 2011 will be approximately 600 fewer than the number trained in 2010.

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

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

Utilization rates in the first quarter of 2011 for the North American Ortho increased to 6.5 cases per doctor reflecting continued penetration into the North American Ortho practices due in part to an increase in the number of patients visiting dental offices throughout the first quarter as reported by our customers, patient interest in higher value procedures and the availability of Invisalign G3 designed to make it easier to use Invisalign with more complex and challenging cases. Although we expect that over the long-term our utilization rates will gradually improve, we expect that period over period comparisons of our utilization rates will fluctuate.

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Seasonal fluctuations. Seasonal fluctuations in the number of doctors in their offices and available to take appointments have affected, and are likely to continue to affect our business. Specifically, our customers often take vacation during the summer months and therefore tend to start fewer cases, especially North American GPs and European doctors.

In 2010, sequential case growth from second quarter to the third quarter in the North American Ortho channel was essentially flat. With the availability of Invisalign Teen, we can actively compete for a share of teen patient starts. Summer is typically the busiest season for orthodontists with practices that have a high percentage of adolescent and teenage patients. Many parents want to get their teens started in treatment before the start of the school year. We believe that Invisalign Teen helped moderate the historical downward trend we have typically seen for our North American orthodontic customers during the summer months. In the third quarter of 2010, we saw a decline in the number of cases submitted as well as a decline in the number of submitters in our North American GP channel which is consistent with our historical trend during this quarter.

Acquisition of Cadent. On April 29, 2011, we acquired privately-held Cadent, a leading provider of 3D digital scanning solutions for orthodontics and dentistry for $190 million in cash. The acquisition of Cadent positions us as a leader in one of the best growth opportunities in dentistry and medical devices today. Over the next five years, we expect that intra-oral scanners will become widely used in dental practices. We believe that the combination of the two companies will help accelerate the use of intra-oral scanning in the dental industry by leveraging Align s global sales reach, extensive professional and consumer marketing capabilities and base of over 55 thousand ClinCheck software users. Cadent also strengthens our ability to drive adoption of Invisalign by integrating Invisalign treatment more fully with mainstream tools and procedures in doctors practices. As part of an ongoing program to evaluate interoperability of intra-oral scanning systems for future use with Invisalign treatment, we are in final beta tests with Cadent s systems and we expect to announce interoperability for Cadent scanners in the second quarter of 2011.

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

Growth of international markets. In October 2010, we announced regulatory approval to market and sell Invisalign in China and expect to begin commercial launch before the end of the second quarter of 2011. While we do not expect meaningful revenue from China for several years, our focused strategy to launch Invisalign in key major cities of China provides us a large growth opportunity long term.

Operating Expenses. In the second quarter of 2011, we expect operating expenses to increase reflecting the remaining transaction costs related to the acquisition of Cadent, including investment banking fees, legal, accounting and advisory fees. Additionally, we will expect additional media spending in preparation for the summer months and continued commercialization activities for Invisalign G3 internationally.

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Results of Operations

Net revenues and case volume by channel and product:

Invisalign product revenues by channel and other non-case revenues, which represents training, retainer and ancillary products, for the three months ended March 31, 2011 and 2010 are as follows (in millions):

	Three Months Ended March 31,			
Net revenues	**2011**	**2010**	**Net Change**	**% Change**
North America:				
Ortho	$ 35.0	$ 28.2	$ 6.8	24.1%
GP	39.3	37.2	2.1	5.6%
Total North American Invisalign	74.3	65.4	8.9	13.6%
International Invisalign	25.2	20.0	5.2	26.0%
Total Invisalign revenues	99.5	85.4	14.1	16.5%
Non-case revenues	5.4	4.7	0.7	14.9%
Total net revenues	$ 104.9	$ 90.1	$ 14.8	16.4%

Case volume data which represents Invisalign case shipments by channel, for the three months ended March 31, 2011 and 2010 are as follows (in thousands):

	Three Months Ended March 31,			
Invisalign case volume	**2011**	**2010**	**Net Change**	**% Change**
North America:				
Ortho	26.9	22.1	4.8	21.7%
GP	28.3	28.5	(0.2)	(0.7%)
Total North American Invisalign	55.2	50.6	4.6	9.1%
International Invisalign	16.2	13.0	3.2	24.6%
Total Invisalign case volume	71.4	63.6	7.8	12.3%

Invisalign revenues by product and other non-case revenues, which represents training, retainer and ancillary products, for the three months ended March 31, 2011 and 2010 are as follows (in millions):

	Three Months Ended March 31,			
Net revenues	**2011**	**2010**	**Net Change**	**% Change**
Invisalign Full	$ 71.1	$ 65.7	$ 5.4	8.2%
Invisalign Express/Lite	10.1	8.6	1.5	17.4%
Invisalign Teen	11.9	8.2	3.7	45.1%
Invisalign Assist	6.4	2.9	3.5	120.7%
Non-case revenues	5.4	4.7	0.7	14.9%

Total net revenues	$ 104.9	$ 90.1	$ 14.8	16.4%

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Case volume data which represents Invisalign case shipments by product, for the three months ended March 31, 2011 and 2010 are as follows (in thousands):

	Three Months Ended March 31,			
Invisalign case volume	**2011**	**2010**	**Net Change**	**% Change**
Invisalign Full	48.1	43.7	4.4	10.1%
Invisalign Express/Lite	10.5	9.2	1.3	14.1%
Invisalign Teen	7.9	7.4	0.5	6.8%
Invisalign Assist	4.9	3.3	1.6	48.5%
Total Invisalign case volume	71.4	63.6	7.8	12.3%

Total net revenues increased for the three months ended March 31, 2011 as compared to the same period in 2010 primarily as a result of worldwide volume growth across all customer channels.

In the three months ended March 31, 2011, North America revenue increased 13.6% compared to the same period in 2010 primarily due to case volume growth, particularly in the North American Ortho channel, due to higher patient traffic and strong demand for our Invisalign Full product. Additionally, revenue increased due to lower revenue deferral rates for our Invisalign Teen and Invisalign Assist products. Since the second quarter of 2010, we established an estimated usage rate for Invisalign Teen replacement aligners, which reduced the deferral rate. Furthermore, in the first quarter of 2011 and in accordance with ASU 2009-13, we began recognizing Invisalign Assist revenue over the course of treatment as each stage is shipped instead of deferring until the final batch shipment.

Our International Invisalign revenue also increased 26.0% for the three months ended March 31, 2011 mainly due to growth in case volumes of 24.6% from all products supplemented by favorable exchange rates of the Euro against the U.S. dollar.

Other non-case revenues, consisting of training fees and sales of ancillary products, were higher for the three month ended March 31, 2011 compared to the same period in 2010 primarily due to increased sales of our Vivera and retainer products which was partially offset by higher training discounts.

Cost of revenues and gross profit (in millions):

	Three Months Ended March 31,		
	2011	**2010**	**Change**
Cost of revenues	$ 22.6	$ 20.4	$ 2.2
% of net revenues	21.6%	22.6%	
Gross profit	$ 82.2	$ 69.7	$ 12.5
Gross margin	78.4%	77.4%	

Cost of revenues includes salaries for staff involved in the production process, the cost of materials, packaging, shipping costs, depreciation on capital equipment used in the production process and stock-based compensation expense.

Gross margin improved for the three months ended March 31, 2011 compared to the same period in 2010 primarily due to higher production volumes related to increased sales during the first quarter of 2011. Additionally, the gross margin for the first quarter of 2010 reflects charges that were not included in the gross margin during the first quarter of 2011. Gross margin during the first quarter of 2010 included the final amortization of the Ormco royalties of $0.8 million, and $0.5 million of net training costs that were subsequently included in sales and marketing following the first quarter of 2010.

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Sales and marketing (in millions):

	Three Months Ended March 31,		
	2011	2010	Change
Sales and marketing	$ 32.8	$ 27.9	$ 4.9
% of net revenues	31.3%	31.0%	

Sales and marketing expense includes sales force compensation (including travel-related costs), marketing personnel-related costs, media and advertising, clinical education, product marketing and stock-based compensation expense.

Our sales and marketing expense for the three months ended March 31, 2011 increased compared to the same period in 2010 primarily due to higher payroll and payroll-related costs of approximately $2.5 million and higher marketing and travel related costs of approximately $1.3 million. Additionally, we also incurred higher clinical education costs of approximately $0.8 million during the first quarter of 2011 of which $0.5 million was attributed to these expenses being included in cost of sales during the first quarter of 2010.

General and administrative (in millions):

	Three Months Ended March 31,		
	2011	2010	Change
General and administrative	$ 19.0	$ 15.0	$ 4.0
% of net revenues	18.1%	16.6%	

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

General and administrative expense increased for the three months ended March 31, 2011 compared to the same period in 2010 primarily due higher legal and accounting fees of approximately $2.2 million of which approximately $1.5 million was due to transaction costs related to our acquisition of Cadent that was incurred during the first quarter of 2011. We also incurred higher payroll and payroll-related costs of approximately $2.1 million during the first quarter of 2011 as compared to 2010.

Research and development (in millions):

	Three Months Ended March 31,		
	2011	2010	Change
Research and development	$ 9.4	$ 6.1	$ 3.3
% of net revenues	9.0%	6.8%	

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

Research and development expense increased during the three months ended March 31, 2011 compared to the same period in 2010 primarily due to a $2.0 million payment to Cadent under the Joint Development agreement that we entered into in January 2011. We also incurred higher payroll and payroll-related costs relating to an increase in headcount of approximately $0.9 million.

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Interest and other income (expense), net (in millions):

	Three Months Ended March 31,		
	2011	2010	Change
Interest income	$ 0.2	$ 0.1	$ 0.1
Other income (expense), net	(0.1)	(0.7)	0.6
Total interest income and other income (expense), net	$ 0.1	$ (0.6)	$ 0.7

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

Interest income for the three months ended March 31, 2011 was comparable to the same period in 2010.

Other expense, net for the three months ended March 31, 2011 decreased as compared with the same period in 2010 reflecting a reduction in foreign exchange losses.

Income tax (in millions):

	Three Months Ended March 31,		
	2011	2010	Change
Provision for income taxes	$ 5.3	$ 5.2	$ 0.1

We recorded an income tax provision of $5.3 million and $5.2 million for the three months ended March 31, 2011 and 2010, respectively, representing effective tax rates of 25.0% and 25.9%. Our effective tax rate for the remainder of 2011 may fluctuate based upon our operating results for each taxable jurisdiction in which we operate and the amount of statutory tax that we incur in each jurisdiction.

We exercised significant judgment in regards to estimates of future market growth, forecasted earnings and projected taxable income, in determining the provision for income taxes, and for purposes of assessing our ability to utilize any future benefit from deferred tax assets. As of March 31, 2011, we have recorded a valuation allowance of approximately $6.1 million related to capital loss and foreign loss carryforwards because we cannot forecast sufficient future capital gains or foreign source income to realize these deferred tax assets. These net operating loss and capital loss carryforwards will result in an income tax benefit if and when we conclude it is more likely than not that the related deferred tax assets will be realized.

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Liquidity and Capital Resources

We fund our operations from product sales and the proceeds from the sale of our common stock. As of March 31, 2011 and December 31, 2010, we had the following cash and cash equivalents, and short-term and long-term investments (in thousands):

	March 31, 2011	December 31, 2010
Cash and cash equivalents	$ 308,608	$ 294,664
Marketable securities, short-term	8,328	8,615
Marketable securities, long-term	5,615	9,089
Total	$ 322,551	$ 312,368

Cash flows (in thousands):

	Three Months Ended March 31, 2011	2010
Net cash flow provided by (used in) :		
Operating activities	$ 17,248	$ 18,645
Investing activities	(7,226)	212
Financing activities	3,749	5,261
Effects of exchange rate changes on cash and cash equivalents	173	(198)
Net increase in cash and cash equivalents	$ 13,944	$ 23,920

Operating Activities

For the period ended March 31, 2011, cash flows from operations of approximately $17.2 million resulted primarily from our net income of approximately $15.8 million adjusted for the following reasons:

Non-cash activities

Deferred taxes were $4.0 million primarily due to the utilization of our deferred tax assets.

Stock-based compensation expense was $4.3 million related to equity incentive compensation granted to employees.

Net other non-cash activities including depreciation and amortization, benefit from doubtful accounts, and the amortization of intangibles of $3.5 million.

Changes in working capital

Accounts receivable increased by $7.3 million due to the increase in revenues during the first quarter of 2011, reducing our cash inflow from operating activities.

Accrued and other long-term liabilities decreased by $5.3 million primarily due the payments of our incentive compensation and commission-related costs partially offset by higher sales rebate costs, reducing our cash inflow from operations.

Deferred revenue increased by $3.0 million primarily due to higher sales during the first quarter of 2011, increasing our cash inflow from operations.

Other working capital comprising of inventories, prepaid expenses and other assets, and accounts payable, resulted in a net decrease of $0.7 million, reducing our cash inflow from operations.

For the period ended March 31, 2010, cash flows from operations of $18.6 million resulted primarily from our net income of approximately $14.9 million adjusted for the following reasons:

Non-cash activities

Deferred taxes were approximately $5.0 million primarily due to the utilization of our deferred tax assets.

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Net other non-cash activities including depreciation and amortization, stock-based compensation, provision for doubtful accounts, excess tax provision for our share-based payments, and loss on the retirement/disposal of our fixed assets of $7.7 million.

Changes in working capital

Accounts receivable increased by approximately $4.9 million due to the increase in revenues during the three months ended March 31, 2010, reducing our cash inflow from operating activities.

Accrued and other long-term liabilities decreased by $7.9 million primarily due to payments of incentive compensation and commission-related, reducing our cash inflow from operations.

Deferred revenue increased by $5.1 million primarily due to higher sales with deferred revenue components, increasing our cash inflow from operations.

Other working capital comprising of inventories, prepaid expenses and other assets, and accounts payable resulted in a net decrease of $1.3 million, reducing our cash inflow from operations.

Investing Activities

Net cash used in investing activities was $7.2 million for the three months ended March 31, 2011 primarily consisted of $2.8 million used for the purchase of property and equipment and $8.0 million of cash used to fund an escrow account related to the Leiszler class action suit. These items were partially offset by maturities of our marketable securities of $3.8 million.

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

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

Financing Activities

Net cash provided by financing activities was $3.7 million for the three months ended March 31, 2011 primarily resulting from $5.1 million in proceeds from the issuances of our common stock, which were partially offset by $1.3 million of taxes paid on the vesting of restricted stock units related to our employee stock plan.

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

Contractual Obligations

On April 29, 2011 we completed the acquisition of Cadent and acquired all of their outstanding capital stock for $190 million in cash. The payment will be net of any estimated amount of any unpaid Cadent transaction expenses incurred in connection with the acquisition.

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

on acceptable terms when needed could have a material adverse effect on our business, results of operations and financial condition.

Critical Accounting Policies

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

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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, 2010.

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

Revenue recognition

We recognize revenue when persuasive evidence of an arrangement exists, delivery has occurred, the price is fixed or determinable, and collectability is reasonably assured. Revenues are recognized from product sales, net of discounts and rebates. Service revenues related to the training of dental professionals and staff on the Invisalign treatment process is recorded when the services are completed.

We enter into arrangements (treatment plans) that involve multiple future product deliverables. For example, included in the price of Invisalign Full, Invisalign Teen and Invisalign Assist, we offer optional case refinement, which is a finishing tool used to adjust a patient s teeth to the desired final position. Case refinement may be elected by the dental professional at any time during treatment however it is generally ordered in the last stages of orthodontic treatment. Invisalign Teen also includes six optional replacement aligners in the price of the product and may be ordered at any time throughout treatment.

Beginning January 1, 2011, we adopted revenue recognition guidance under Accounting Standards Update (ASU) 2009-13, Revenue Recognition: Multiple-Deliverable Revenue Arrangements, on a prospective basis for new or materially modified arrangements. This update amends the guidance on revenue arrangements with multiple deliverables and eliminates the use of the residual method. We use vendor specific objective evidence (VSOE) adjusted by estimated usage rates for case refinement and replacement aligners to determine the respective estimated selling price (ESP). In the absence of VSOE, we determine our best estimate of selling price, as if it is sold on a stand-alone basis, and take into consideration our pricing and discounting strategies, market conditions, as well as historical price. We regularly review our VSOE and ESP and maintain internal controls over the establishment and update of these estimates.

A deliverable constitutes a separate unit of accounting when it has stand-alone value, even if the deliverable is not sold separately. We determined that our treatment plans are comprised of four possible deliverables that represent separate units of accounting: single-batched aligners, multiple-batched aligners, case refinement and replacement aligners. We allocate revenue for each treatment plan based on each unit s relative selling price and recognize the revenue upon the delivery of each unit in the treatment plan.

The adoption of ASU 2009-13 did not have a material impact on our financial statements and is not expected to have a material impact in future periods. Although the financial statement impact was not material, the adoption of ASU 2009-13 did impact our accounting for Invisalign Assist with the progress tracking feature, in which aligners are shipped to the dental professional every nine stages (a batch). We determined that each batch has stand-alone value and therefore represents a separate unit of accounting. The estimated selling price for Invisalign Assist with progress tracking is allocated according to the estimated number of batches.

Prior to January 1, 2011, we used VSOE as fair value to allocate revenue to the case refinement and replacement aligner deliverables. We deferred the fair value of case refinement and replacement aligner deliverables based on a breakage factor and recognized the residual revenue upon initial batch shipment. The deferred revenue was subsequently recognized as the refinement and replacement aligners were shipped. For Invisalign Assist with the progress tracking feature, we did not have independent evidence of fair value for the separate batches of aligners, so all batches of aligners were considered a single unit of accounting prior to January 1, 2011. For these treatment plans, revenue was deferred upon the first batched shipment and recognized upon the final batched shipment.

We estimate and record a provision for amounts of estimated losses on sales, if any, in the period such sales occur. We have not recorded any estimated losses for the periods presented. Provisions for discounts and rebates to customers are provided for in the same period that the related product sales are recorded based upon historical discounts and rebates

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We establish a breakage factor to estimate the number of replacement and case refinement aligners, and batches for Invisalign Assist with progress tracking that will ultimately be ordered based on our historical utilization rates. Judgment is also required to determine the estimated selling price for our products with multiple element arrangements. The assumptions used in making these estimates represent management s best estimates but they involve inherent uncertainties and the application of management s judgment. As a result, if factors change and we use different assumptions, our revenue and deferred revenue could be materially different in the future.

Recent Accounting Pronouncements

See Note 1 Summary of Significant Accounting Policies of the Notes to Condensed Consolidated Financial Statements for a discussion of recent accounting pronouncements.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

For quantitative and qualitative disclosures about market risk affecting us, see Item 7A, Quantitative and Qualitative Disclosures About Market Risk, in our Annual Report on Form 10-K for the year ended December 31, 2010, which is incorporated herein by reference. Our exposure to market risk has not changed materially since December 31, 2010.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of disclosure controls and procedures.

Under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, we have evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of the end of the period covered by this Quarterly Report on Form 10-Q. Based upon that evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that our disclosure controls and procedures are effective as of March 31, 2011 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.

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PART II OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

Weber

On May 18, 2007, Debra A.Weber filed a consumer class action lawsuit against us, OrthoClear, Inc. and OrthoClear Holdings, Inc. (d/b/a OrthoClear, Inc.) in Syracuse, New York, U.S. District Court. The complaint alleges two causes of action against the OrthoClear defendants and one cause of action against us for breach of contract. The cause of action against us titled Breach of Third Party Benefit Contract references our agreement to make Invisalign treatment available to OrthoClear patients, alleging that we failed to provide the promised treatment to Plaintiff or any of the class members. On June 2, 2010, the Court granted our motion for summary judgment and dismissed us from the action.

On June 29, 2010, Weber requested that the Court enter final judgment as to Align pursuant to Federal Rule of Civil Procedure 54(b) in order to certify Align s dismissal for immediate appeal. We filed an opposition to Weber s request on July 19, 2010, on the grounds that Weber failed to show that exceptional circumstances warranted the entry of a final judgment where fewer than all claims or parties had been dismissed. On August 20, 2010, the Court denied Weber s motion. On October 29, 2010, the Court dismissed the action against OrthoClear and OrthoClear Holdings Inc. with prejudice at the request of the remaining parties pursuant to a settlement. The Stipulation and Order of Dismissal with Prejudice entered by the Court provides that the settlement and dismissal does not affect any rights Weber may have to appeal dismissal of the action as against us.

Leiszler

On May 10, 2010, Christopher J. Leiszler filed a complaint against us in the United States District Court for the Northern District of California. The complaint alleges that we implemented unfair and fraudulent requirements for the prescription of Invisalign through the Invisalign Proficiency Requirements for minimum case submission and continuing education credits requirements. In January 2010 Dr. Leiszler s Invisalign provider status was suspended for failing to meet the Proficiency Requirements. Dr. Leiszler sued on behalf of himself and all others similarly situated. The complaint seeks a refund of the price paid to us for Invisalign training. On October 19, 2010, we entered into a memorandum of understanding to resolve this litigation, and on November 30, 2010, we executed a formal Stipulation of Settlement. On December 23, 2010, the Court granted preliminary approval of the proposed settlement and on April 8, 2011, granted final approval of the settlement. Pursuant to its terms, the settlement will become effective in mid-May 2011. Under terms of the settlement, class members who did not elect to receive the cash remedy prior to the Court-ordered deadline will be reinstated to prescribe Invisalign treatment after the effective date under certain circumstances (the Reinstatement Benefit). In January 2011, we deposited approximately $8.0 million into an escrow account to pay eligible class members who elect the cash remedy, as well as legal fees and other costs. We recorded a total litigation settlement charge of $4.5 million during 2010 for our estimated liability related to this settlement. We will continue to assess and evaluate the matter with our legal counsel and update the estimated settlement charge as appropriate as new information becomes available.

Securities Litigation

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

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ITEM 1A. RISK FACTORS

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

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

Consumers may not adopt Invisalign as rapidly as we anticipate due to a variety of factors including a continued weakness in general economic conditions.

Consumer spending habits are affected by, among other things, prevailing economic conditions, levels of employment, salaries and wage rates, gas prices, consumer confidence and consumer perception of economic conditions. A general slowdown in the United States economy and certain international economies or an uncertain economic outlook would adversely affect consumer spending habits which may, among other things, result in a decrease in the number of overall orthodontic case starts, reduced the patient traffic in dentists offices, reduction in consumer spending on higher value procedures or a reduction in the demand for Invisalign generally, each of which would have a material adverse effect on our sales and operating results. In addition, Invisalign represents a significant change from traditional orthodontic treatment, and consumers may be reluctant to accept it or may not find it preferable to traditional treatment. We have generally received positive feedback from orthodontists, GPs and consumers regarding Invisalign as both an alternative to braces and as a clinical method for treatment of malocclusion, but a number of dental professionals believe that Invisalign is appropriate for only a limited percentage of their patients. Increased market acceptance will depend in part upon the recommendations of dental professionals, as well as other factors including effectiveness, safety, ease of use, reliability, aesthetics, greater comfort and hygiene compared to traditional orthodontic products and price for Invisalign compared to competing products.

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

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

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

In response to challenges in our business, including increased competition, we have in the past reduced the list price of our products. We also provide volume based discount programs to our doctors. In addition, we sell a number of products at different list prices. If we introduce any price reductions, or consumer rebate programs, expand our discount programs in the future, if participation in these programs increases, if our product mix shifts to lower priced products or newer products that have a higher percentage of deferred revenue, or if sales by our international distributors, particularly in the Asia-Pacific region, grows at a faster pace than our direct sales, our average selling price would be adversely affected and our revenues, gross margin and net profits (losses) may be reduced. Furthermore, although the U.S. dollar is our reporting currency, a portion of our revenues and profits are generated in foreign currencies. Revenues and profits generated by subsidiaries operating outside of the United States are translated into U.S. dollars using exchange rates effective during the respective period and are affected by changes in exchange rates. As a result, negative movements in currency exchange rates against the U.S. dollar will adversely affect our average selling price and consequently the amount of revenues and profits in our consolidated financial statements.

As we continue to grow, we are subject to growth related risks, including risks related to capacity constraints at our existing facilities.

We are subject to growth-related risks, including capacity constraints and pressure on our internal systems and personnel. In order to manage current operations and future growth effectively, we will need to continue to implement and improve our operational, financial and management information systems and to hire, train, motivate, manage and retain employees. We may be unable to manage such growth effectively. Any such failure could have a material adverse impact on our business, operations and prospects. In addition, in order to meet the demands from expected volumes and continued international expansion, we intend to open a new manufacturing facility in Juarez, Mexico by the end of 2011. Our ability to plan, construct and equip additional manufacturing facilities is subject to significant risk and uncertainty, including risks inherent in the establishment of a new manufacturing facility, such as:

Hiring and retaining employees;

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Delays and cost overruns as a result of a number of factors, any of which may be out of our control, such as:

- Labor shortages and disputes;
- Delays in government approvals;
- Delays in the customization, delivery and installation of equipment; and
- Production start-up problems;

Implementing, integrating and improving operational and financial systems, procedures and controls, including our computer systems

If the opening of this facility is significantly delayed or demand for our product in 2011 exceeds our current expectations, we may not be able to fulfill orders timely, which may negatively impact our financial results and overall business. Conversely, if demand for our products decreases, the fixed costs associated with excess manufacturing capacity may harm our financial results.

We may never achieve the anticipated benefits from our recent acquisition of Cadent Holdings, Inc. which may have an adverse effect on our business.

We acquired Cadent Holdings, Inc. in April 2011. We acquired Cadent for their people, their technology and their existing revenue streams such as OrthoCAD iQ and iCast in addition to their intra-oral scanning technology. This acquisition is expected to strengthen our ability to drive adoption of Invisalign by integrating Invisalign treatment more fully with mainstream tools and procedures in doctors practices. In addition, we believe that the combination of the two companies will help accelerate the use of intra-oral scanning in the dental industry by leveraging Align s global sales reach, extensive professional and consumer marketing capabilities and large customer base. We may, however, experience difficulties in achieving the anticipated financial or strategic benefits of this acquisition. Potential risks include:

- slower adoption or lack of acceptance for intra-oral scanning products in general,
- difficulty in integrating the technology, operations, internal accounting controls or work force of the acquired business with our existing business,
- diversion of management resources and focus from ongoing business matters,
- retention of key employees following the acquisition,
- delay in expected timing of interoperability of Cadent s iTero and iOC anners with the Invisalign system
- aggressive competition from other manufacturers of intraoral scanners could lengthen the customer evaluation process and result in price reductions and loss of sales,

difficulty dealing with tax, employment, logistics, and other related issues unique to international operations in Israel,

possible impairment of relationships with employees and customers as a result of the integration of the Cadent and Align businesses,,

possible inconsistencies in standards, controls, procedures and policies among Cadent and Align, which may make it more difficult to implement and harmonize company-wide financial reporting, accounting, billing, information technology and other systems;

a large portion of Cadent s operations are located in Israel, accordingly, any increase in hostilities in the Middle East involving Israel may cause interruption or suspension of business operations without warning, and

we may experience negative impact on our results of operations and financial condition from acquisition-related charges, amortization of intangible assets and/or asset impairment charges.

If we cannot successfully integrate the acquired business with our existing business, our results of operations and financial condition could be adversely affected.

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

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

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

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

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

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

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

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

changes in product mix;

if participation in our customer rebate program increases our average selling price will be adversely affected;

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

success of or changes to our marketing programs from quarter to quarter;

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

changes to our effective tax rate;

unanticipated delays in production caused by insufficient capacity;

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

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

aggressive price competition from competitors;

costs and expenditures in connection with litigation;

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

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

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

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

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

Our future success may depend on our ability to develop, manufacture, market, and obtain regulatory approval or clearance of new products. In October 2010, we introduced Invisalign G3, a collection of new features and innovations that touch every product and virtually every system at Align. There can be no assurance that we will be able to successfully develop, sell and achieve market acceptance of these and other new products and applications and enhanced versions of our existing product. The extent of, and rate at which, market acceptance and penetration are achieved by future products is a function of many variables, which include, among other things, our ability to include functionality and features that address customer requirements, compatibility of our computer operating systems and hardware configurations with customers, the availability of third-party reimbursement of procedures using our new products, the existence of competing products and general economic conditions affecting purchasing patterns. In addition, even if our new products are successfully introduced, it is unlikely that they will rapidly gain market share and acceptance primarily due to the relatively long period of time it takes to successfully treat a patient. Since it takes approximately 12 to 24 months to treat a patient, our customers may be unwilling to rapidly adopt our new products until they successfully complete at least one case or until more historical clinical results are available.

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

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

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

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

Our key production steps are performed in operations located outside of the U.S. At our facility in Costa Rica, technicians use a sophisticated, internally developed computer-modeling program to prepare digital treatment plans, which are then transmitted electronically to Juarez, Mexico. These digital files form the basis of the ClinCheck treatment plan and are used to manufacture aligner molds. Our order acquisition, aligner fabrication and shipping operations are conducted in Juarez, Mexico. In addition to the research and development efforts conducted in our San Jose, California facility, we also carry out research and development at locations in San Jose, Costa Rica and Moscow, Russia. In addition, our customer-care, accounts receivable, credit and collections and customer event registration organizations are located at our facility in Costa Rica. Our reliance on international operations exposes us to risks and uncertainties that may affect our business or results of operation, including:

- difficulties in hiring and retaining employees generally, as well as difficulties in hiring and retaining employees with the necessary skills to perform the more technical aspects of our operations;
- difficulties in managing international operations;
- fluctuations in currency exchange rates;
- import and export license requirements and restrictions;

controlling production volume and quality of the manufacturing process;

political, social and economic instability, including as a result of increased levels of violence in Juarez, Mexico;

acts of terrorism and acts of war;

interruptions and limitations in telecommunication services;

product or material transportation delays or disruption, including as a result of health epidemics restricting travel to and from Mexico or as a result of natural disasters, such as earthquakes or volcanic eruptions;

burdens of complying with a wide variety of local country and regional laws;

trade restrictions and changes in tariffs; and

potential adverse tax consequences.

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

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

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

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

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

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

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

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

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

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We are currently focused on adding more functionality into our business enterprise systems to more efficiently integrate these systems with our other system applications, such as customer facing and manufacturing tools, and intend to continue this effort for the foreseeable future. System upgrades and enhancements, including those upgrades and enhancements associated with the launch in the fall of 2010 of Invisalign G3 that touched every product and virtually each of our systems, require significant expenditures and allocation of valuable employee resources. Delays in integration or disruptions to our business from implementation of these new or upgraded systems could have a material adverse impact on our financial condition and operating results. Furthermore, we continuously upgrade our customer facing software applications, specifically the ClinCheck software and the Invisalign Doctor Site. Software applications frequently contain errors or defects, especially when they are first introduced or when new versions are released. The discovery of a defect or error or the incompatibility with the computer operating system and hardware configurations of customers in a new upgraded version or the failure of our primary information systems may result in the following consequences, among others: loss of revenue or delay in market acceptance, damage to our reputation or increased service costs, any of which could have a material adverse effect on our business, financial condition or results of operations.

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

Our success will depend in part on our ability to maintain existing intellectual property and to obtain and maintain further intellectual property protection for our products, both in the U.S. and in other countries. Our inability to do so could harm our competitive position. As of March 31, 2011, we had 170 issued U.S. patents, 127 pending U.S. patent applications, and 77 issued foreign patents, and 132 pending foreign patent applications.

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

Litigation is subject to inherent uncertainties and unfavorable rulings could occur. An unfavorable ruling could include monetary damages or, in cases where injunctive relief is sought, an injunction prohibiting us from selling our products. Any of these results from our litigation could adversely affect our results of operations and stock price.

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

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

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

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

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

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

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

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

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

Our ability to sell our products and generate revenues depends upon our direct sales force within our North American and international markets. As of March 31, 2011, our North American sales organization consisted of 174 people, of which 135 were quota carrying sales representatives and 39 were regional sales managers and administration. Internationally, we had 60 people engaged in sales and sales support as of March 31, 2011. We do not have any long-term employment contracts with the members of our direct sales force. The loss of the services provided by these key personnel may harm our business. If we are unable to retain our direct sales force personnel or replace them with individuals of equivalent technical expertise and qualifications, or if we are unable to successfully instill such technical expertise or if we fail to establish strong relationships with our customers within a relatively short period of time, our revenues and our ability to maintain market share could be materially harmed. In addition, due to our large and fragmented customer base, we may not be able to provide all of our customers with product support immediately upon the launch of a new product. As a result, adoption of new products by our customers may be slower than anticipated and our ability to grow market share and increase our revenues may be harmed.

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

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

product design, development, manufacturing and testing;

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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. For instance, on November 18, 2010, we received a Warning Letter from the FDA, which requested additional documentation relating to our written implemented corrective actions to our Complaint and Medical Device Reporting procedures. We responded to the Warning Letter on November 22, 2010, and we are working closely with the FDA to address their concerns and close the matter. Should we fail to promptly and fully address the issues listed in the Warning Letter may result in further regulatory sanctions, including additional Warning Letters, adverse publicity, refusal to clear or approve applications for new or modified products, injunctions, fines, civil penalties or criminal prosecution. Any FDA enforcement action could have a material adverse effect on us.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

quarterly variations in our results of operations and liquidity;

changes in recommendations by the investment community or in their estimates of our revenues or operating results;

speculation in the press or investment community concerning our business and results of operations;

strategic actions by our competitors, such as product announcements or acquisitions;

announcements of technological innovations or new products by us, our customers or competitors; and

general economic market conditions.

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

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

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

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

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

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

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

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

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

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

redemption of the rights issued under the shareholder rights plan.

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

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

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Government of Costa Rica, granted a twelve year extension of the tax incentives which were previously granted in 2002. Under these incentives, all of the income we earn in Costa Rica during these twelve year incentive periods is subject to reduced rates of Costa Rica income tax. The incentive tax rates will expire in various years beginning in 2017. The Costa Rica corporate income tax rate that would apply, absent the incentives, is 30% for 2011. As a result of these incentives, income taxes were reduced by $12.7 million in 2010. In order to receive the benefit of the incentives, we must hire specified numbers of employees and maintain minimum levels of fixed asset investment in Costa Rica. If we do not fulfill these conditions for any reason, our incentive could lapse and our income in Costa Rica would be subject to taxation at higher rates, which could have a negative impact on our operating results.

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

Not applicable.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

ITEM 4. REMOVED AND RESERVED

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

(a) Exhibits:

Exhibit Number	Description	Filing	Date	Exhibit Number	Filed herewith
10.1	Summary of 2010 Incentive Awards for Named Executive Officers	Form 8-K	02/04/2011		
10.2	Form of Market Stock Unit Agreement (officer)	Form 8-K	02/04/2011	10.1	
10.3	Form of Market Stock Unit Agreement (CEO)	Form 8-K	02/23/2011	10.2	
10.4	Description of Executive Officer Incentive Plan	Form 8-K	02/23/2011	Item 5.02	
10.5	Agreement and Plan of Merger, dated as of March 29, 2011, by and among Align Technology, Inc., Bliss Acquisition Corporation, Cadent Holdings, Inc., U.S. Bank National Association as escrow agent and Shareholder Representative Services LLC as security holder representative.	Form 8-K	03/29/2011	2.1	
10.6	Employment Agreement between Align and Timothy A. Mack dated March 29, 2011, effective April 29, 2011.				*
31.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				*
31.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				*
32.1					*

Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

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Exhibit Number	Description	Filing	Date	Exhibit Number	Filed herewith
101.INS	XBRL Instance Document				*
101.SCH	XBRL Taxonomy Extension Schema Document				*
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document				*
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document				*
101.LAB	XBRL Taxonomy Extension Label Linkbase Document				*
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document				*

Management contract or compensatory plan or arrangement filed as an Exhibit to this form pursuant to Items 14(a) and 14(c) of Form 10-K.

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SIGNATURES

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

ALIGN TECHNOLOGY, INC.

Date May 5, 2011

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

By: /s/ KENNETH B. AROLA
Kenneth B. Arola
Chief Financial Officer and Vice President, Finance

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