ALIGN TECHNOLOGY INC
Form 10-Q
November 04, 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 September 30, 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 October 28, 2011 was 78,544,695.

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

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PART I FINANCIAL INFORMATION

ITEM 1 FINANCIAL STATEMENTS

ALIGN TECHNOLOGY, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per share data)

(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Net revenues (1)	$ 125,894	$ 95,947	$ 350,836	$ 294,233
Cost of net revenues	33,524	21,014	85,103	62,572
Gross profit	92,370	74,933	265,733	231,661
Operating expenses:				
Sales and marketing	34,655	26,905	106,062	83,790
General and administrative	21,609	16,203	66,695	46,159
Research and development	8,926	6,592	27,586	19,104
Litigation settlement		3,310		3,310
Insurance settlement				(8,666)
Amortization of acquired intangible assets	868		1,460	
Total operating expenses	66,058	53,010	201,803	143,697
Profit from operations	26,312	21,923	63,930	87,964
Interest and other income (expense), net	(118)	(83)	(335)	(480)
Net profit before provision for income taxes	26,194	21,840	63,595	87,484
Provision for income taxes	6,930	5,025	17,328	23,136
Net profit	$ 19,264	$ 16,815	$ 46,267	$ 64,348
Net profit per share:				
Basic	$ 0.25	$ 0.22	$ 0.60	$ 0.85
Diluted	$ 0.24	$ 0.22	$ 0.58	$ 0.83
Shares used in computing net profit per share:				
Basic	78,455	76,081	77,735	75,653
Diluted	80,266	78,109	80,040	77,852

(1) The nine months ended September 30, 2010 includes a $14.3 million release of previously deferred revenue for Invisalign Teen replacement aligners.

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

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ALIGN TECHNOLOGY, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands, except per share data)

(unaudited)

	September 30, 2011	December 31, 2010
ASSETS		
Current assets:		
Cash and cash equivalents	$ 202,229	$ 294,664
Marketable securities, short-term	8,185	8,615
Accounts receivable, net of allowance for doubtful accounts of $417 and $735, respectively	86,648	65,430
Inventories	8,278	2,544
Prepaid expenses and other current assets	21,794	17,358
Total current assets	327,134	388,611
Marketable securities, long-term	677	9,089
Property, plant and equipment, net	46,388	30,684
Goodwill	135,743	478
Intangible assets, net	50,279	2,188
Deferred tax asset	22,945	42,439
Other assets	2,754	3,454
Total assets	$ 585,920	$ 476,943
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 14,138	$ 7,768
Accrued liabilities	58,281	51,358
Deferred revenues	47,768	33,848
Total current liabilities	120,187	92,974
Other long-term liabilities	8,857	6,222
Total liabilities	129,044	99,196
Commitments and contingencies (Notes 7 and 10)		
Stockholders equity:		
Preferred stock, $0.0001 par value (5,000 shares authorized; none issued)		
Common stock, $0.0001 par value (200,000 shares authorized; 78,531 and 76,390 issued and outstanding, respectively)	8	8
Additional paid-in capital	588,501	555,851
Accumulated other comprehensive income, net	346	134
Accumulated deficit	(131,979)	(178,246)
Total stockholders equity	456,876	377,747
Total liabilities and stockholders equity	$ 585,920	$ 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)

	Nine Months Ended September 30,	
	2011	**2010**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net profit	$ 46,267	$ 64,348
Adjustments to reconcile net profit to net cash provided by operating activities:		
Deferred taxes	13,506	17,631
Depreciation and amortization	9,099	8,694
Stock-based compensation	14,206	12,138
Amortization of intangibles	4,008	2,100
Amortization of prepaid royalties		827
Benefit from doubtful accounts	(131)	(10)
Loss (gain) on retirement and disposal of fixed assets	(25)	60
Changes in assets and liabilities, net of acquired assets and liabilities:		
Accounts receivable	(16,086)	(9,962)
Inventories	(2,975)	(343)
Prepaid expenses and other assets	522	(3,086)
Accounts payable	3,748	13
Accrued and other long-term liabilities	5,504	6,260
Deferred revenues	10,836	(1,666)
Net cash provided by operating activities	88,479	97,004
CASH FLOWS FROM INVESTING ACTIVITIES:		
Acquisition, net of cash acquired	(186,920)	
Purchase of property, plant and equipment	(21,029)	(11,932)
Puchases of marketable securities		(12,742)
Maturities of marketable securities	8,842	17,474
Other assets	(190)	(1,356)
Net cash used in investing activities	(199,297)	(8,556)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock	19,882	10,907
Employees taxes paid upon the vesting of restricted stock units	(1,481)	(889)
Net cash provided by financing activities	18,401	10,018
Effect of foreign exchange rate changes on cash and cash equivalents	(18)	(29)
Net increase (decrease) in cash and cash equivalents	(92,435)	98,437
Cash and cash equivalents, beginning of period	294,664	166,487
Cash and cash equivalents, end of period	$ 202,229	$ 264,924

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 September 30, 2011, our results of operations for the three and nine months ended September 30, 2011 and 2010, and our cash flows for the nine months ended September 30, 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 and nine months ended September 30, 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.

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. A deliverable constitutes a separate unit of accounting when it has stand-alone value, even if the deliverable is not sold separately.

Invisalign

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.

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.

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.

Scanners and CAD/CAM Services

We recognize revenues from the sales of iTero and iOC scanners and CAD/CAM services. CAD/CAM services include scanning services, extended warranty for the scanners, a range of iTero restorative services and OrthoCAD services, such as OrthoCAD iCast, OrthoCAD iQ, and OrthoCAD iRecord. We sell scanners and services through both our direct sales force and distributors. The scanner sales price includes one year of warranty, and for additional fees, the customer may select an unlimited scanning service agreement over a fixed period of time or extended warranty periods. When scanners are sold with either an unlimited scanning service agreement and/or extended warranty, we allocate revenue based on each element s relative selling price. We estimate the selling price of each element, as if it is sold on a stand-alone basis, taking into consideration historical prices as well as our pricing and discounting strategies. We will continue to review our estimates as we continue to integrate Cadent into our business.

Revenues for unlimited scanning service agreements and extended warranty are recognized ratably over the service periods. If a customer selects a pay per use basis for scanning service fees, the revenue is recognized as the service is provided.

For direct sales and sales to certain distributors, scanner revenue is recognized once the scanner has been installed and on-site training is completed. For other distributors who provide training to the customer, we recognize scanner revenue when the scanner is shipped to the distributor assuming all of the other revenue recognition criteria have been met.

Revenues from iTero restorative services and OrthoCAD services are recognized as the services are provided.

Recent Accounting Pronouncements

In May 2011, the FASB issued ASU 2011-04, Fair Value Measurement (ASC 820): Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRSs. This new accounting standard update provides certain amendments to the fair value measurement guidance and includes some enhanced disclosure requirements. The most significant change in disclosures is an expansion of the information required for Level 3 measurements based on unobservable inputs. The standard is effective for the year beginning after December 15, 2011. We will adopt this standard in the first quarter of 2012 and are currently evaluating the impact of this new standard on our consolidated financial statements and disclosures.

In June 2011, the FASB issued ASU 2011-05, Comprehensive Income (ASC 220): Presentation of Comprehensive Income. This new accounting standard update eliminates the current option to report other comprehensive income and its components in the statement of stockholders equity. Instead, an entity will be required to present items of net income and other comprehensive income in one continuous statement or in two separate statements. The standard is effective for the year beginning after December 15, 2011. Early adoption is permitted, however, we are still determining the period of adoption.

In September 2011, FASB issued ASU 2011-08, Intangibles - Goodwill and Other (ASC 350): Testing Goodwill for Impairment. This new revised accounting standard is intended to reduce the cost and complexity of the annual goodwill impairment test by providing entities an option to perform a qualitative assessment to determine whether further impairment testing is necessary. Specifically, an entity has the option to first assess qualitative factors to determine whether it is necessary to perform the current two-step test. If an entity believes, as a result of its qualitative assessment, that it is more-likely-than-not that the fair value of a reporting unit is less than its carrying amount, the quantitative impairment test is required. Otherwise, no further testing is required. This standard is effective for annual and interim goodwill impairment tests performed for fiscal years beginning after December 15, 2011. We will adopt this standard in the first quarter of 2012 and are currently evaluating its impact on our financial statements.

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Note 2. Marketable Securities and Fair Value Measurements

Our short-term and long-term marketable securities as of September 30, 2011 and December 31, 2010 are as follows (in thousands):

Short-term

September 30, 2011	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Corporate bonds	$ 4,910	$ 1	$ (6)	$ 4,905
Foreign bonds	1,263		(10)	1,253
Agency bonds	2,023	4		2,027
Total	$ 8,196	$ 5	$ (16)	$ 8,185

Long-term

September 30, 2011	Amortized Cost	Gross Unrealized Losses	Fair Value
Corporate bonds	$ 678	$ (1)	$ 677

Short-term

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

Long-term

December 31, 2010	Amortized Cost	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

For the three and nine months ended September 30, 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 September 30, 2011.

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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 and agency bonds. We did not hold any Level 2 liabilities as of September 30, 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 September 30, 2011. The following table summarizes our financial assets measured at fair value on a recurring basis as of September 30, 2011 (in thousands):

Description	Balance as of September 30, 2011	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)
Cash equivalents:			
Money market funds	$ 82,395	$ 82,395	
Short-term investments:			
Corporate bonds	4,905		4,905
Foreign bonds	1,253		1,253
Agency bonds	2,027		2,027
Long-term investments:			
Corporate bonds	677		677
	$ 91,257	$ 82,395	$ 8,862

Note 3. Balance Sheet Components

Inventories

Inventories are comprised of (in thousands):

	September 30, 2011	December 31, 2010
Raw materials	$ 4,991	$ 1,272
Work in process	1,529	1,030
Finished goods	1,758	242
	$ 8,278	$ 2,544

Work in process includes costs to produce the Invisalign and scanner products. Finished goods primarily represent our scanners and ancillary products that support the Invisalign system.

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Accrued liabilities

Accrued liabilities consist of the following (in thousands):

	September 30, 2011	December 31, 2010
Accrued payroll and benefits	$ 30,395	$ 26,551
Accrued litigation settlement		4,549
Accrued income taxes	310	1,936
Accrued sales rebate	6,374	3,826
Accrued sales tax and value added tax	6,624	2,940
Accrued warranty	3,273	2,607
Accrued sales and marketing expenses	2,889	2,955
Other	8,416	5,994
	$ 58,281	$ 51,358

Note 4. Business Combination

On April 29, 2011, we completed the acquisition of Cadent Holdings, Inc. (Cadent) pursuant to the Agreement and Plan of Merger (the Merger Agreement). Cadent is a provider of 3D digital scanning solutions for the orthodontic and dental industry. We expect the acquisition of Cadent to strengthen our ability to drive the adoption of Invisalign by integrating Invisalign treatment more fully with mainstream tools and procedures in doctors practices.

Pursuant to the terms and subject to the conditions set forth in the Merger Agreement, we acquired Cadent, which became a wholly owned subsidiary of Align, for an aggregate cash purchase price of approximately $187.0 million.

The following table summarizes the allocation of the preliminary purchase price as of April 29, 2011 (in thousands):

Assets	$ 16,161
Property, plant and equipment	3,645
Acquired identifiable intangible assets:	
Trademarks (one to fifteen-year useful lives)	10,300
Existing technology (thirteen year useful life)	11,900
Customer relationships (eleven year useful life)	29,900
Goodwill	135,265
Liabilities assumed	(20,171)
Total	$ 187,000

The preliminary allocation is based on estimates, assumptions, valuations and other studies which have not progressed to a stage where there is sufficient information to make a definitive allocation. Accordingly, the allocation will remain preliminary until we have all information to finalize the allocation of the purchase price. We have incurred direct transaction costs of approximately $6.4 million that include investment banking, legal and accounting fees, and other external costs directly related to the acquisition. These costs were expensed as incurred as part of our operating expenses.

Goodwill of $135.3 million represents the excess of the purchase price over the fair value of the underlying net tangible and identifiable intangible assets, and represents the expected synergistic benefits of the transaction and the knowledge and experience of the workforce in place. None of this goodwill will be deductible for tax purposes. Under the applicable accounting guidance, goodwill will not be amortized but will be tested for impairment on an annual basis or more frequently if certain indicators are present. As of September 30, 2011, we are still in the process of assessing the assignment of this goodwill to the appropriate reporting unit or units.

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During the period of May 2011 through September 2011, Cadent contributed revenues of approximately $18.1million and net loss of approximately $6.2 million.

The following table presents the results of Align and Cadent for three and nine months ended September 30, 2011 and 2010, on a pro forma basis, as though the companies had been combined as of the beginning of January 1, 2011 and 2010. The pro forma financial information is presented for informational purposes only and is not indicative of the results of operations that would have been achieved if the acquisition had taken place at the beginning of January 1, 2011 and 2010 or of results that may occur in the future (in thousands):

	Proforma Net Revenues and Net Profit Three Months Ended September 30,		Proforma Net Revenues and Net Profit Nine Months Ended September 30,	
	2011	2010	2011	2010
Net revenues	$ 125,894	$ 105,596	$ 363,563	$ 322,788
Net profit	$ 19,264	$ 16,188	$ 41,967	$ 62,498

Note 5. Goodwill

The change in the carrying value of goodwill for the nine months ended September 30, 2011 is as follows (in thousands):

Balance as of December 31, 2010	$ 478
Goodwill from the Cadent acquisition	135,265
Balance as of September 30, 2011	$ 135,743

Goodwill of $135.3 million as a result of the Cadent acquisition represents the excess of the purchase price over the fair value of the underlying net tangible and identifiable intangible assets, and represents the expected synergistic benefits of the transaction and the knowledge and experience of the workforce in place. Under the applicable accounting guidance, goodwill will not be amortized but will be tested for impairment on an annual basis or more frequently if certain indicators are present.

Note 6. Intangible Assets

Acquired intangible assets

Information regarding our intangible assets as a direct result from the Cadent acquisition is being amortized as follows (in thousands):

	Gross Carrying Amount as of April 29, 2011	Accumulated Amortization	Net Carrying Value as of September 30, 2011
Trademarks	$ 10,300	$ (341)	$ 9,959
Existing technology	11,900	(449)	11,451
Customer relationships	29,900	(1,120)	28,780
	$ 52,100	$ (1,910)	$ 50,190

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Amortization of the acquired existing technology is recorded in cost of revenue, while the amortization of acquired trademarks and customer relationships are included in operating expenses. The following table summarizes the amortization expense of acquired intangible assets for the periods indicated (in thousands):

	Three Months Ended September 30, 2011	Nine Months Ended September 30, 2011
Amortization of acquired intangible assets		
In cost of revenue	$ 267	$ 450
In operating expense	868	1,460
Total	$ 1,135	$ 1,910

The total estimated annual future amortization expense for these acquired intangible assets as of September 30, 2011 is as follows (in thousands):

Fiscal Year	
2011 (remaining 3 months)	$ 1,163
2012	4,452
2013	4,352
2014	4,307
2015	4,285
2016 and thereafter	31,631
Total	$ 50,190

Non-compete Agreements

The non-compete intangible assets represent 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 September 30, 2011 and December 31, 2010, the net carrying value of these non-compete agreements was $0.1 million (net of $13.9 million of accumulated amortization) and $2.2 million (net of $11.8 million of accumulated amortization), respectively.

The total estimated annual future amortization expense for these intangible assets as of September 30, 2011 is $0.1 million. These non-compete intangible assets will be fully amortized by the end of October 2011.

Impairment assessment

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.

Note 7. Legal Proceedings

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 on June 8, 2011, the Court granted our motion to dismiss with leave to amend. On July 22, 2011, the lead plaintiff filed a second amended complaint adding allegations that Align and Mr. Prescott issued a number of purportedly false and misleading statements throughout the class period concerning our ClinAdvisor product Align and Mr. Prescott moved to dismiss the amended complaint. The hearing on that motion is currently scheduled for January 13, 2012. 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 September 30, 2011.

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Note 8. 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 alleged 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 sought 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. The settlement took effect on May 18, 2011. Under the 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. In January 2011, we deposited approximately $8.0 million into an escrow account to pay eligible class members who elected the cash remedy, as well as legal fees and other costs. We recorded a total litigation settlement charge of $4.5 million during the third and fourth quarter of 2010 for this settlement. In early June 2011, payments were made from the escrow account to class members who elected the cash remedy and the remaining balance of the escrow has been refunded to Align, except for a nominal amount which has been retained for administrative purposes. As of September 30, 2011, we have no further liability related to this matter.

Note 9. 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 September 30, 2011, we had no outstanding borrowings under this credit facility and are in compliance with the financial covenants.

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Note 10. Commitments and Contingencies

Operating Leases

As of September 30, 2011, minimum future lease payments for non-cancelable leases are as follows (in thousands):

Fiscal Year	
2011 (remaining 3 months)	$ 1,659
2012	6,193
2013	4,787
2014	3,546
2015	3,206
2016 and thereafter	5,334
Total	$ 24,725

Warranty

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.

Invisalign

We warrant our Invisalign 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.

Scanners

We warrant our scanners for a period of one year, which include materials and labor. Extended warranty may be purchased for additional fees. We accrue for these warranty costs based on average historical repair costs.

The following table reflects the change in our warranty accrual during the nine months ended September 30, 2011 and 2010, respectively (in thousands):

	Nine Months Ended September 30,	
	2011	2010
Balance at beginning of period	$ 2,607	$ 2,376
Charged to cost of revenues	2,601	2,212
Assumed warranty from Cadent	350	
Actual warranty expenses	(2,285)	(1,930)
Balance at end of period	$ 3,273	$ 2,658

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Note 11. Stock-based Compensation

Summary of stock-based compensation expense

On May 19, 2011 the Shareholders approved an increase of 3,000,000 shares to the 2005 Incentive Plan (as amended) for a total reserve of 16,283,379 shares for issuance, plus up to an aggregate of 5,000,000 shares that would have been returned to our 2001 Stock Incentive Plan as a result of termination of options on or after March 28, 2005.

Stock-based compensation expense is based on the estimated fair value of awards, net of estimated forfeitures and recognized over the requisite service period on a straight line basis. 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 and nine months ended September 30, 2011 and 2010 are as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Cost of revenues	$ 421	$ 399	$ 1,378	$ 1,237
Sales and marketing	1,416	1,280	3,949	3,387
General and administrative	2,372	2,141	6,813	5,960
Research and development	745	594	2,066	1,554
Total stock-based compensation expense	$ 4,954	$ 4,414	$ 14,206	$ 12,138

Options

Activity for the nine months period ended September 30, 2011 under the stock option plans are set forth below (in thousands, except years and per share amounts):

	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	421	22.07		
Exercised	(1,354)	10.90		
Cancelled or expired	(110)	15.29		
Outstanding as of September 30, 2011	6,772	$ 13.94		
Vested and expected to vest at September 30, 2011	6,626	$ 13.85	5.1	$ 19,510
Exercisable at September 30, 2011	5,099	$ 13.05	4.8	$ 17,096

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
	*			
Stock Options:				
Expected term (in years)		4.4	4.4	4.4
Expected volatility		63.4%	61.0%	63.3%
Risk-free interest rate		1.5%	1.7%	1.9%
Expected dividend				
Weighted average fair value per share at grant date	$	$ 7.28	$ 10.87	$ 9.06

* There were no stock options granted during the three months ended September 30, 2011.

As of September 30, 2011, we expect to recognize $11.5 million of total unamortized compensation cost, net of estimated forfeitures, related to stock options over a weighted average period of 2.2 years.

Restricted Stock Units

A summary of the nonvested shares for the nine months ended September 30, 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	748		
Vested and released	(375)		
Forfeited	(55)		
Nonvested as of September 30, 2011	1,223	1.53	$ 18,553

As of September 30, 2011 the total unamortized compensation cost related to restricted stock units, net of estimated forfeitures, was $15.6 million, which we expect to recognize over a weighted average period of 2.6 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.

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The following table summarizes the MSU performance as of September 30, 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	138,200		
Vested and released			
Forfeited			
Nonvested as of September 30, 2011	138,200	1.9	$ 2,096

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

As of September 30, 2011, we expect to recognize $1.8 million of total unamortized compensation cost, net of estimated forfeitures, related to MSU over a weighted average period of 1.9 years. There were no MSUs granted during the third quarter of 2011.

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.

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 September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Employee Stock Purchase Plan:				
Expected term (in years)	1.2	1.3	1.2	1.3
Expected volatility	44.9%	53.4%	43.2%	55.9%
Risk-free interest rate	0.3%	0.4%	0.4%	0.4%
Expected dividend				
Weighted average fair value per share at grant date	$ 7.46	$ 6.87	$ 7.29	$ 7.22

As of September 30, 2011, we expect to recognize $2.2 million of the total unamortized compensation cost related to employee purchases over a weighted average period of 0.5 years.

Note 12. 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 third quarter of fiscal 2011, the amount of unrecognized tax benefits was increased by approximately $1.0 million. The total amount of unrecognized tax benefits was $14.0 million as of September 30, 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 2006.

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Note 13. 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 September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Net profit	$ 19,264	$ 16,815	$ 46,267	$ 64,348
Weighted-average common shares outstanding, basic	78,455	76,081	77,735	75,653
Effect of potential dilutive common shares	1,811	2,028	2,305	2,199
Total shares, diluted	80,266	78,109	80,040	77,852
Basic net profit per share	$ 0.25	$ 0.22	$ 0.60	$ 0.85
Diluted net profit per share	$ 0.24	$ 0.22	$ 0.58	$ 0.83

For the three and nine months ended September 30, 2011, stock options and restricted stock units totaling 1.9 million and 1.8 million, respectively, were excluded from diluted net profit per share because of their anti-dilutive effect. For the three and nine months ended September 30, 2010, stock options and restricted stock units totaling 3.3 million and 3.0 million, respectively, were excluded from diluted net profit per share because of their anti-dilutive effect.

Note 14. 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 September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Net profit	$ 19,624	$ 16,815	$ 46,267	$ 64,348
Foreign currency translation adjustments	(23)	585	1	(120)
Change in unrealized gains on available-for-sale securities	(375)	(18)	211	(18)
Comprehensive income	$ 19,226	$ 17,382	$ 46,479	$ 64,210

Note 15. Segments and Geographical Information

Segment Information

Operating segments are defined as components of an enterprise about which separate financial information is available that is evaluated regularly by the Chief Operating Decision Maker (CODM), or decision-making group, in deciding how to allocate resources and in assessing performance. Currently, the CODM is the Chief Executive Officer. We report segment information based on the management approach. The management approach designates the internal reporting used by management for making decisions and assessing performance as the source of

our reportable segment. During all periods presented, we operated as a single business segment based on the decisions and performance assessment of Align by our CODM.

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Geographical Information

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Net revenues:				
North America	$ 93,925	$ 72,555	$ 263,047	$ 223,141
Europe	27,583	22,280	79,734	68,085
Other international	4,386	1,112	8,055	3,007
Total net revenues	$ 125,894	$ 95,947	$ 350,836	$ 294,233

	As of September 30, 2011	As of December 31, 2010
Long-lived assets:		
North America	$ 41,029	$ 31,381
Europe	1,515	837
Other international	6,597	1,919
Total long-lived assets	$ 49,141	$ 34,137

Note 16. Subsequent Event

On October 27, 2011, we announced that our Board of Directors approved a stock repurchase program pursuant to which we may repurchase up to $150.0 million of common stock. Purchases under the stock repurchase program may be made from time to time in the open market.

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

In addition to historical information, this quarterly report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. These statements include, among other things, our expectations regarding the anticipated impact of our new products and product enhancements, including Invisalign G3 and G4, 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 about the timing of Invisalign interoperability with iTero 4.0, our expectations to increase our investment in manufacturing capacity, our expectations regarding the continued expansion of our international markets, the timing of our plans and transition into a new manufacturing facility , 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.

Align Technology, Inc (We , Our , Align) designs, manufactures and markets the Invisalign system and the iTero and iOC scanning system and services. 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. On April 29, 2011, we acquired Cadent Holdings, Inc, the manufacturer of the iTero and iOC digital intra-oral scanners and provider of CAD/CAM (computer-aided design and computer-aided manufacturing) restorative models for use by general dentists and/or labs and of services for orthodontic digital procedures. For the third quarter of 2011, Invisalign revenues represent approximately ninety-one percent of worldwide revenue, while the scanning products and services represent the remaining nine percent of worldwide revenues.

Invisalign System and Services

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 Invisalign 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 10 previously 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 10 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 10 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.

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Scanners and CAD/CAM Services

On April 29, 2011, we acquired privately-held Cadent Holdings, Inc, a manufacturer of 3D digital intra-oral scanners and provider of CAD/CAM (computer-aided design and computer-aided manufacturing) restorative models for use by GPs and/or labs and of services for orthodontic digital procedures. We paid approximately $187 million in exchange for all shares of Cadent.

Intra-oral scanners which are comprised of a mobile computer unit, display screen, a control foot pedal and scanning wand are used by dental professionals to scan a patient s full or partial arch dentition. The iTero software captures the contours of the patient s dentition, gingival structures and the bite, without the use of powder, resulting in an accurate digital orthodontic scan in minutes ready for immediate viewing on the screen. The 3D digital model file can then be used for various procedures and services including, fabrication of physical dental models for use by labs to create restorative units such as veneers, inlays, onlays, crowns, bridges and implant abutments; manufacturing of Invisalign treatment aligners; digital records storage; or orthodontic diagnosis and computer aided placement of traditional braces.

The Cadent family of products includes the iTero and iOC scanning systems, both based on the iTero platform but modified slightly with features to better suit our two distinct channels; the orthodontist (iOC system) and the restorative dentists including the GP, Prosthodontist, Periodontist, and Oral Surgeon (iTero system). In addition, we offer a range of iTero restorative services and OrthoCAD services OrthoCAD iCast , OrthoCAD iQ , and OrthoCAD iRecord . iTero restorative services including models and dies provide a GP or lab of choice with a fabricated or milled physical dental model used to create restorative units such as veneers, inlays, onlays, crowns, bridges and implant abutments, from single units to full arches. OrthoCAD iCast provides a digital alternative to traditional stone cast models which allows for simplified storage and digital record retrieval. The iCast digital model contains a full ABO (American Board of Orthodontics) base and can be fabricated from a traditional impression or iOC digital impression. OrthoCAD iRecord provides a digital alternative to traditional stone cast models which allows for simplified storage and digital record retrieval when initiated from a digital impression. OrthoCAD iQ uses the 3D digital model as a digital guide for optimal bracket placement and the creation of customized indirect bonding trays. OrthoCAD iQ services are available from traditional PVS impressions and iOC digital impressions.

Upon purchase of a scanner, one of our technical trainers will help install and train the dental professional on the system and services. To start a new digital impression (quadrant, expanded quadrant or full arch), upon completion of the digital prescription, the dental professional places the wand on one side of the patient s mouth as indicated by the system and activates the wand to capture 1-3 teeth per scan, then moves the wand to the next set of teeth. This guided scanning process continues until all of the teeth are captured. During the scanning process the images are merged together. Upon completion of each scanning segment the user can evaluate the digital impression and add data as needed to complete the model. Currently, our iOC customers who wish to submit scans for Invisalign treatment options must first take the initial one day Invisalign training course and then enable the Invisalign option on the system.

On May 16, 2011, we introduced iOC 4.0 which includes new software features such as the eraser tool and edge trim tool, a simplified graphic user interface and application tools including connectivity to the Invisalign Doctor Site, providing orthodontists with expanded features to ensure accurate digital impressions for Invisalign treatment. During the third quarter of 2011, we began a phased rollout of the iTero 4.0 Real Time Modeling (RTM) upgrade. The first phase includes the new 4.0 user interface, RTM scanning protocol and other key software features. These users will also have improved digital workflows for both the Straumann® and Biomet 3i® fixture level implant integrations with new detailed implant prescription options. The second phase will include Invisalign interoperability which will be available by year-end. We distribute scanners and services to our customers: the orthodontist, general dentist, prosthodontist, oral surgeon, periodontist and dental laboratory. In North America, scanners and services are sold through our direct sales force and distributors. In Europe, and other regions outside of North America, we use a distributor model for the sale of our scanner products and services.

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 2011, we announced Invisalign G4, our next generation of clinical and product innovations designed to help doctors succeed with a wider range of complex treatment and challenging tooth movements. Available to our customers worldwide on November 14, 2011, the Invisalign G4 feature set expands on Invisalign G3 innovations launched in October 2010, which first introduced new aligner and software features that make it easier to use Invisalign when treating patients with Class II and Class III malocclusion. The new and improved SmartForce features in Invisalign G4 are engineered to help doctors achieve even better clinical results for open bite treatments, more predictable movement of upper laterals, and improved root control for canines and central incisors. We believe that, in addition to an increase in the number of patients visiting dental offices throughout 2011 as reported by our customers, and patient interest in higher value procedures, Invisalign G3

was an important contributor to the increased utilization in 2011 by our North American Ortho customer. Additionally, since most of our international customers are Orthodontists, we believe the international launch of Invisalign G3 in May 2011 was important for continued growth both in our existing international markets and to support our expansion in new markets like China. We expect that the innovations in G4 will build on the success we have seen with Invisalign G3 and encourage even greater confidence and adoption in our customers practices. Although we expect that over the long-term these types of product of clinical innovation will increase adoption, it is difficult to predict the adoption which may vary by region and channel.

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Investments to Increase Manufacturing Capacity. We expect capital expenditures to continue 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, in September 2011 we purchased a manufacturing facility in Juarez, Mexico, adding approximately 150,000 square feet of space. This new property is in addition to our existing manufacturing facility in Juarez. We paid approximately $3.2 million in cash for the property. We plan to transition our aligner fabrication and scanner related activities into this facility in 2012. The lease on our existing facility expires in July 2013. 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, or if the timing of receipt of case product orders during a given quarter is different from our expectations, we may not be able to fulfill orders timely, which may negatively impact our financial results and overall business.

Consolidation of New Jersey Operations. In September 2011, we announced plans to consolidate our CAD/CAM services and scanner-related activities based in Carlstadt, New Jersey with our existing manufacturing and shared services organizations in order to optimize efficiency, consolidate customer-facing functions, and reduce operating costs. All existing scanner research and development and manufacturing operations will remain in Or Yehuda, Israel. These actions include a phased transition of the following activities over the next few quarters:

- Consolidation of customer care for CAD/CAM services and scanners into our existing shared services organization in San Jose, Costa Rica;
- Transition of CAD/CAM services and scanner distribution and repair to our Treat operations in San Jose, Costa Rica and our manufacturing facility in Juarez, Mexico; and
- Consolidation of accounting and finance functions at our corporate headquarters in San Jose, California; and
- Closure of the New Jersey facility by the third quarter of 2012.

The consolidation of our New Jersey operations includes a total reduction of 119 full time headcount in Carlstadt, New Jersey. The transition began in the fourth quarter of 2011 and is expected to be completed by the third quarter of 2012. As part of this consolidation, we will incur costs for severance estimated to be approximately $2.0 million, of which approximately $1.1 million will be realized in 2011 and $0.9 million over the first three quarters of 2012. After the New Jersey consolidation is complete, we expect to realize annualized net savings of approximately $4.0 million per year. *See Part II, Item 1A Risk Factors for risks related to the Consolidation of New Jersey Operations .*

Number of new Invisalign doctors trained. We continue to expand our Invisalign customer base through training new doctors. We expect to train approximately 3,100 GPs and orthodontists in North America in 2011, approximately 820 more than we trained in 2010. Internationally, we plan to train approximately 2,600 doctors in 2011, approximately 850 more than we trained in 2010.

Invisalign 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:

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

Total utilization in the third quarter of 2011 remained unchanged at 4.0 cases per doctor. Utilization among the North American Ortho increased to 7.1 cases per doctor. This increase in utilization reflects continued penetration into the North American Ortho practices due to a number of factors, including the availability of Invisalign G3 designed to make it easier to use Invisalign with more complex and challenging cases and increased growth in teenage cases driven by the Invisalign Teen product in the third quarter, which is the peak of the season for Teen orthodontic case starts.

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.

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 Invisalign cases, especially our European doctors.

In 2011, sequential case growth from second quarter to the third quarter in the North American Ortho channel was up approximately 5.0% and the North American GP channel was essentially flat. 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 with the availability of Invisalign Teen, we can now actively compete for a share of teenage patient starts during the summer months.

Acquisition of Cadent. On April 29, 2011, we acquired privately-held Cadent, a leading provider of 3D digital scanning solutions for orthodontics and dentistry. Interoperability with Invisalign is available on the OrthoCAD iOC system with the latest software version iOC 4.0. We expect the interoperability with the iTero 4.0 scanning software will be available by the end of 2011. 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. We may, however, experience difficulties in achieving the anticipated financial or strategic benefits of the acquisition. Information regarding risks associated with the Cadent acquisition may be found in *Item 1A of this Quarterly Report on Form 10-Q under the heading Risk Factors.*

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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.

Expansion of international markets. In October 2010, we announced regulatory approval to market and sell Invisalign in China and began sales during 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 in the long term. In the fourth quarter of 2011, Invisalign became available in the Middle East, and we also expect to receive regulatory approval in Russia by the end of 2011. We do not anticipate that either of these regions will contribute to our revenues significantly for the next several years.

Gross Margin and Operating Expenses. We expect gross margins in the fourth quarter of 2011 to decrease slightly compared to the third quarter primarily due to higher spending as we expand our manufacturing capacity in Juarez, Mexico, as well as higher training and product costs for Invisalign as we anticipate an increased amount of aligners per case and can address even more complex cases due to the features in G3 and G4. We also expect operating expenses to increase in the fourth quarter compared to the third quarter of 2011, primarily reflecting additional sales headcount.

Stock Repurchase. On October 27, 2011, we announced that our Board of Directors approved a stock repurchase program pursuant to which we may repurchase up to $150.0 million of common stock. Purchases under the stock repurchase program may be made from time to time in the open market.

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Results of Operations

Net revenues and case volume by channel and product:

Invisalign, scanner, and CAD/CAM service revenues by channel and other Invisalign non-case revenues, which represents training, retainer and ancillary products, for the three and nine months ended September 30, 2011 and 2010 are as follows (in millions):

	Three Months Ended September 30,				Nine Months Ended September 30,			
Net revenues	**2011**	**2010**	**Net Change**	**% Change**	**2011**	**2010**	**Net Change**	**% Change**
North America:								
Ortho	$ 42.6	$ 31.1	$ 11.5	37.0%	$ 117.5	$ 88.4	$ 29.1	32.9%
GP	46.1	36.8	9.3	25.3%	130.4	111.4	19.0	17.1%
Total North America	88.7	67.9	20.8	30.6%	247.9	199.8	48.1	24.1%
International	30.9	23.2	7.7	33.2%	85.2	65.2	20.0	30.7%
Total revenues	119.6	91.1	28.5	31.3%	333.1	265.0	68.1	25.7%
Invisalign Teen deferred revenue release				0.0%		14.3	(14.3)	N/A
Invisalign non-case revenues	6.3	4.8	1.5	31.3%	17.7	14.9	2.8	18.8%
Total net revenues	$ 125.9	$ 95.9	$ 30.0	31.3%	$ 350.8	$ 294.2	$ 56.6	19.2%

Case volume data which represents Invisalign case shipments by channel, for the three and nine months ended September 30, 2011 and 2010 are as follows (in thousands):

	Three Months Ended September 30,				Nine Months Ended September 30,			
Invisalign case volume	**2011**	**2010**	**Net Change**	**% Change**	**2011**	**2010**	**Net Change**	**% Change**
North America:								
Ortho	30.1	23.2	6.9	29.7%	85.5	68.4	17.1	25.0%
GP	31.1	26.8	4.3	16.0%	90.1	83.8	6.3	7.5%
Total North American Invisalign	61.2	50.0	11.2	22.4%	175.6	152.2	23.4	15.4%
International Invisalign	18.2	16.2	2.0	12.3%	51.2	45.1	6.1	13.5%
Total Invisalign case volume	79.4	66.2	13.2	19.9%	226.8	197.3	29.5	15.0%

Invisalign, scanner, and CAD/CAM service revenues by product and other Invisalign non-case revenues, which represents training, retainer and ancillary products, for the three and nine months ended September 30, 2011 and 2010 are as follows (in millions):

	Three Months Ended September 30,				Nine Months Ended September 30,			
Net revenues	**2011**	**2010**	**Net Change**	**% Change**	**2011**	**2010**	**Net Change**	**% Change**
Invisalign Full	$ 75.1	$ 66.6	$ 8.5	12.8%	$ 222.8	$ 199.8	$ 23.0	11.5%
Invisalign Express/Lite	10.5	8.9	1.6	18.0%	31.7	26.3	5.4	20.5%
Invisalign Teen (1)	15.4	11.3	4.1	36.3%	40.1	42.2	(2.1)	(5.0)%
Invisalign Assist	7.0	4.3	2.7	62.8%	20.4	11.0	9.4	85.5%

Non-case revenues	6.3	4.8	1.5	31.3%	17.7	14.9	2.8	18.8%
Scanners (2)	5.4		5.4	N/A	8.1		8.1	N/A
CAD/CAM Services (2)	6.2		6.2	N/A	10.0		10.0	N/A
Total net revenues	$ 125.9	$ 95.9	$ 30.0	31.3%	$ 350.8	$ 294.2	$ 56.6	19.2%

(1) The nine months ended September 30, 2010 includes a $14.3 million release of previously deferred revenue for Invisalign Teen replacement aligners.

(2) As the acquisition of Cadent closed on April 29, 2011, the nine months ended September 30, 2011 balances for scanners and CAD/CAM services only reflect five months of revenues.

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Case volume data which represents Invisalign case shipments by product, for the three and nine months ended September 30, 2011 and 2010 are as follows (in thousands):

	Three Months Ended September 30,				Nine Months Ended September 30,			
Invisalign case volume	**2011**	**2010**	**Net Change**	**% Change**	**2011**	**2010**	**Net Change**	**% Change**
Invisalign Full	51.4	44.9	6.5	14.5%	150.6	135.7	14.9	11.0%
Invisalign Express/Lite	11.0	9.8	1.2	12.2%	32.8	28.6	4.2	14.7%
Invisalign Teen	11.7	7.6	4.1	53.9%	28.2	21.8	6.4	29.4%
Invisalign Assist	5.3	3.9	1.4	35.9%	15.2	11.2	4.0	35.7%
Total Invisalign case volume	79.4	66.2	13.2	19.9%	226.8	197.3	29.5	15.0%

Total net revenues increased for the three and nine months ended September 30, 2011 as compared to the same period in 2010 primarily as a result of worldwide volume growth across all customer channels as well as the sales of scanners and CAD/CAM services resulting from our acquisition of Cadent, Inc. in April 2011.

North America

North America revenue increased 30.6% for the three months ended September 30, 2011 compared to the same period in 2010 was driven by increases in case volume and the inclusion of scanners and CAD/CAM service revenues, which were partially offset by Invisalign discount and rebate programs.

North America revenue increased 24.1% for the nine months ended September 30, 2011 compared to the same period in 2010, primarily due to higher case volume, and the inclusion of scanner and CAD/CAM services revenues. Additionally for the nine months ended September 30, 2011, we had increased revenue from our Invisalign Assist product primarily due to the shipment of final batches that were previously deferred in 2010. Though case volume for Invisalign Teen increased, Invisalign Teen revenue decreased for the nine month period due to the one-time release of $14.3 million in the second quarter of 2010 of previously deferred revenue for Invisalign Teen replacement aligners. When we released the deferred revenue, we also established an estimated usage rate for Invisalign Teen replacement aligners, which reduced the deferral rate.

International

International revenue increased 33.2% and 30.7% for the three and nine months ended September 30, 2011 compared to the same periods of 2010 primarily due to the growth in case volumes of 12.3% and 13.5%, respectively and the inclusion of scanner and CAD/CAM service revenues. Additionally, for the three and nine months ended September 30, 2011, we had favorable exchange rates of approximately $2.8 million and $5.1 million, respectively.

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Cost of revenues and gross profit (in millions):

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2011	2010	Change	2011	2010	Change
Cost of revenues	$ 33.5	$ 21.0	$ 12.5	$ 85.1	$ 62.6	$ 22.5
% of net revenues	26.6%	21.9%		24.3%	21.3%	
Gross profit	$ 92.4	$ 74.9	$ 17.5	$ 265.7	$ 231.7	$ 34.0
Gross margin	73.4%	78.1%		75.7%	78.7%	

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

Gross margin decreased for the three and nine months ended September 30, 2011 compared to the same period in 2010 primarily due to the addition of our scanner and services products related to the acquisition of Cadent which carries a lower margin than our Invisalign products. We also incurred amortization costs related to the acquired technology from Cadent of approximately $0.3 million and $0.5 million during the three and nine months ended September 30, 2011, respectively.

Additionally, we incurred approximately $0.2 million of severance and benefit costs in the third quarter of 2011 related to the consolidation of our New Jersey operations, which is expected to continue through the third quarter of 2012. After the New Jersey consolidation is completed, we expect to realize annualized net savings of approximately $4.0 million per year.

Gross margin for the nine months ended September 30, 2010 included the final amortization of the Ormco royalties of $0.8 million during the first quarter of 2010.

Sales and marketing (in millions):

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2011	2010	Change	2011	2010	Change
Sales and marketing	$ 34.7	$ 26.9	$ 7.8	$ 106.1	$ 83.8	$ 22.3
% of net revenues	27.5%	28.0%		30.2%	28.5%	

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 September 30, 2011 increased compared to the same period in 2010 primarily due to higher payroll and payroll-related costs of approximately $4.5 million resulting from additional international headcount as well as the inclusion of Cadent sales and marketing personnel. We also incurred higher marketing, advertising, and travel costs of approximately $1.5 million related to our Invisalign products.

Additionally, clinical education costs increased approximately $1.4 million during the third quarter of 2011 as compared to the same period in 2010 as the majority of these costs were included in gross margin in 2010 as part of the Proficiency Program which was eliminated in October 2010.

Our sales and marketing expense for the nine months ended September 30, 2011 increased compared to the same period in 2010 primarily due to higher payroll and payroll-related costs of approximately $10.4 million resulting from additional international headcount as well as the inclusion of Cadent sales and marketing personnel. We incurred higher marketing, travel, and advertising costs of approximately $5.7 million primarily due to targeted TV advertising and the International launch of Invisalign G3. Additionally, increases in clinical education costs of approximately $3.7 million during the first three quarters of 2011 were primarily due to the Invisalign Summit in the second quarter of 2011 which, in 2010, was held in the fourth quarter.

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General and administrative (in millions):

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2011	2010	Change	2011	2010	Change
General and administrative	$ 21.6	$ 16.2	$ 5.4	$ 66.7	$ 46.2	$ 20.5
% of net revenues	17.2%	16.9%		19.0%	15.7%	

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 September 30, 2011 compared to the same period in 2010 primarily due to higher payroll and payroll-related costs of approximately $2.7 million resulting from compensation adjustments and an increase in headcount due to the Cadent acquisition. We also incurred higher consulting, accounting, legal, and travel costs of approximately $2.3 million primarily related to the acquisition and integration of Cadent into our business operations.

General and administrative expense increased for the nine months ended September 30, 2011 compared to the same period in 2010 primarily due higher consulting, accounting, legal, and travel costs of approximately $11.3 million mostly related to the integration of Cadent into our business operations. We also incurred higher payroll and payroll-related costs of $9.1 million resulting from compensation adjustments and an increase in headcount due to the Cadent acquisition.

Research and development (in millions):

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2011	2010	Change	2011	2010	Change
Research and development	$ 8.9	$ 6.6	$ 2.3	$ 27.6	$ 19.1	$ 8.5
% of net revenues	7.1%	6.9%		7.9%	6.5%	

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 September 30, 2011 compared to the same period in 2010 primarily due to higher payroll related costs of approximately $1.8 million resulting from an increase in headcount due to the Cadent acquisition. We also incurred higher travel and outside service costs of approximately $0.4 million primarily related to the integration of Cadent into our business operations.

Research and development expense increased during the nine months ended September 30, 2011 compared to the same period in 2010 primarily due to higher payroll related costs of approximately $4.6 million resulting primarily from an increase in headcount due to the Cadent acquisition. In addition, we paid $2.0 million related the Cadent Joint Development agreement that we entered into in January 2011 before the completion of our acquisition in April 2011. We also incurred higher travel and outside service costs of approximately $0.8 million.

Amortization of acquired intangible assets (in millions):

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2011	2010	Change	2011	2010	Change
Amortization of acquired intangible assets	$ 0.9	$	$ 0.9	$ 1.5	$	$ 1.5
% of net revenues	0.7%			0.4%		

Amortization of acquired intangibles related to operating expense for the three and nine month ended September 30, 2011 was approximately $0.9 million and $1.5 million, respectively, which were related to trademarks and customer relationships that were acquired as part of the Cadent acquisition during the second quarter of 2011.

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Litigation settlement (in millions):

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2011	2010	Change	2011	2010	Change
Litigation settlement	$	$ 3.3	$ (3.3)	$	$ 3.3	$ (3.3)
% of net revenues	0.0%	3.4%		0.0%	1.1%	

On October 19, 2010 we entered into a memorandum of understanding to resolve a complaint filed by Dr. Leiszler. As a result we recorded a litigation settlement charge of $3.3 million in the third quarter of 2010 for settlement costs. There were no litigation settlement charges for the three and nine months ended September 30, 2011.

Insurance settlement (in millions):

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2011	2010	Change	2011	2010	Change
Insurance settlement	$	$	$	$	$ (8.7)	$ 8.7
% of net revenues	0.0%	0.0%		0.0%	2.9%	

In June 2010, we received an $8.7 million insurance settlement over a disputed coverage under our general liability umbrella that was not previously reimbursed by our insurer related to the OrthoClear litigation. There were no insurance settlements during the three and nine months ended September 30, 2011.

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

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2011	2010	Change	2011	2010	Change
Interest income	$ 0.1	$ 0.1	$	$ 0.4	$ 0.4	$
Other income (expense), net	(0.2)	(0.2)		(0.7)	(0.9)	0.2
Total interest income and other income (expense), net	$ (0.1)	$ (0.1)	$	$ (0.3)	$ (0.5)	$ 0.2

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 and nine months ended September 30, 2011 was comparable to the same period in 2010.

Other expense, net for the three and nine months ended September 30, 2011 was comparable to the same period in 2010.

Income tax (in millions):

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2011	2010	Change	2011	2010	Change
Provision for income taxes	$ 6.9	$ 5.0	$ 1.9	$ 17.3	$ 23.1	$ (5.8)

We recorded an income tax provision of $6.9 million and $5.0 million for the three months ended September 30, 2011 and 2010, respectively, representing effective tax rates of 26.5% and 23.1%.

We recorded an income tax provision of $17.3 million and $23.1 million for the nine months ended September 30, 2011 and 2010, respectively, representing effective tax rates of 27.2% and 26.5%.

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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 September 30, 2011, we have recorded a valuation allowance of approximately $20.9 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 (DTAs). Of the $20.9 million of valuation allowance, $14.8 million relates to Cadent s foreign DTAs. 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 DTAs will be realized.

Liquidity and Capital Resources

We fund our operations from product sales and the proceeds from the sale of our common stock. As of September 30, 2011 and December 31, 2010, we had the following cash and cash equivalents, and short-term and long-term investments (in thousands):

	September 30 , 2011	December 31, 2010
Cash and cash equivalents	$ 202,229	$ 294,664
Marketable securities, short-term	8,185	8,615
Marketable securities, long-term	677	9,089
Total	$ 211,091	$ 312,368

Cash flows (in thousands):

	Nine Months Ended September 30, 2011	2010
Net cash flow provided by (used in) :		
Operating activities	$ 88,479	$ 97,004
Investing activities	(199,297)	(8,556)
Financing activities	18,401	10,018
Effects of exchange rate changes on cash and cash equivalents	(18)	(29)
Net increase (decrease) in cash and cash equivalents	$ (92,435)	$ 98,437

As of September 30, 2011, we had $211.1 million of cash, cash equivalents, and marketable securities. Cash equivalents and marketable securities are comprised of money market funds and highly liquid debt instruments which include corporate bonds, foreign bonds, and agency bonds.

As of September 30, 2011, approximately $49.2 million of the $119.8 million of cash was held by our foreign subsidiaries. U.S. taxes have not been provided on the undistributed earnings from non U.S. operations as such earnings are intended to be reinvested permanently outside the U.S.

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Operating Activities

For the nine months ended September, 2011, cash flows from operations of approximately $88.5 million resulted primarily from our net profit of approximately $46.3 million adjusted for the following:

Non-cash activities

Depreciation, amortization, and the amortization of intangibles were approximately $13.1 million including the impact of the acquired assets and intangible assets resulting from the Cadent acquisition.

Stock-based compensation expense was approximately $14.2 million related to equity incentive compensation granted to employees.

Deferred taxes were approximately $13.5 million primarily due to the utilization of our deferred tax assets.

Other non-cash activities including the benefit from doubtful accounts and the gain on the retirement/disposal of our fixed assets of approximately $0.2 million.

Changes in working capital

Accounts receivable increased by approximately $16.1 million due to the increase in revenues during the nine months ended September 30, 2011, reducing our cash inflow from operating activities.

Deferred revenues increased by approximately $10.8 million primarily due to higher sales during the first three quarters of 2011, increasing our cash inflow from operating activities.

Other working capital comprising of inventories, prepaid expenses and other assets, accounts payable, and accrued and other long-term liabilities resulted in a net decrease of approximately $6.8 million, increasing our cash inflow from operations.

For the nine months period ended September 30, 2010, cash flows from operations of approximately $97.0 million resulted primarily from our net profit of approximately $64.3 million adjusted for the following:

Non-cash activities

Deferred taxes were approximately $17.6 million primarily due to the utilization of our deferred tax assets.

Stock-based compensation expense was $12.1 million related to equity incentive compensation granted to employees.

Net other non-cash activities including depreciation and amortization, benefit from doubtful accounts, amortization of prepaid royalties, and loss on the retirement/disposal of our fixed assets of $11.7 million.

Changes in working capital

Accounts receivable increased by approximately $10.0 million due to the increase in revenues during the nine months ended September 30, 2010, reducing our cash inflow from operating activities.

Deferred revenue decreased by $1.7 million primarily due to the release of previously deferred revenue for Invisalign Teen replacement aligners in June 2010 partially offset by higher sales of Invisalign products that carry higher deferral rates, reducing our cash inflow from operating activities.

Other working capital comprised of inventories, prepaid expenses and other assets, accounts payable, and accrued and other long-term liabilities increased $2.8 million, increasing our cash inflow from operations.

Investing Activities

Net cash used in investing activities was $199.3 million for the nine months ended September 30, 2011 primarily consisted of our cash paid for the acquisition of Cadent of approximately $187.0 million and approximately $21.1 million of property, plant, and equipment purchases. These costs were partially offset by $8.8 million of maturities of our marketable securities.

Net cash used in investing activities was $8.6 million for the nine month ended September 30, 2010 primarily consisting of $13.3 million for purchases of property, equipment and other assets, which were partially offset by net maturities of marketable securities of $4.7 million.

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.

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Financing Activities

Net cash provided by financing activities was $18.4 million for the nine months ended September 30, 2011 primarily resulting in $20.0 million in proceeds from the issuance of our common stock, which were partially offset by $1.5 million of taxes paid on the vesting of restricted stock units related to our employee stock plan.

Net cash provided by financing activities was $10.0 million for the nine months ended September 30, 2010 primarily resulting from $10.9 million in proceeds from the issuance of our common stock, which were partially offset by $0.9 million for taxes paid on the vesting of our restricted stock units related to our employee stock plan.

Stock Repurchase

On October 27, 2011, we announced that our Board of Directors approved a stock repurchase program pursuant to which we may repurchase up to $150.0 million of common stock. Purchases under the stock repurchase program may be made from time to time in the open market.

Contractual Obligations

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 condensed consolidated 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, intangible assets, legal contingencies and income taxes. We use authoritative pronouncements, historical experience and other assumptions as the basis for making estimates. Actual results could differ from those estimates.

We believe the following critical accounting policies reflect our most significant estimates, judgments and assumptions used in the preparation of our consolidated financial statements. These critical accounting policies and related disclosures appear in our Annual Report on Form 10-K, with the exception of goodwill, 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;

Goodwill.

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.

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. A deliverable constitutes a separate unit of accounting when it has stand-alone value, even if the deliverable is not sold separately.

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Invisalign

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.

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.

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.

Scanners and CAD/CAM Services

We recognize revenues from the sales of iTero and iOC scanners and CAD/CAM services. CAD/CAM services include scanning services, extended warranty for the scanners, a range of iTero restorative services and OrthoCAD services such as OrthoCAD iCast, OrthoCAD iQ, and OrthoCAD iRecord. We sell scanners and services through both our direct sales force and distributors. The scanner sales price includes one year of warranty, and for additional fees, the customer may select an unlimited scanning service agreement over a fixed period of time or extended warranty periods. When scanners are sold with either an unlimited scanning service agreement and/or extended warranty, we allocate revenue based on each element s relative selling price. We estimate the selling price of each element, as if it is sold on a stand-alone basis, taking into consideration historical prices as well as our pricing and discounting strategies. We will continue to review our estimates as we continue to integrate Cadent into our business.

Revenues for unlimited scanning service agreements and extended warranty are recognized ratably over the service periods. If a customer selects a pay per use basis for scanning service fees, the revenue is recognized as the service is provided.

For direct sales and sales to certain distributors, scanner revenue is recognized once the scanner has been installed and on-site training is completed. For other distributors who provide training to the customer, we recognize scanner revenue when the scanner is shipped to the distributor assuming all of the other revenue recognition criteria have been met.

Revenues from iTero restorative services and OrthoCAD services are recognized as the services are provided.

Goodwill

Goodwill represents the excess of the purchase price paid over the fair value of tangible and identifiable intangible net assets acquired in business combinations. Goodwill is reviewed annually in the fourth quarter and whenever events or circumstances occur which indicate that goodwill might be impaired.

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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 September 30, 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.

Except as described below, there were no changes in our internal control over financial reporting during the third quarter of fiscal year 2011 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. On April 29, 2011, we completed the acquisition of Cadent Holdings, Inc. Refer to Note 4 of Notes to Condensed Consolidated Financial Statements for additional information regarding this event. We plan to exclude this acquisition from the scope of our annual report on internal controls over financial reporting for the period ended December 31, 2011, as permitted by Securities and Exchange Commission guidance. We are in the process of integrating Cadent into our overall internal control over financial reporting process. This process may result in additions or changes to our internal control over financial reporting.

PART II OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

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 on June 8, 2011, the Court granted our motion to dismiss with leave to amend. On July 22, 2011, the lead plaintiff filed a second amended complaint adding allegations that Align and Mr. Prescott issued a

number of purportedly false and misleading statements throughout the class period concerning our ClinAdvisor product. Align and Mr. Prescott moved to dismiss the amended complaint. The hearing on that motion is currently scheduled for January 13, 2012. 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.

Demand for our products may not increase 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 dental services generally, each of which would have a material adverse effect on our sales and operating results. Continued weakness in the global economy results in a challenging environment for selling dental technologies and dentists may postpone investments in capital equipment, such as intra-oral scanners. In addition, Invisalign, which currently accounts for the vast majority of our revenues, represents a significant change from traditional orthodontic treatment, and customers 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 of all of our products will depend in part upon the recommendations of dental professionals, as well as other factors including effectiveness, safety, ease of use, reliability, aesthetics, and price compared to competing products.

The frequency of use of the Invisalign system 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 products that have a higher percentage of deferred revenue, or if sales by our distributors 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. We plan to transition aligner fabrication from our current facilities into this new facility during 2012. 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:

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Hiring and retaining employees;

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; and

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 exceeds our current expectations, we may not be able to fulfill orders timely, which may negatively impact our financial results and overall business. Because we cannot always immediately adapt our production capacity and related cost structures to changing market conditions, our manufacturing capacity may at times exceed or fall short of our production requirements. Any or all of these problems could result in the loss of customers, provide an opportunity for competing products to gain market acceptance and otherwise harm our business and financial results.

We may experience unexpected problems and expenses associated with the consolidation of our New Jersey Operations with Existing Manufacturing and Shared Services Organizations.

In September 2011, we announced plans to consolidate our CAD/CAM services and scanner-related activities based in Carlstadt, New Jersey with our existing manufacturing and shared services organizations. We expect this consolidation to be completed by the third quarter of 2012. This consolidation is accompanied by a number of risks and uncertainties that may affect our results of operations and statement of cash flows, including:

failure to successfully coordinate and phase the relocation of these CAD/CAM services and scanner customer care may cause our customers to experience decrease in service levels;

the relocation may absorb significant management and key employee attention and resources that would otherwise be available for the ongoing development of our business;

failure to retain key employees who possess specific knowledge or expertise and who we are depending upon for the timely and successful transition; and

difficulties hiring employees in Costa Rica and Mexico with the necessary skills to perform these functions.

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

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 or our chairside features,

our inability to increase utilization by integrating Invisalign treatment more fully with intra-oral scanners,

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 scanners with the Invisalign system

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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.

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;

our inability to predict from period to period the number of trainers or the availability of doctors required to complete scanner installations, which may impact the timing of when revenue is recognized.

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;

our reliance on our contract manufacturers for the production of sub-assemblies for our intra-oral scanners;

timing of industry tradeshows;

changes in relationships with our distributors;

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;

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aggressive price competition from competitors;

costs and expenditures in connection with litigation;

the timing of new product introductions by us and our competitors;

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

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

Our future success may depend on our ability to develop, manufacture, market, and obtain regulatory approval or clearance of new products. 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 or software. 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:

correctly identify customer needs and preferences and predict future needs and preferences;

include functionality and features that address customer requirements;

ensure compatibility of our computer operating systems and hardware configurations with those of our customers;

allocate our research and development funding to products with higher growth prospects;

anticipate and respond to our competitors development of new products and technological innovations;

differentiate our offerings from our competitors offerings;

innovate and develop new technologies and applications;

the availability of third-party reimbursement of procedures using our products;

obtain adequate intellectual property rights; and

encourage customers to adopt new technologies.

If we fail to accurately predict customer needs and preferences or fail to produce viable technologies, we may invest heavily in research and development of products that do not lead to significant revenue. Even if we successfully innovate and develop new products and produce enhancements, we may incur substantial costs in doing so, and our profitability may suffer. 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 to our customers. 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.

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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. With the acquisition of Cadent in April 2011, we now also have operations in Israel where the design and wand assembly, scanner manufacturing and digital modeling of our intra-oral scanners occurs. 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 or the Middle East;
- 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 our international locations or as a result of natural disasters, such as earthquakes or volcanic eruptions;
- burdens of complying with a wide variety of local country and regional laws;
- trade restrictions and changes in tariffs; and
- potential adverse tax consequences.

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

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

Training production technicians 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 deliver our products within the timeframe our customers expect. 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 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.

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Competition in the markets for our products is intense and we expect aggressive competition from existing competitors and other companies that may introduce new technologies in the future.

Currently, our products compete directly against products manufactured and distributed by various companies, both within and outside the United States. Many of these manufacturers, including Danaher Corporation, 3M, Sirona Dental Systems, Inc. and Dentsply International, have substantially greater financial resources and manufacturing and marketing experience than we do and may, in the future, attempt to develop an orthodontic system similar to ours 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 use of our products, 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, our information systems and applications require an ongoing commitment of significant resources to maintain, protect and enhance existing systems and develop new systems to keep pace with continuing changes in information processing technology, evolving industry and regulatory standards and changing customer preferences. If the information we rely upon to run our businesses were to be found to be inaccurate or unreliable, if we fail to properly maintain our information systems and data integrity, or if we fail to develop new capabilities to meet our business needs in a timely manner, we could have operational disruptions, have customer disputes, lose our ability to produce timely and accurate reports, have regulatory or other legal problems, have increases in operating and administrative expenses, lose existing customers, have difficulty in attracting new customers or in implementing our growth strategies, or suffer other adverse consequences. In addition, experienced computer programmers and hackers may be able to penetrate our network security and misappropriate our confidential information or that of third parties, create system disruptions or cause shutdowns. Furthermore, sophisticated hardware and operating system software and applications that we either internally develop or procure from third parties may contain defects in design and manufacture, including bugs and other problems that can unexpectedly interfere with the operation of the system. The costs to eliminate or alleviate security problems, viruses and bugs could be significant, and the efforts to address these problems could result in interruptions that may have a material adverse impact on our operations, revenues and operating results.

We are currently focused on adding more functionality into our business enterprise systems to more efficiently integrate these systems with our other system applications, such as customer facing and manufacturing tools, and intend to continue this effort for the foreseeable future. System upgrades and enhancements 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.

Additionally, we continuously upgrade our customer facing software applications, specifically the ClinCheck and MyAligntech 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.

Furthermore, our business requires the secure transmission of confidential information over public networks. Because of the confidential health information we store and transmit, security breaches could expose us to a risk of regulatory action, litigation, possible liability and loss. Our security measures may be inadequate to prevent security breaches, and our business operations and profitability would be adversely affected by, among other things, loss of customers and potential criminal and civil sanctions if they are not prevented.

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There can be no assurance that our process of improving existing systems, developing new systems to support our expanding operations, integrating new systems, protecting confidential patient information, and improving service levels will not be delayed or that additional systems issues will not arise in the future. Failure to adequately protect and maintain the integrity of our information systems and data may result in a material adverse effect on our financial position, results of operations and cash flows.

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.

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

Our success will depend in part on our ability to maintain existing intellectual property and to obtain and maintain further intellectual property protection for our products, both in the U.S. and in other countries. Our inability to do so could harm our competitive position. As of September 30, 2011, we had issued 247 U.S. patents, 133 pending U.S. patent applications, and 171 issued foreign patents, and 140 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. In addition, Cadent was a private company and has not been subject to periodic reporting as a public company. There can be no assurance that the Cadent system of internal control over financial reporting would meet the standards required for

public companies. Establishing, testing and maintaining an effective system of internal control over financial reporting requires significant resources and time commitments on the part of our management and our finance staff, may require additional staffing and infrastructure investments, and would increase our costs of doing business. We plan to exclude them from the scope of our annual report on internal controls over financial reporting for the period ended December 31, 2011. 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 our goodwill or amortizable intangible assets become impaired, we may be required to record a significant charge to earnings.

Under US GAAP, we review our goodwill and amortizable intangible assets for impairment when events or changes in circumstances indicate the carrying value may not be recoverable. Additionally, goodwill is required to be tested for impairment at least annually. The valuations used to determine the fair values used to test goodwill or amortizable intangible assets are dependent upon various assumptions and reflect management s best estimates. Net sales growth, discount rates, earnings multiples and future cash flows are critical assumptions used to determine these fair values. Slower net sales growth rates in the dental industry, an increase in discount rates, unfavorable changes in earnings multiples or a decline in future cash flows, among other factors, may cause a change in circumstances indicating that the carrying value of goodwill or amortizable intangible assets may not be recoverable. We may be required to record a significant charge to earnings in the financial statements during the period in which any impairment of goodwill or amortizable intangible assets is determined.

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, training 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. In addition, our ability to recognize revenue on the direct sales of our scanners depends in part upon our ability to schedule and staff trainings. The loss of the services provided by these individuals or our ability to timely hire such personnel in sufficient numbers based on our volume growth, may harm our business. If we are unable to retain our trainers or replace such individuals with persons having equivalent technical expertise and qualifications, or if we are unable to successfully instill such technical expertise in newly hired personnel or accurately predict the number of such personnel needed, our revenues 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, as well as the optics, electronic and other mechanical components of our scanners. 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. If these or other suppliers encounter financial, operating or other difficulties or if our relationship with them changes, we might not be able to quickly establish or qualify replacement sources of supply and could face production interruptions, delays and inefficiencies. 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. Conversely, in order to secure supplies for production of products, we sometimes enter into non-cancelable purchase commitments with vendors, which could impact our ability to adjust our inventory to reflect declining market demands. If demand for our products is less than we expect, we may experience additional excess and obsolete inventories and be forced to incur additional charges and our profitability may suffer. 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.

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We depend on a single contract manufacturer and supplier of parts used in our iOC and iTero scanners and any disruption in this relationship may cause us to fail to meet the demands of our customers and damage our customer relationships.

We rely on a third party manufacturer in Israel to assemble our iOC and iTero scanners. As a result, if this third party manufacturer fails to deliver its components or if we lose its services, we may be unable to deliver our products in a timely manner and our business may be harmed. Any difficulties encountered by the third party manufacturer with respect to hiring personnel, and maintaining acceptable manufacturing standards, controls, procedures and policies could disrupt our ability to deliver our products in a timely manner. Finding a substitute manufacturer may be expensive, time-consuming or impossible and could result in a significant interruption in the supply of our intra-oral scanning products. Any failure by our contract manufacturer that results in delays in our fulfillment of customer orders may cause us to lose revenues and suffer damage to our customer relationships.

We primarily 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 primarily depends upon our direct sales force within our North American and international markets. As of September 30, 2011, our North American sales organization consisted of 174 people, of which 146 were quota carrying sales representatives and 28 were regional sales managers and administration. Internationally, we had 64 people engaged in sales and sales support as of September 30, 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.

If our distributor relationships are not successful, our ability to market and sell our products would be harmed and our financial performance will be adversely affected.

We depend on relationships with distributors for the marketing and sales of our products in various geographic regions, and we have a limited ability to influence their efforts. Relying on distributors for our sales and marketing could harm our business for various reasons, including:

- agreements with distributors may terminate prematurely due to disagreements or may result in litigation between the partners;
- we may not be able to renew existing distributor agreements on acceptable terms;
- our distributors may not devote sufficient resources to the sale of products;
- our distributors may be unsuccessful in marketing our products;
- our existing relationships with distributors may preclude us from entering into additional future arrangements with other distributors; and
- we may not be able to negotiate future distributor agreements on acceptable terms.

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

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

product design, development, manufacturing and testing;

product labeling;

product storage;

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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 17, 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 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 may have to pay an excise tax in an amount equal to 2.3 percent of the price for which such manufacturer sells its medical devices. This tax applies to all medical devices, including our products. These taxes, will result in a significant increase in the tax burden on our industry, which could have a material, negative impact on our

results of operations and our cash flows.

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

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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.

Outside of North America, we currently sell our products in Europe, Asia Pacific, Latin America and the Middle East and may expand into other countries from time to time. For 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.

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.

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

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

revenue recognition;

accounting for share-based payments;

and leases.

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 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.

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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 here with
10.1	Conditional Purchase and Sales Agreement between Lexmark International S.A. de C.V. and Aligntech de Mexico S. de. R.L de C.V				*
31.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				*
31.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				*
32.1	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				*
101.INS	XBRL Instance Document				*
101.SCH	XBRL Taxonomy Extension Schema Document				*
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document				*
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document				*
101.LAB	XBRL Taxonomy Extension Label Linkbase Document				*
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document				*

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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 November 4, 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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