

ALIGN TECHNOLOGY INC

Form 10-Q

November 09, 2012

Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2012

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

(State or other jurisdiction of
incorporation or organization)

2560 Orchard Parkway

San Jose, California 95131

(Address of principal executive offices)

(408) 470-1000

(Registrant's telephone number, including area code)

94-3267295

(I.R.S. Employer

Identification Number)

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

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

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

Large accelerated filer	<input checked="" type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input type="checkbox"/>

(Do not check if a 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

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The number of shares outstanding of the registrant's Common Stock, \$0.0001 par value, as of November 2, 2012 was 81,384,625.

Table of Contents

ALIGN TECHNOLOGY, INC.

INDEX

PART I	<u>FINANCIAL INFORMATION</u>	<u>3</u>
ITEM 1.	<u>FINANCIAL STATEMENTS (UNAUDITED):</u>	<u>3</u>
	<u>CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS</u>	<u>3</u>
	<u>CONDENSED CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME</u>	<u>4</u>
	<u>CONDENSED CONSOLIDATED BALANCE SHEETS</u>	<u>5</u>
	<u>CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS</u>	<u>6</u>
	<u>NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS</u>	<u>7</u>
ITEM 2.	<u>MANAGEMENT’S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS</u>	<u>22</u>
ITEM 3.	<u>QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK</u>	<u>36</u>
ITEM 4.	<u>CONTROLS AND PROCEDURES</u>	<u>37</u>
PART II	<u>OTHER INFORMATION</u>	<u>38</u>
ITEM 1.	<u>LEGAL PROCEEDINGS</u>	<u>38</u>
ITEM 1A.	<u>RISK FACTORS</u>	<u>38</u>
ITEM 2.	<u>UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS</u>	<u>51</u>
ITEM 3.	<u>DEFAULTS UPON SENIOR SECURITIES</u>	<u>52</u>
ITEM 4.	<u>MINE SAFETY DISCLOSURES</u>	<u>52</u>
ITEM 5.	<u>OTHER INFORMATION</u>	<u>52</u>
ITEM 6.	<u>EXHIBITS</u>	<u>52</u>
	<u>SIGNATURES</u>	<u>54</u>

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Table of Contents

PART I—FINANCIAL INFORMATION

ITEM 1 FINANCIAL STATEMENTS

ALIGN TECHNOLOGY, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per share data)

(unaudited)

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2012	2011	2012	2011
Net revenues	\$136,496	\$125,894	\$417,201	\$350,836
Cost of net revenues	36,146	33,524	107,291	85,103
Gross profit	100,350	92,370	309,910	265,733
Operating expenses:				
Sales and marketing	36,468	34,655	114,272	106,062
General and administrative	23,892	21,609	68,670	66,695
Research and development	9,952	8,926	31,158	27,586
Impairment of goodwill	24,665	—	24,665	—
Amortization of acquired intangible assets	870	868	2,624	1,460
Total operating expenses	95,847	66,058	241,389	201,803
Profit from operations	4,503	26,312	68,521	63,930
Interest and other income (expense), net	(353) (118) (624) (335
Net profit before provision for income taxes	4,150	26,194	67,897	63,595
Provision for income taxes	4,494	6,930	18,765	17,328
Net profit (loss)	\$(344) \$19,264	\$49,132	\$46,267
Net profit (loss) per share:				
Basic	\$(0.00) \$0.25	\$0.61	\$0.60
Diluted	\$(0.00) \$0.24	\$0.59	\$0.58
Shares used in computing net (loss) profit per share:				
Basic	81,437	78,455	80,356	77,735
Diluted	81,437	80,266	83,016	80,040

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

Table of Contents

ALIGN TECHNOLOGY, INC.

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

(in thousands)

(unaudited)

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2012	2011	2012	2011
Net profit (loss)	\$(344) \$19,264	\$49,132	\$46,267
Foreign currency translation adjustments	248	(375) (108) 211
Change in unrealized gains (losses) on available-for-sale securities, net of tax	73	(23) 43	1
Other comprehensive income (losses)	321	(398) (65) 212
Comprehensive income (loss)	\$(23) \$18,866	\$49,067	\$46,479

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

Table of Contents

ALIGN TECHNOLOGY, INC.
 CONDENSED CONSOLIDATED BALANCE SHEETS
 (in thousands, except per share data)
 (unaudited)

	September 30, 2012	December 31, 2011
ASSETS		
Current assets:		
Cash and cash equivalents	\$304,907	\$240,675
Restricted cash	1,564	4,026
Marketable securities, short-term	23,142	7,395
Accounts receivable, net of allowance for doubtful accounts and returns of \$1,381 and \$780, respectively	105,902	91,537
Inventories	15,137	9,402
Prepaid expenses and other current assets	33,594	31,781
Total current assets	484,246	384,816
Marketable securities, long-term	20,802	—
Property, plant and equipment, net	75,248	53,965
Goodwill	111,162	135,383
Intangible assets, net	46,817	50,022
Deferred tax assets	27,189	22,337
Other assets	2,700	2,741
Total assets	\$768,164	\$649,264
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$14,415	\$19,265
Accrued liabilities	71,949	76,600
Deferred revenues	65,324	52,252
Total current liabilities	151,688	148,117
Other long-term liabilities	14,311	10,366
Total liabilities	165,999	158,483
Commitments and contingencies (Note 7)		
Stockholders' equity:		
Preferred stock, \$0.0001 par value (5,000 shares authorized; none issued)	—	—
Common stock, \$0.0001 par value (200,000 shares authorized; 81,784 and 78,776 issued and outstanding, respectively)	8	8
Additional paid-in capital	676,605	607,240
Accumulated other comprehensive income (loss), net	(19) 46
Accumulated deficit	(74,429) (116,513
Total stockholders' equity	602,165	490,781
Total liabilities and stockholders' equity	\$768,164	\$649,264
The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.		

Table of Contents

ALIGN TECHNOLOGY, INC.
 CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
 (in thousands)
 (unaudited)

	Nine Months Ended September 30,	
	2012	2011 Revised*
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net profit	\$49,132	\$46,267
Adjustments to reconcile net profit to net cash provided by operating activities:		
Deferred taxes	13,165	13,506
Depreciation and amortization	9,214	9,099
Amortization of intangibles	3,330	4,008
Stock-based compensation	15,504	14,206
Excess tax benefit from share-based payment arrangements	(18,140)	(5,988)
Impairment of goodwill	24,665	—
Other	848	(156)
Changes in assets and liabilities, net of acquired assets and liabilities:		
Accounts receivable	(15,460)	(16,086)
Inventories	(5,735)	(2,975)
Prepaid expenses and other assets	(1,620)	522
Accounts payable	(3,888)	3,748
Accrued and other long-term liabilities	(669)	5,504
Deferred revenues	12,674	10,836
Net cash provided by operating activities	83,020	82,491
CASH FLOWS FROM INVESTING ACTIVITIES:		
Release of restricted cash	2,462	—
Purchase of property, plant and equipment	(31,485)	(21,029)
Acquisition, net of cash acquired	—	(186,920)
Purchase of marketable securities	(53,862)	—
Maturities of marketable securities	17,363	8,842
Other assets	(126)	(190)
Net cash used in investing activities	(65,648)	(199,297)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock	40,194	19,882
Common stock repurchase	(9,796)	—
Excess tax benefit from share-based payment arrangements	18,140	5,988
Employees' taxes paid upon the vesting of restricted stock units	(1,719)	(1,481)
Net cash provided by financing activities	46,819	24,389
Effect of foreign exchange rate changes on cash and cash equivalents	41	(18)
Net increase (decrease) in cash and cash equivalents	64,232	(92,435)
Cash and cash equivalents, beginning of the period	240,675	294,664
Cash and cash equivalents, end of the period	\$304,907	\$202,229

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

*See Note 1 of Condensed Consolidated Financial Statements.

Table of Contents

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 results of operations for the three and nine months ended September 30, 2012 and 2011, our comprehensive income for the three and nine months ended September 30, 2012 and 2011, our financial position as of September 30, 2012 and our cash flows for the nine months ended September 30, 2012 and 2011. The Condensed Consolidated Balance Sheet as of December 31, 2011 was derived from the December 31, 2011 audited financial statements.

The results of operations for the three and nine months ended September 30, 2012 are not necessarily indicative of the results that may be expected for the year ending December 31, 2012 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, 2011.

Use of estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America (“U.S.”) requires our management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. Actual results could differ materially from those estimates. On an ongoing basis, we evaluate our estimates, including those related to the fair values of financial instruments, intangible assets and goodwill, useful lives of intangible assets and property and equipment, stock-based compensation, income taxes, and contingent liabilities, among others. We base our estimates on historical experience and on various other assumptions that are believed to be reasonable, the results of which form the basis for making judgments about the carrying values of assets and liabilities.

Revision of Prior Period Financial Statements

In connection with the preparation of our consolidated financial statements for the third quarter of 2012, we determined that we had not correctly recognized the excess tax benefits related to stock-based awards in the first, second, and third quarters of 2011 and the first quarter of 2012.

In accordance with Staff Accounting Bulletin (SAB) No. 99, “Materiality”, and SAB No. 108, “Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements”, we evaluated the materiality of the errors from qualitative and quantitative perspectives, and evaluated the quantified errors under both the iron curtain and the roll-over methods. We concluded that the errors were not material to the financial statements for the first, second and third quarters of 2011 and the first quarter of 2012. We have revised the presentation of the statement of cash flows for the third quarter of 2011 and we will revise the presentation of the first quarter of 2012 statement of cash flows in future periods.

The following tables summarize the effects of the revision on our Condensed Consolidated Balance Sheets and Condensed Consolidated Statement of Cash Flows. The revision did not impact our Condensed Consolidated Statement of Operations for any of the applicable periods.

7

Table of Contents

Balance Sheets

	March 31, 2011 (in thousands)		
	Previously Reported	Adjustment	As Revised
Balance Sheet:			
Deferred tax assets	\$38,024	\$2,068	\$40,092
Total assets	496,982	2,068	499,050
Additional paid-in capital	563,878	2,068	565,946
Total stockholders' equity	402,105	2,068	404,173
	June 30, 2011 (in thousands)		
	Previously Reported	Adjustment	As Revised
Balance Sheet:			
Deferred tax assets	\$28,546	\$5,374	\$33,920
Total assets	547,049	5,374	552,423
Additional paid-in capital	580,274	5,374	585,648
Total stockholders' equity	429,782	5,374	435,156
	September 30, 2011 (in thousands)		
	Previously Reported	Adjustment	As Revised
Balance Sheet:			
Deferred tax assets	\$22,945	\$5,988	\$28,933
Total assets	585,920	5,988	591,908
Additional paid-in capital	588,501	5,988	594,489
Total stockholders' equity	456,876	5,988	462,864
	March 31, 2012 (in thousands)		
	Previously Reported	Adjustment	As Revised
Balance Sheet:			
Deferred tax assets	\$17,612	\$8,043	\$25,655
Total assets	670,436	8,043	678,479
Additional paid-in capital	619,991	8,043	628,034
Total stockholders' equity	523,022	8,043	531,065

Cash flows

	Three Months Ended March 31, 2011 (in thousands)		
	Previously Reported	Adjustment	As Revised
Statement of Cash Flows			
Net cash provided by operating activities	\$17,248	\$(2,068)	\$15,180
Net cash provided by financing activities	3,749	2,068	5,817
Net increase cash and cash equivalents	13,944	—	13,944

Table of Contents

	Six Months Ended June 30, 2011 (in thousands)		
	Previously Reported	Adjustment	As Revised
Statement of Cash Flows			
Net cash provided by operating activities	\$46,944	\$(5,374)) \$41,570
Net cash provided by financing activities	15,128	5,374	20,502
Net increase (decrease) cash and cash equivalents	(126,057)) —	(126,057)
	Nine Months Ended September 30, 2011 (in thousands)		
	Previously Reported	Adjustment	As Revised
Statement of Cash Flows			
Net cash provided by operating activities	\$88,479	\$(5,988)) \$82,491
Net cash provided by financing activities	18,401	5,988	24,389
Net increase (decrease) cash and cash equivalents	(92,435)) —	(92,435)
	Three Months Ended March 31, 2012 (in thousands)		
	Previously Reported	Adjustment	As Revised
Statement of Cash Flows			
Net cash provided by operating activities	\$15,424	\$(8,043)) \$7,381
Net cash provided by financing activities	6,248	8,043	14,291
Net increase (decrease) in cash and cash equivalents	(16,314)) —	(16,314)

Recent Accounting Pronouncements

In May 2011, the FASB issued ASU 2011-04, "Fair Value Measurement (Accounting Standards Codification "ASC" 820): Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRSs." This 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 adopted this standard in the first quarter of 2012, and the adoption of this standard did not have an impact on our condensed consolidated financial statements.

In June 2011, the FASB issued ASU 2011-05, "Comprehensive Income (ASC 220): Presentation of Comprehensive Income." This accounting standard update eliminated the 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. We adopted this standard in the first quarter of 2012 as a separate statement in our condensed consolidated financial statement.

In September 2011, FASB issued ASU 2011-08, "Intangibles—Goodwill and Other (ASC 350): Testing Goodwill for Impairment." This accounting standard update 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 adopted this

standard in the first quarter of 2012, and the adoption of this standard did not have an impact on our condensed consolidated financial statements.

In July 2012, FASB issued ASU 2012-2, "Intangibles—Goodwill and Other (ASC 350): Testing Indefinite-Lived Intangible Assets for Impairment." This accounting standard update applies to long-lived intangible assets, other than goodwill,

9

Table of Contents

that are not subject to amortization on the basis that they have indefinite useful lives. This standard is intended to simplify impairment testing by adding a qualitative review step to assess whether the required quantitative impairment analysis is necessary. Under the new standard, a company will not be required to calculate the fair value of the intangible asset unless it concludes, based on the qualitative assessment, that it is more likely than not that the fair value of that asset is less than its book value. If such a decline in fair value is deemed more likely than not to have occurred, then the quantitative impairment test must be completed; otherwise, the asset is deemed to be not impaired and no further testing is required until the next annual test date (or sooner if conditions or events before that date raise concerns of potential impairment of the asset). The amended impairment guidance does not affect the manner in which fair value is determined. The new guidance is effective for annual and interim impairment tests performed for fiscal years beginning after September 15, 2012, with early adoption permitted. We adopted this standard in the third quarter of 2012, and the adoption of this standard did not have an impact on our condensed consolidated financial statements as we do not have any indefinite-lived intangible assets other than goodwill.

Note 2. Marketable Securities and Fair Value Measurements

Our short-term and long-term marketable securities as of September 30, 2012 and December 31, 2011 are as follows (in thousands):

Short-term

September 30, 2012	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Commercial paper	\$5,197	\$1	\$—	\$5,198
Corporate bonds	15,741	12	(4) 15,749
Foreign bonds	2,190	5	—	2,195
Total	\$23,128	\$18	\$(4) \$23,142

Long-term

September 30, 2012	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Corporate bonds	\$16,758	\$24	\$(1) \$16,781
Foreign bonds	4,012	10	(1) 4,021
Total	\$20,770	\$34	\$(2) \$20,802

Short-term

December 31, 2011	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Corporate bonds	\$4,135	\$—	\$(1) \$4,134
Foreign bonds	1,248	—	(5) 1,243
Agency bonds	2,015	3	—	2,018
Total	\$7,398	\$3	\$(6) \$7,395

For the three and nine months ended September 30, 2012 and 2011, no significant gains or losses were realized on the sale of marketable securities. We had no long-term investments as of December 31, 2011.

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.

Table of Contents

Our Level 1 assets consist of money market funds. We did not hold any Level 1 liabilities as of September 30, 2012.

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 commercial paper, corporate bonds, foreign bonds, agency bonds, and our Israeli severance funds that are mainly invested in insurance policies. We obtain these fair values for level 2 investments from our asset manager for each of our portfolios. Our custody bank and asset managers independently use professional pricing services to gather pricing data which may include quoted market prices for identical or comparable financial instruments, or inputs other than quoted prices that are observable either directly or indirectly, and we are ultimately responsible for these underlying estimates.

We did not hold any Level 2 liabilities as of September 30, 2012.

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, 2012.

The following table summarizes our financial assets measured at fair value on a recurring basis as of September 30, 2012 (in thousands):

Description	Balance as of September 30, 2012	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)
Cash equivalents:			
Money market funds	\$119,787	\$119,787	\$—
Commercial paper	2,550	—	2,550
Short-term investments:			
Commercial paper	5,198	—	5,198
Corporate bonds	15,749	—	15,749
Foreign bonds	2,195	—	2,195
Long-term investments:			
Corporate bonds	16,781	—	16,781
Foreign bonds	4,021	—	4,021
Other assets:			
Israeli severance funds	1,933	—	1,933
	\$168,214	\$119,787	\$48,427

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

Table of Contents

Description	Balance as of December 31, 2011	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)
Cash equivalents:			
Money market funds	\$ 86,897	\$86,897	\$—
Short-term investments:			
Corporate bonds	4,134	—	4,134
Foreign bonds	1,243	—	1,243
Agency bonds	2,018	—	2,018
Other assets:			
Israeli severance funds	1,859	—	1,859
	\$ 96,151	\$86,897	\$9,254

Note 3. Balance Sheet Components

Inventories

Inventories are comprised of (in thousands):

	September 30, 2012	December 31, 2011
Raw materials	\$4,445	\$4,542
Work in process	3,396	2,486
Finished goods	7,296	2,374
	\$15,137	\$9,402

Work in process includes costs to produce our clear aligner and intra-oral scanner products. Finished goods primarily represent our intra-oral scanners and ancillary products that support our clear aligner products. During the first three quarters of 2012, we increased our production volumes of our intra-oral scanners in anticipation of our move to a new facility in Israel which was completed in October 2012.

Accrued liabilities

Accrued liabilities consist of the following (in thousands):

	September 30, 2012	December 31, 2011
Accrued payroll and benefits	\$34,352	\$41,827
Accrued sales rebate	8,501	8,358
Accrued sales tax and value added tax	6,360	7,052
Unclaimed merger consideration	1,564	4,026
Accrued warranty	4,130	3,177
Accrued sales and marketing expenses	2,681	3,508
Accrued accounts payable	2,991	3,048
Accrued professional fees	2,165	654
Customer deposits	2,792	206

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Accrued income taxes	461	426
Other	5,952	4,318
Total	\$71,949	\$76,600

Warranty

We regularly review the accrued balances and update these balances based on historical warranty trends. Actual warranty

12

Table of Contents

costs incurred have not materially differed from those accrued. However, future actual warranty costs could differ from the estimated amounts.

Clear Aligner

We warrant our Invisalign products against material defects until the Invisalign case is complete. We accrue for warranty costs in cost of net 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 from the date of training and installation. We accrue for these warranty costs which includes materials and labor based on estimated historical repair costs. Extended service packages may be purchased for additional fees.

The following table reflects the change in our warranty accrual during the nine months ended September 30, 2012 and 2011, respectively (in thousands):

	Nine Months Ended September 30,	
	2012	2011
Balance at beginning of period	\$3,177	\$2,607
Charged to cost of revenues	3,647	2,601
Assumed warranty from Cadent	—	350
Actual warranty expenditures	(2,694) (2,285
Balance at end of period	\$4,130	\$3,273

Note 4. Business Combination

On April 29, 2011, we completed the acquisition of Cadent Holdings, Inc. (“Cadent”) for an aggregate cash purchase price of approximately \$187.6 million. Cadent is a leading provider of 3D digital scanning solutions for orthodontics and dentistry. We believe that the combination of Align’s and Cadent’s technologies and capabilities creates greater growth opportunities for Align by bringing innovative new Invisalign treatment tools to customers and by extending the value of intra-oral scanning in dental practices.

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

Assets	\$15,745
Property, plant and equipment	3,624
Acquired identifiable intangible assets:	
Trademarks (one to fifteen-year useful lives)	7,100
Existing technology (thirteen year useful life)	12,600
Customer relationships (eleven year useful life)	33,500
Goodwill	135,349
Liabilities assumed	(20,330
Total	\$187,588

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 synergies of the transaction and the knowledge

and experience of the workforce in place. None of the goodwill is deductible for tax purposes. In connection with the acquisition, we allocated approximately \$77.3 million of the goodwill from the Cadent acquisition to our Scanner and CAD/CAM Services ("SCCS") reporting unit and approximately \$58.0 million to our Clear Aligner reporting unit based on the expected relative synergies generated by the acquisition. In the third quarter of 2012, we determined that there were sufficient indicators of a potential impairment to the goodwill attributed to the SCCS reporting unit, therefore we conducted step one of the goodwill impairment analysis and concluded that the goodwill was impaired. Based on our preliminary analysis, we recorded an estimate of \$24.7 million for the SCCS goodwill impairment charge. We expect to finalize step 2 of our goodwill impairment analysis and record

Table of Contents

any change from our estimate, if necessary, during the fourth quarter of 2012. See Note 5 for discussion of our goodwill impairment in the third quarter of 2012.

For the three and nine months ended September 30, 2012, Cadent contributed net revenues of approximately \$9.8 million and \$33.5 million and gross profit of approximately \$2.0 million and \$8.6 million, respectively. During the period of May 2011 through September 2011, Cadent contributed net revenues of approximately \$18.1 million and gross profit of approximately \$4.6 million. Sales, marketing, development and administrative activities for our Clear Aligner and SCCS reporting units were integrated during the post-acquisition period, therefore the operating results below gross profit are not available.

The following table presents the results of Align and Cadent for three and nine months ended September 30, 2011, on a proforma basis, as though the companies had been combined as of January 1, 2011. The proforma 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 as of January 1, 2011 or of results that may occur in the future (in thousands):

	Proforma Net Revenues and Net Profit Three Months Ended September 30, 2011	Proforma Net Revenues and Net Profit Nine Months Ended September 30, 2011
Net revenues	\$ 125,894	\$ 363,563
Net profit	\$ 19,264	\$ 41,967

Note 5. Goodwill and Acquired Intangible Assets

Goodwill

The change in the carrying value of goodwill for the period ended September 30, 2012 is as follows (in thousands):

Balance as of December 31, 2011	\$ 135,383
Adjustments to goodwill (1)	444
Impairment of goodwill	(24,665)
Balance as of September 30, 2012	\$ 111,162

(1) Pursuant to the accounting guidance for business combinations, we recorded goodwill adjustments for the effect on goodwill of changes to net assets acquired related our acquisition of Cadent during the measurement period (up to one year from April 29, 2011, the date of our acquisition of Cadent). Goodwill adjustments were not significant to our previously reported operating results or financial position.

Impairment of Goodwill

We test our goodwill balances for impairment annually on November 30th or more frequently if indicators are present or circumstances change that suggest an impairment may exist. During the third quarter of 2012, we determined that sufficient indicators of potential impairment existed to require an interim goodwill impairment analysis of our SCCS reporting unit. These indicators included the termination of an exclusive distribution arrangement with Straumann for iTero intra-oral scanners in Europe, as well as the termination of their non-exclusive distribution arrangement for iTero intra-oral scanners in North America, together with market conditions and business trends within the SCCS reporting unit. While we continue to expect revenue growth in our SCCS business, our expectations for future growth and profitability rates projected for the SCCS reporting unit are lower than our previous estimates primarily driven by

overall lower than expected financial results.

As of September 30, 2012, we performed step one of the goodwill impairment test, which consists of a comparison of the fair value of the SCCS reporting unit against its carrying amount, including the goodwill allocated to it. In deriving the fair value of the SCCS reporting unit, we utilized a combination of both the income and market approach. The income approach provides an estimate of fair value based on discounted expected future cash flows. The market approach provides an estimate of fair value using various prices or market multiples applied to the reporting unit's operating results and then applies an appropriate control premium. As a result of our step one analysis, we concluded that the fair value of the SCCS reporting unit was less than its carrying value, therefore, the SCCS goodwill is impaired and we must perform step two of the goodwill impairment analysis.

Table of Contents

Step two of the goodwill impairment analysis measures the impairment charge by allocating the reporting unit's fair value to all of the assets and liabilities of the reporting unit in a hypothetical analysis that calculates the implied fair value of goodwill in the same manner as if the reporting unit was being acquired in a business combination. Any excess of the carrying value of the reporting unit's goodwill over the implied fair value of the reporting unit's goodwill is recorded as an impairment loss. Due to the complexity and effort required to estimate the fair value of all assets and liabilities of the reporting unit, the fair value estimates were derived from preliminary assumptions and analyses that are subject to change. Based on our preliminary analysis, the implied fair value of goodwill was substantially lower than the carrying value of the goodwill for the SCCS reporting unit by an estimated \$24.7 million which we recorded as impairment to goodwill in the third quarter of 2012. As of September 30, 2012, the remaining amount of goodwill associated with our SCCS reporting unit is \$52.6 million. In the fourth quarter of 2012, we expect to finalize the step two analysis and, if necessary, record any change from our original estimate.

The declines expected in our SCCS reporting unit did not impact our assumptions related our Clear Aligner reporting unit, however, we will complete our annual goodwill impairment review for both reporting units as of November 30, 2012. If there are changes to our stock price, or significant changes in the business climate or operating results of our reporting units, we may incur additional goodwill impairment charges.

The following table summarizes goodwill by reportable segment as of September 30, 2012 and December 31, 2011 (in thousands):

	Clear Aligner	Scanner and CAD/CAM Services	Total
As of September 30, 2012	\$58,543	\$52,619	\$111,162
As of December 31, 2011	\$58,445	\$76,938	\$135,383

Acquired Intangible assets

In conjunction with our goodwill impairment analysis, we first tested our long-lived assets related to the SCCS reporting unit as of September 30, 2012 and, based on the undiscounted cash flows, we determined that these assets were not impaired. Information regarding our intangible assets either as a direct result from the Cadent acquisition or individually acquired are being amortized as follows (in thousands):

	Gross Carrying Amount as of September 30, 2012	Accumulated Amortization	Net Carrying Value as of September 30, 2012
Trademarks	\$7,100	\$(788)) \$6,312
Existing technology	12,600	(1,440)) 11,160
Customer relationships	33,500	(4,276)) 29,224
Other	125	(4)) 121
	\$53,325	\$(6,508)) \$46,817

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

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	Three Months Ended		Nine Months Ended	
	September 30, 2012	2011	September 30, 2012	2011
Amortization of acquired intangible assets				
In cost of net revenues	\$213	\$267	\$706	\$450
In operating expenses	870	868	2,624	1,460
Total	\$1,083	\$1,135	\$3,330	\$1,910

The total estimated annual future amortization expense for these acquired intangible assets as of September 30, 2012 is as follows (in thousands):

15

Table of Contents

Fiscal Year	
2012 (remaining three months)	\$1,134
2013	4,537
2014	4,493
2015	4,470
2016	4,470
Thereafter	27,713
Total	\$46,817

Note 6. 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, 2012, we had no outstanding borrowings under this credit facility and are in compliance with the financial covenants.

Note 7. Commitments and Contingencies

Operating Leases

As of September 30, 2012, minimum future lease payments for non-cancelable leases are as follows (in thousands):

Fiscal Year	Operating leases
2012 (remaining three months)	\$2,233
2013	7,713
2014	6,969
2015	5,741
2016	5,703
Thereafter	3,059
Total minimum lease payments	\$31,418

Note 8. 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. 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, 2012 and 2011 are as follows (in thousands):

16

Table of Contents

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2012	2011	2012	2011
Cost of net revenues	\$446	\$421	\$1,365	\$1,378
Sales and marketing	1,448	1,416	4,066	3,949
General and administrative	2,657	2,372	7,579	6,813
Research and development	811	745	2,494	2,066
Total stock-based compensation expense	\$5,362	\$4,954	\$15,504	\$14,206

Options

Activity for the nine month period ended September 30, 2012 under the stock option plans are set forth below (in thousands, except years and per share amounts):

	Stock Options Number of Shares Underlying Stock Options	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding as of December 31, 2011	6,190			
Granted (1)	—			
Exercised	(2,635)			
Cancelled or expired	(29)			
Outstanding as of September 30, 2012	3,526	\$15.17	4.65	\$76,880
Vested and expected to vest at September 30, 2012	3,483	\$15.12	4.65	\$76,098
Exercisable at September 30, 2012	2,788	\$14.51	4.55	\$62,627

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

	Three Months Ended		Nine Months Ended		
	September 30,		September 30,		
	2012	2011	2012	2011	
Stock options (1):					
Expected term (in years)	—	—	—	4.4	
Expected volatility	—	—	—	61.0	%
Risk-free interest rate	—	—	—	1.7	%
Expected dividends	—	—	—	—	
Weighted average fair value at grant date	\$—	\$—	\$—	\$10.87	

(1) There were no stock options granted during the three months ended September 30, 2012 and 2011 and for the nine months ended September 30, 2012.

As of September 30, 2012, the total unamortized compensation cost related to stock options, net of estimated forfeitures, is \$5.9 million, which we expect to recognize over a weighted average period of 1.6 years.

Restricted Stock Units (“RSUs”)

A summary of the nonvested shares for the nine months ended September 30, 2012 is as follows (in thousands, except years):

17

Table of Contents

	Number of Shares Underlying RSUs	Weighted Remaining Vesting Period (in years)	Aggregate Intrinsic Value
Nonvested as of December 31, 2011	1,208		
Granted	843		
Vested and released	(414))	
Forfeited	(68))	
Nonvested as of September 30, 2012	1,569	1.54	\$58,000

As of September 30, 2012 the total unamortized compensation cost related to restricted stock units, net of estimated forfeitures, was \$8.3 million, which we expect to recognize over a weighted average period of 2.6 years.

On February 20, 2012 and February 18, 2011, we granted market-performance based restricted stock units (“MSUs”) to our executive officers. Each MSU represents the right to one share of Align’s common stock and will be issued through our amended 2005 Incentive Plan. The actual number of MSUs which will be eligible to vest will be based on the performance of Align’s stock price relative to the performance of the NASDAQ Composite Index over the vesting period, generally two to three years, up to 150% of the MSUs initially granted.

The following table summarizes the MSU performance for the nine months ended September 30, 2012 (in thousands, except years):

	Number of Shares Underlying MSUs	Weighted Average Remaining Vesting Period (in years)	Aggregate Intrinsic Value
Nonvested as of December 31, 2011	128		
Granted	192		
Vested and released	—		
Forfeited	—		
Nonvested as of September 30, 2012	320	1.79	\$11,851

As of September 30, 2012, we expect to recognize \$1.7 million of total unamortized compensation cost, net of estimated forfeitures, related to MSU over a weighted average period of 1.8 years.

Employee Stock Purchase Plan

In May 2010, our shareholders approved the 2010 Employee Stock Purchase Plan (the “2010 Purchase Plan”) to replace the 2001 Purchase Plan. 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 purchase under the 2010 Purchase Plan is 2,400,000 shares. As of September 30, 2012, there remains 1,899,845 shares available for purchase under the 2010 Purchase Plan.

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, 2012		Nine Months Ended September 30, 2011	
Employee Stock Purchase Plan:				

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Expected term (in years)	1.2	1.2	1.2	1.2	
Expected volatility	48.0	% 44.9	% 49.7	% 43.2	%
Risk-free interest rate	0.2	% 0.3	% 0.2	% 0.4	%
Expected dividends	—	—	—	—	
Weighted average fair value at grant date	\$11.99	\$7.46	\$11.10	\$7.29	

As of September 30, 2012, we expect to recognize \$1.2 million of the total unamortized compensation cost related to

18

Table of Contents

employee purchases over a weighted average period of 1.0 year.

Note 9. Common Stock Repurchase Program

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. During the third quarter of 2012, we repurchased approximately 0.2 million shares of common stock at an average price of \$34.15 per share for an aggregate purchase price of approximately \$7.3 million including commissions. The common stock repurchases reduced additional paid-in capital by approximately \$1.9 million and increased accumulated deficit by \$5.4 million. All repurchased shares were retired.

Note 10. Accounting for Income Taxes

During the third quarter of fiscal 2012, the amount of gross unrecognized tax benefits increased by \$0.2 million primarily due to current period exposures. The total amount of unrecognized tax benefits was \$19.3 million as of September 30, 2012, all of which would impact our effective tax rate if recognized. We do not expect any significant changes to the amount of unrecognized tax benefit within the next twelve months.

We are subject to taxation in the U.S., 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. We are currently under audit in Israel for tax years 2006 through 2009. With few exceptions, we are no longer subject to examination by foreign tax authorities for years before 2006.

Note 11. Net Profit Per Share

Basic net profit per share is computed using the weighted average number of shares of common stock outstanding during the period. Diluted net profit per share is computed using the weighted average number of shares of common stock, adjusted for the dilutive effect of potential common stock. Potential common stock, computed using the treasury stock method, includes options, RSUs, MSUs and the dilutive component of our employee stock purchase plan.

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, 2012		Nine Months Ended, September 30, 2011	
Numerator:				
Net profit (loss)	\$(344) \$19,264	\$49,132	\$46,267
Denominator:				
Weighted-average common shares outstanding, basic	81,437	78,455	80,356	77,735
Dilutive effect of potential common stock	—	1,811	2,660	2,305
Total shares, diluted	81,437	80,266	83,016	80,040
Net profit (loss) per share, basic	\$(0.00) \$0.25	\$0.61	\$0.60
Net profit (loss) per share, diluted	\$(0.00) \$0.24	\$0.59	\$0.58

For the three and nine months ended September 30, 2012, stock options, RSUs, MSUs and our employee stock purchase plan totaling 2.5 million and 0.1 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, 2011, stock options, RSUs, MSUs and our employee stock purchase plan totaling 1.9 million and 1.8 million, respectively, were excluded from diluted net profit per share because of their anti-dilutive effect.

Note 12. Segments and Geographical Information

19

Table of Contents

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. Our CODM is our Chief Executive Officer. We report segment information based on the “management” approach. The management approach designates the internal reporting used by management for decision making and performance assessment as the basis for determining our reportable segments. The performance measures of our reportable segments include net revenues and gross profit.

We have grouped our operations into two reportable segments which are also our reporting units: Clear Aligner segment and SCCS segment.

Our Clear Aligner segment consists of our Invisalign system which includes Invisalign Full, Express/Lite, Teen, Assist, Vivera retainers, along with our training and ancillary products for treating malocclusion.

Our SCCS segment consists of intra-oral scanning systems and additional services available with the intra-oral scanners that provide digital alternatives to the traditional cast models. This segment includes our iTero scanners, iOC scanners, and OrthoCAD services.

These reportable operating segments are based on how our CODM views and evaluates our operations as well as allocation of resources (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Revenue				
Clear Aligner	\$126,725	\$ 114,278	\$383,722	\$332,781
Scanners and CAD/CAM Services (1)	9,771	11,616	33,479	18,055
Total	\$136,496	\$ 125,894	\$417,201	\$350,836
Gross profit				
Clear Aligner	\$98,334	\$ 89,813	\$301,340	\$261,143
Scanners and CAD/CAM Services (1)	2,016	2,557	8,570	4,590
Total	\$100,350	\$ 92,370	\$309,910	\$265,733
	As of September 30, 2012	As of December 31, 2011		
Total Assets including goodwill				
Clear Aligner	\$583,832	\$ 469,084		
Scanners and CAD/CAM Services	184,332	180,180		
Total	\$768,164	\$ 649,264		
Goodwill				
Clear Aligner	\$58,543	\$ 58,445		
Scanners and CAD/CAM Services	52,619	76,938		
Total	\$111,162	\$ 135,383		

(1) The SCCS (Scanner and CAD/CAM Services) segment was created as a result of our acquisition of Cadent on April 29, 2011 and the financial results for that segment reflect activity since that date.

In the third quarter of 2012, we determined that there were sufficient indicators of a potential impairment to the goodwill attributed to the SCCS reporting unit, therefore we conducted step one of the goodwill impairment analysis and concluded that the goodwill was impaired. Based on our preliminary analysis, we recorded an estimate of \$24.7

million for the SCCS goodwill impairment charge. We expect to finalize step 2 of our goodwill impairment analysis and record any change from our estimate, if necessary, during the fourth quarter of 2012. See Note 5 for discussion of our goodwill impairment in the third quarter of 2012.

Geographical Information

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

20

Table of Contents

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2012	2011	2012	2011
Net revenues (1):				
United States	\$105,173	\$93,925	\$319,269	\$263,047
the Netherlands	28,335	27,583	90,242	79,734
Other international	2,988	4,386	7,690	8,055
Total net revenues	\$136,496	\$125,894	\$417,201	\$350,836
	As of September	As of December		
	30,	31,		
	2012	2011		
Long-lived assets:				
United States	\$58,614	\$45,720		
the Netherlands	4,791	1,726		
Other international	14,542	9,261		
Total long-lived assets	\$77,947	\$56,707		

(1) Net Revenues are attributed to countries based on location of where revenue is recognized.

Note 13. Exit Activities

In October 2012, we completed the consolidation of our CAD/CAM services and intra-oral 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 intra-oral scanner research and development and manufacturing operations remain in Or Yehuda, Israel. The transition included the following activities:

- Consolidation of customer care for CAD/CAM services and intra-oral scanners into our existing shared services organization in San Jose, Costa Rica;
 - Transition of CAD/CAM services and intra-oral scanner distribution and repair to our Treat operations in San Jose, Costa Rica and our new manufacturing facility in Juarez, Mexico; and
 - Consolidation of accounting and finance functions at our corporate headquarters in San Jose, California.
- The consolidation of our New Jersey operations, which began in the fourth quarter of 2011, resulted in a total reduction of 119 full time headcount in Carlstadt, New Jersey. With the New Jersey consolidation completed, we expect to realize annualized net savings of approximately \$4.0 million per year.

Activity and liability balances related to this exit activity during the first three quarters of 2012 are as follows (in thousands):

	Severance and Benefits
Balance at December 31, 2011	\$1,010
Exit cost incurred during the period	780
Cash payments	(1,729)
Balance at September 30, 2012	\$61

During the first three quarters of 2012, we incurred approximately \$0.8 million in exit costs of which approximately \$0.5 million were recorded in our cost of net revenues and \$0.3 million in operating expenses.

Table of Contents

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

In addition to historical information, this quarterly report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. These statements include, among other things, our expectations regarding the anticipated impact of our new products and product enhancements will have on doctor utilization and our market share, our expectations regarding product mix and product adoption, our expectations regarding the existence and impact of seasonality, our expectations regarding the financial and strategic benefits of the Cadent Holdings, Inc. (“Cadent”) acquisition, our expectations to increase our investment in manufacturing capacity, our expectation on the timing and amount of the impairment charge related to our Scanner and CAD/CAM Services ("SCCS") reporting unit, our expectations regarding the continued expansion of our international markets, the timing of our plans and transition into our new manufacturing facilities, the anticipated number of new doctors trained and their impact on volumes, our expectations regarding the International Scanner and CAD/CAM Services revenues, 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. is a global medical device company that pioneered the invisible orthodontics market with the introduction of the Invisalign system in 1999. Today, we are focused on designing, manufacturing and marketing innovative, technology-rich products to help dental professionals achieve the clinical results they expect and deliver effective, convenient cutting-edge dental treatment options to their patients. Align Technology was founded in March 1997 and is headquartered in San Jose, California with offices worldwide. Our international headquarters are located in Amsterdam, the Netherlands. We have two operating segments: (1) Clear Aligner, known as the Invisalign system; and (2) Scanner and CAD/CAM Services ("SCCS"), known as iTero and iOC intra-oral scanners and OrthoCAD services.

We received FDA clearance in 1998 as a Class II medical device. Commercial sales to U.S. orthodontists began in 1999 followed by U.S General Practitioner Dentists (GPs) in 2002. Over the next decade, we introduced Invisalign to the European market and Japan, added distribution partners in Asia Pacific, Latin America, and EMEA, and introduced a full range of treatment options including Invisalign Express 10, Invisalign Teen, Invisalign Assist, and Vivera retainers. Most recently we launched Invisalign G3 and Invisalign G4, which includes significant new aligner and software features across all Invisalign products that make it easier for doctors to use Invisalign on more complex cases, and introduced Invisalign to the People’s Republic of China.

In 2011, we acquired Cadent Holdings, Inc., a leading provider of 3D digital scanning solutions for orthodontics and dentistry, and makers of the iTero and iOC intra-oral scanners and OrthoCAD services. We believe that the combination of Align’s and Cadent’s technologies and capabilities creates greater growth opportunities for Align by

bringing innovative new Invisalign treatment tools to customers and by extending the value of intra-oral scanning in dental practices. Intra-oral scanners provide a dental “chair-side” platform for accessing valuable digital diagnosis and treatment tools, with potential for enhancing accuracy of records, treatment efficiency, and the overall patient experience. We believe there are numerous benefits for customers and the opportunity to accelerate the adoption of Invisalign through interoperability with our intra-oral scanners. The use of digital technologies such as CAD/CAM for restorative dentistry or in-office restorations has been growing rapidly and intra-oral scanning is a critical part of enabling these new digital technologies and procedures in dental practices.

The Invisalign system is offered in more than 45 countries and has been used to treat more than 2.0 million patients. Our iTero and iOC intra-oral scanners are available in over 25 countries and provide dental professionals with an open choice to send digital impressions to any laboratory-based CAD/CAM system or to any of the more than 1,800 dental labs worldwide.

Our goal is to establish the Invisalign system as the standard method for treating malocclusion and to establish our intra-oral scanning platform as the preferred scanning protocol for 3D digital scans, ultimately driving increased product adoption by

Table of Contents

dental professionals. We intend to achieve this by focusing on the key strategic initiatives set forth in our Annual Report on Form 10-K.

In addition to the successful execution of our business strategy, there are a number of other factors which may affect our results in 2012 and beyond, which are updated below:

Product innovation and clinical effectiveness. We believe feature innovations introduced in Invisalign G3 and Invisalign G4 are important contributors to the increased utilization across our channels worldwide. Additionally, due to the higher number of complex malocclusion cases in international markets compared to North America, we believe the international launches of Invisalign G3 in May 2011 and Invisalign G4 in November 2011 were important for continued growth both in our existing international markets and to support our expansion in new markets like China. We expect that these innovations, as well as the recently announced introduction of SmartTrack, a proprietary, custom engineered, aligner material, designed to deliver gentle, more constant force to improve control of tooth movements with Invisalign clear aligner treatment, will build on the success we have seen with Invisalign G3/G4 and encourage even greater confidence and adoption in our customers' practices. Additionally, with the introduction of new software features to the iOC and iTero intra-oral scanners along with Invisalign interoperability, we believe that over the long-term these types of product and clinical innovations will increase adoption of Invisalign and increase sales of our intra-oral scanners. However, it is difficult to predict the rate of adoption which may vary by region and channel.

Investments to Increase Manufacturing Capacity. We are currently transitioning from our existing clear aligner manufacturing facility in Juarez, Mexico into our new 150,000 square foot facility purchased in September 2011, which is also located in Juarez, Mexico. Although the lease on our existing facility expires in July 2013, we will likely continue to perform a small portion of our manufacturing process at this facility beyond this date. In addition, in October 2012, we completed the transition of our intra-oral scanner research and development and manufacturing operations in Or Yehuda, Israel into a new, larger facility in the same city. Our ability to plan, construct and equip manufacturing facilities is subject to significant risk and uncertainty, including delays and cost overruns. If the opening of manufacturing facilities is significantly delayed for any reason, or if demand for our product in 2012 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 in a timely manner, which may negatively impact our financial results and overall business.

Consolidation of New Jersey Operations. In October 2012, we completed the consolidation of our CAD/CAM services and intra-oral 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 intra-oral scanner research and development and manufacturing operations remain in Or Yehuda, Israel. The transition included the following activities:

• Consolidation of customer care for CAD/CAM services and intra-oral scanners into our existing shared services organization in San Jose, Costa Rica;

• Transition of CAD/CAM services and intra-oral scanner distribution and repair to our Treat operations in San Jose, Costa Rica and our new manufacturing facility in Juarez, Mexico; and

• Consolidation of accounting and finance functions at our corporate headquarters in San Jose, California.

The consolidation of our New Jersey operations, which began in the fourth quarter of 2011, resulted in a total reduction of 119 full time headcount in Carlstadt, New Jersey. As part of this consolidation, we incurred costs for severance of approximately \$1.9 million, of which approximately \$1.1 million was realized in 2011 and \$0.8 million over the first three quarters of 2012. With the New Jersey consolidation completed, we expect to realize annualized net savings of approximately \$4.0 million per year. In the course of creating a more integrated business, we have recently experienced lower service levels in our SCCS business negatively impacting our customer-facing functions such as customer service and technical support. We are committed to improving customer service levels, however if these issues persist, our financial results may be affected. See Part II, Item 1A— "Risk Factors" for risks related to the

Consolidation of New Jersey Operations”.

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 11 quarters are as follows:

23

Table of Contents

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

Total utilization in the third quarter of 2012 decreased slightly to 4.2 cases per doctor compared to 4.3 cases in the second quarter driven primarily by the decrease in utilization by our North American General Practitioner ("GP") customers from 3.1 to 2.9 cases per doctor. This decrease by our North American GP customers reflects a decline in the number of cases shipped across all levels of GP submitters, in particular our mid-to-high volume GPs, while utilization among our North American orthodontist customers and our International customers remained relatively flat. We believe that this is due in part to more doctors being out of the office for summer vacation and holidays.

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.

Acquisition of Cadent. On April 29, 2011, we acquired privately-held Cadent, a leading provider of 3D digital scanning solutions for orthodontics and dentistry. 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. Intra-oral scanners also strengthen 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 See Part II, Item A – "Risk Factors" for risks related to the acquisition of Cadent.

Number of new Invisalign doctors trained. We continue to expand our Invisalign customer base through training new doctors. In 2012, we expect to train approximately 6,500 orthodontists and GPs in North America and internationally, which is 500 doctors more than we trained in 2011.

International Clear Aligner. We will continue to focus our efforts towards increasing adoption of our products by dental professionals in our core European markets as well as expansion into new markets. In the third quarter of 2012, Clear Aligner International case volumes increased 20.6% compared to the same quarter in 2011, driven primarily by growth in our direct business in Europe as well as by continued strong performance by our distribution partners.

Although sales through our distribution partners represented 8% of total worldwide case shipments in the third quarter of 2012, sales through our distributors, particularly our partner covering the Asia

Table of Contents

Pacific region, continued to grow at a faster rate than direct sales in other international geographic regions and we expect this trend to continue in the near term. Based on the continued progress in the Asia Pacific region, we expect to revert to a direct sales model in this region beginning in second quarter of 2013. Therefore, we will not renew our distribution agreement when it expires in April 2013. In order to ensure a seamless transition and continuity of business for the customers impacted by this change, we expect to incur additional operating expenses during the fourth quarter of 2012 and the first quarter of 2013. After the transition in the second quarter of 2013, we will begin to recognize direct sales at our full average sales price, rather than at the discounted average sales price under the terms of the distribution agreement. While we believe that we will quickly gain revenue and contribution margin leverage, we may experience difficulties in achieving the anticipated financial benefits of this transaction.

International SCCS. In the third quarter of 2012, International SCCS revenue declined significantly from the same quarter in 2011. In October 2012, we reached a mutual agreement to terminate the exclusive distribution arrangement with Straumann for iTero intra-oral scanners in Europe, as well as the non-exclusive distribution agreement for iTero intra-oral scanners in North America. The global market for restorative dentistry is far more fragmented and complex than orthodontics with hundreds of thousands of labs, suppliers, general dentists and specialists. In Europe, adoption of digital restorative technology has been slowed due to challenging economic conditions and reluctance to invest in capital equipment. In view of these conditions, we have decided to market iTero on a more limited basis directly in Europe focusing on our existing Invisalign customers and pursue global scanner sales on a more opportunistic basis. We expect our International SCCS revenues in the fourth quarter of 2012 will be flat compared to the third quarter and will again consist primarily of CAD/CAM services revenues. Straumann will continue to offer first-level equipment support in Europe for at least the next 12 months, after which full responsibility for regional customer service will transfer to Align. The two companies are currently working together on plans for a smooth transition and will communicate details to customers as soon as they are finalized. Our direct sales model remains unchanged in North America where most of the SCCS revenue is generated.

Goodwill Impairment. During the third quarter of 2012, we determined that sufficient indicators of potential impairment existed to require an interim goodwill impairment analysis of our SCCS reporting unit. These indicators included the termination of the distribution arrangement with Straumann for iTero intra-oral scanners in Europe and North America, together with market conditions and business trends within the SCCS reporting unit. While we continue to expect revenue growth in our SCCS business, our expectations for future growth and profitability rates projected for the SCCS reporting unit are lower than our previous estimates primarily driven by overall lower than expected financial results. As of September 30, 2012, we concluded that the fair value of the SCCS reporting unit was less than its carrying value, therefore, the SCCS goodwill is impaired and we must perform step two of the goodwill impairment analysis. Due to the complexity and the effort required in the step two analysis, the fair value estimates were derived from preliminary assumptions and analyses that are subject to change. Based on our preliminary analysis, the implied fair value of goodwill was substantially lower than the carrying value of the goodwill for the SCCS reporting unit by an estimated \$24.7 million which we recorded as impairment to goodwill in the third quarter of 2012. In the fourth quarter of 2012, we expect to finalize the step two analysis and, if necessary, record any change from our original estimate. More information regarding our goodwill impairment, including a description of steps one and two of the analysis, and the approaches taken in the analysis of goodwill, can be found in Note 5 of the Condensed Consolidated Financial Statements included in Part I of this Form 10-Q.

Increase in Invisalign Selling Price. In recent years, we have significantly increased investment in research and development-resulting in product innovations such as Invisalign G3, Invisalign G4 and SmartTrack material. We have also continued to increase our consumer advertising spending to drive more patient demand. In addition, beginning January 1, 2013, the Federal Government will impose a new excise tax on medical device manufacturers, and Invisalign clear aligners are considered a taxable medical device. As a result of this new tax and our continued investments in R&D and consumer advertising, we are increasing Invisalign pricing by \$26.00 to \$50.00 per case, effective January 1, 2013. The prices for Invisalign Teen, Invisalign retainers, and Vivera retainers will remain unchanged.

Foreign exchange rates. Although the U.S. dollar is our reporting currency, a portion of our net revenues and profits are generated in foreign currencies. Net revenues and profits generated by subsidiaries operating outside of the U.S.

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 net

Table of Contents

revenues and profits in our consolidated financial statements.

Recent Developments

Hurricane Sandy

On October 29, 2012, Hurricane Sandy made landfall in New Jersey causing damage across large portions of the Mid-Atlantic, Northeastern, and Midwestern United States. Hurricane Sandy caused damage and business interruption to many of our customers in these regions. We are in the early stages of assessing the customer impacts of the storm, and we are, therefore, unable to estimate its full financial and operational impact.

Results of Operations

Net revenues by Reportable Segment

We group our operations into two reportable segments: Clear Aligner segment and Scanners and CAD/CAM Services segment.

Our Clear Aligner segment consists of our Invisalign system which includes Invisalign Full, Express/Lite, Teen, Assist, Vivera retainers, along with our training and ancillary products for treating malocclusion.

Our Scanners and CAD/CAM Services segment consists of intra-oral scanning systems and additional services available with the intra-oral scanners that provide digital alternatives to the traditional cast models. This segment includes our iTero scanners, iOC scanners, and OrthoCAD services.

The below represents net revenues for our Clear Aligner segment by region, channel, and product and our Scanner and CAD/CAM Services segment by region and product for the three and nine months ended September 30, 2012 and 2011 as follows (in millions):

Table of Contents

Clear Aligner:	Three Months Ended September 30,				Nine Months Ended September 30,				
	2012	2011	Net Change	% Change	2012	2011	Net Change	% Change	
Region and Channel									
North America									
Ortho	\$43.1	\$37.5	\$5.6	14.9	% \$128.7	\$109.5	\$19.2	17.5	%
GP	46.4	42.2	4.2	10.0	% 140.7	124.1	16.6	13.4	%
Total North America	89.5	79.7	9.8	12.3	% 269.4	233.6	35.8	15.3	%
International	29.7	28.3	1.4	4.9	% 92.3	81.4	10.9	13.4	%
Invisalign non-case revenues	7.5	6.3	1.2	19.0	% 22.0	17.7	4.3	24.3	%
Total	\$126.7	\$114.3	\$12.4	10.8	% \$383.7	\$332.7	\$51.0	15.3	%
Product									
Invisalign Full	\$80.3	\$75.1	\$5.2	6.9	% \$251.3	\$222.8	\$28.5	12.8	%
Invisalign Express/Lite	12.8	10.5	2.3	21.9	% 38.2	31.7	6.5	20.5	%
Invisalign Teen	19.1	15.4	3.7	24.0	% 50.7	40.1	10.6	26.4	%
Invisalign Assist	7.0	7.0	—	—	% 21.5	20.4	1.1	5.4	%
Invisalign non-case revenues	7.5	6.3	1.2	19.0	% 22.0	17.7	4.3	24.3	%
Total	\$126.7	\$114.3	\$12.4	10.8	% \$383.7	\$332.7	\$51.0	15.3	%
Scanners and CAD/CAM Services (1):									
Region									
North America	\$9.4	\$9.1	\$0.3	3.3	% \$32.3	\$14.4	\$17.9	124.3	%
International	0.4	2.5	(2.1)	(84.0)	% 1.2	3.7	(2.5)	(67.6)	%
Total	\$9.8	\$11.6	\$(1.8)	(15.5)	% \$33.5	\$18.1	\$15.4	85.1	%
Product									
Scanners	\$4.0	\$5.4	\$(1.4)	(25.9)	% \$15.4	\$8.2	\$7.2	87.8	%
CAD/CAM Services	5.8	6.2	(0.4)	(6.5)	% 18.1	9.9	8.2	82.8	%
Total	\$9.8	\$11.6	\$(1.8)	(15.5)	% \$33.5	\$18.1	\$15.4	85.1	%
Total Revenue	\$136.5	\$125.9	\$10.6	8.4	% \$417.2	\$350.8	\$66.4	18.9	%

(1) The Scanners and CAD/CAM Services segment was created as a result of our acquisition of Cadent on April 29, 2011 and the financial results for that segment reflect activity since that date.

Clear Aligner Case Volume by Channel and Product

Case volume data which represents Invisalign case shipments by channel and product, for the three and nine months ended September 30, 2012 and 2011 as follows (in thousands):

Region and Channel	Three Months Ended September 30,				Nine Months Ended September 30,				
	2012	2011	Net Change	% Change	2012	2011	Net Change	% Change	
North America:									
Ortho	35.9	30.1	5.8	19.3	% 103.5	85.5	18.0	21.1	%
GP	34.7	31.1	3.6	11.6	% 105.0	90.1	14.9	16.5	%
Total North American Invisalign	70.6	61.2	9.4	15.4	% 208.5	175.6	32.9	18.7	%
International Invisalign	21.9	18.2	3.7	20.3	% 64.5	51.2	13.3	26.0	%
Total Invisalign case volume	92.5	79.4	13.1	16.5	% 273.0	226.8	46.2	20.4	%
Product									
Invisalign Full	57.4	51.4	6.0	11.7	% 177.0	150.6	26.4	17.5	%

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Invisalign Express/Lite	14.6	11.0	3.6	32.7	%	42.8	32.8	10.0	30.5	%
Invisalign Teen	15.3	11.7	3.6	30.8	%	37.1	28.2	8.9	31.6	%
Invisalign Assist	5.2	5.3	(0.1)	(1.9)	%	16.1	15.2	0.9	5.9	%
Total Invisalign case volume	92.5	79.4	13.1	16.5	%	273.0	226.8	46.2	20.4	%

27

Table of Contents

Total net revenues increased by \$10.6 million and \$66.4 million for the three and nine months ended September 30, 2012, respectively, as compared to the same period in 2011 primarily as a result of worldwide volume growth across all Clear Aligner customer channels and products. For the nine months ended September 30, 2012, increase in revenue was also attributed to the addition of our SCCS segment resulting from the acquisition of Cadent in April 2011.

Clear Aligner

In the three and nine months ended September 30, 2012, Clear Aligner North America net revenues increased by 12.3% and 15.3%, respectively, compared to the same period in 2011. The growth was primarily driven by volume growth across all products and customer channels partially offset by lower average selling price (“ASPs”), as a result of an overall increase in our volume rebates, promotional discounts and deferred revenues.

In the three and nine months ended September 30, 2012, Clear Aligner International net revenues increased by 4.9% and 13.4%, respectively, compared to the same period in 2011, driven primarily by volume growth across all products, partially offset by lower ASPs due to an unfavorable Euro exchange rate against the U.S. dollar, an increase in discounts and distributor mix.

Other non-case revenues, consisting of training fees and sales of ancillary products, increased 19.0% and 24.3% for the three and nine months ended September 30, 2012, respectively, compared to the same period in 2011 primarily due to increased sales of Vivera and training revenue in North America and International.

Scanner and CAD/CAM Services

The SCCS segment was created when we acquired Cadent on April 29, 2011 and the financial results of Cadent have been included in this segment since the acquisition date. SCCS revenue decreased 15.5% and increased 85.1% for the three and nine months ended September 30, 2012, respectively, compared to the same period in 2011. The revenue decrease for the three months ended September 30, 2012 was primarily driven by reduction in scanner volume in International slightly offset by volume growth in North America. The revenue increase for the nine months ended September 30, 2012 was primarily due to the inclusion of Cadent for nine months in 2012 compared to five months in the prior year.

Cost of net revenues and gross profit (in millions):

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2012	2011	Change	2012	2011	Change
Clear Aligner						
Cost of net revenues	\$28.4	\$24.4	\$4.0	\$82.4	\$71.6	\$10.8
% of net segment revenues	22.4	% 21.4	%	21.5	% 21.5	%
Gross profit	\$98.3	\$89.9	\$8.4	\$301.3	\$261.1	\$40.2
Gross margin %	77.6	% 78.6	%	78.5	% 78.5	%
Scanner and CAD/CAM Services (1)						
Cost of net revenues	\$7.8	\$9.1	\$(1.3)	\$24.9	\$13.5	\$11.4
% of net segment revenues	79.4	% 78.5	%	74.4	% 74.6	%
Gross profit	\$2.0	\$2.5	\$(0.5)	\$8.6	\$4.6	\$4.0
Gross margin %	20.6	% 21.5	%	25.6	% 25.4	%
Total cost of net revenues	\$36.2	\$33.5	\$2.7	\$107.3	\$85.1	\$22.2
% of net revenues	26.5	% 26.6	%	25.7	% 24.3	%
Gross profit	\$100.3	\$92.4	\$7.9	\$309.9	\$265.7	\$44.2

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Gross margin % 73.5 % 73.4 % 74.3 % 75.7 %

(1) The Scanners and CAD/CAM services segment was created as a result of our acquisition of Cadent on April 29, 2011 and the financial results for that segment reflect activity since that date.

Cost of net revenues for our Clear Aligner and SCCS includes salaries for staff involved in the production process, the cost of materials, packaging, shipping costs, depreciation on capital equipment used in the production process, amortization of acquired intangible assets from Cadent, training costs and stock-based compensation expense.

28

Table of Contents

Clear Aligner

Gross margin decreased slightly for the three months ended September 30, 2012 compared to the same period in 2011 reflecting lower ASPs for our Clear Aligner products primarily driven by an increase in our volume rebate and other promotions.

Gross margin remained consistent for the nine months ended September 30, 2012 compared to the same period in 2011. Gross margin benefited from higher sales volume and increased cost absorption during the first three quarters of 2012 and was offset by lower ASPs.

Scanner and CAD/CAM Services

Gross margin decreased for the three months ended September 30, 2012 compared to the same period in 2011 largely due to higher excess and obsolescence charges related to raw materials as well as excess training capacity during the third quarter of 2012.

Gross margin remained consistent for nine months ended September 30, 2012 compared to the same period in 2011 largely due to improvements in cost absorption from higher production volumes. These improvements were offset by the increase in our training personnel for our scanner products which reflected a full nine month impact in 2012 compared to only five months in 2011 as the acquisition of Cadent was completed on April 29, 2011.

Sales and marketing (in millions):

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2012	2011	Change	2012	2011	Change
Sales and marketing	\$36.5	\$34.7	\$1.8	\$114.3	\$106.1	\$8.2
% of net revenues	26.7	% 27.5	%	27.4	% 30.2	%

Sales and marketing expense includes sales force and marketing compensation (including travel-related costs), media and advertising, clinical education, expenses for trade shows and industry events, product marketing and stock-based compensation expense.

Our sales and marketing expense for the three months ended September 30, 2012 increased compared to the same period in 2011 primarily due to higher advertising, media, product marketing, and industry event costs of approximately \$1.8 million. We also incurred higher payroll and payroll-related costs of approximately \$0.7 million. These costs were partially offset by lower clinical education costs of approximately \$0.9 million largely as a result of the North America Invisalign Summit which was held during the third quarter of 2011 but not in 2012.

Our sales and marketing expense for the nine months ended September 30, 2012 increased compared to the same period in 2011 primarily due to higher payroll and payroll-related costs of approximately \$5.6 million primarily attributed to the inclusion of Cadent's headcount during the full nine months of the 2012 compared to only five months during same period in 2011 as the acquisition was completed in April 2011. Additionally, we incurred higher advertising and media costs of approximately \$4.3 million. These expenses were partially offset by lower clinical education costs of approximately \$1.8 million primarily because of the European Invisalign Summit which was held during the second quarter of 2011 but not 2012, and the North American Invisalign Summit which was held during the third quarter of 2011 but not in 2012.

General and administrative (in millions):

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	Three Months Ended September 30,			Nine Months Ended September 30,		
	2012	2011	Change	2012	2011	Change
General and administrative	\$23.9	\$21.6	\$2.3	\$68.7	\$66.7	\$2.0
% of net revenues	17.5	% 17.2	%	16.5	% 19.0	%

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

Table of Contents

General and administrative expense increased for the three months ended September 30, 2012 compared to the same period in 2011 largely due to higher legal fees of approximately \$2.4 million as well as higher payroll expense of \$0.7 million resulting from annual compensation adjustments and an increase in headcount. These costs were partially offset by lower exit costs related to our SCCS activities in New Jersey of approximately \$0.6 million.

General and administrative expense increased for the nine months ended September 30, 2012 compared to the same period in 2011 due to higher facility related costs of approximately \$1.9 million as a result of the inclusion of Cadent's operations for the full nine months in 2012 compared to only five months during same period in 2011. We also incurred higher payroll costs of \$1.8 million mainly due to our annual compensation adjustments and an increase in headcount. These increases were partially offset by lower amortization expense of approximately \$2.1 million related to our non-compete agreements which was fully amortized by the end of the third quarter of 2011.

Research and development (in millions):

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2012	2011	Change	2012	2011	Change
Research and development	\$10.0	\$8.9	\$1.1	\$31.2	\$27.6	\$3.6
% of net revenues	7.3	% 7.1	%	7.5	% 7.9	%

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, 2012, compared to the same period in 2011 mostly due to higher payroll costs of approximately \$0.6 million resulting from annual compensation adjustments as well as higher outside consulting, facility, and research material expenses of approximately \$0.4 million.

Research and development expense increased during the nine months ended September 30, 2012, compared to the same period in 2011 mostly due to higher payroll and payroll-related costs of approximately \$3.6 million which was largely attributed to the inclusion of Cadent's headcount for full nine months in 2012 compared to only five months during same period in 2011.

Impairment of goodwill (in millions):

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2012	2011	Change	2012	2011	Change
Impairment of goodwill	\$24.7	\$—	\$24.7	\$24.7	\$—	\$24.7
% of net revenues	18.1	% —	%	5.9	% —	%

During the third quarter of 2012, we determined that sufficient indicators of potential impairment existed to require an interim goodwill impairment analysis of our SCCS reporting unit. We have completed step one of the goodwill impairment test, concluded that the SCCS goodwill is impaired and are in process of preparing step two of the goodwill impairment analysis. Due to the complexity and effort required to estimate the fair value of all assets and liabilities of the reporting unit as required in the step two analysis, the fair value estimates were derived from preliminary assumptions and analyses that are subject to change. Based on our preliminary analysis, the implied fair value of goodwill was substantially lower than the carrying value of the goodwill for the SCCS reporting unit by an

estimated \$24.7 million, which we recorded as impairment to goodwill in the third quarter of 2012. In the fourth quarter of 2012, we expect to finalize the step two analysis and if necessary, record any change from our original estimate. There were no such impairments in the three and nine months ended September 30, 2011.

Amortization of acquired intangible assets (in millions):

30

Table of Contents

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2012	2011	Change	2012	2011	Change
Amortization of acquired intangible assets	\$0.9	\$0.9	\$—	\$2.6	\$1.5	\$1.1
% of net revenues	0.6	% 0.7	%	0.6	% 0.4	%

Amortization of acquired intangible assets related to operating expense for the three months ended September 30, 2012 compared same period in 2011 remained consistent.

Amortization of acquired intangible assets increased for the nine months ended September 30, 2012 compared to the same period in 2011 reflecting a full nine months of amortization expense in 2012 related to the Cadent acquisition in April 2011 compared to only five months during same periods in 2011.

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

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2012	2011	Change	2012	2011	Change
Interest income	\$0.2	\$0.1	\$0.1	\$0.6	\$0.4	\$0.2
Other income (expense), net	(0.6)	(0.2)	(0.4)	(1.2)	(0.7)	(0.5)
Total interest income and other income (expense), net	\$(0.4)	\$(0.1)	\$(0.3)	\$(0.6)	\$(0.3)	\$(0.3)

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, 2012 were relatively consistent compared to the same periods in 2011. Other expense for the three and nine months ended September 30, 2012 compared to the same periods in 2011 increased reflecting higher foreign exchange losses.

Income tax (in millions):

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2012	2011	Change	2012	2011	Change
Provision for income taxes	\$4.5	\$6.9	\$(2.4)	\$18.8	\$17.3	\$1.5

Our effective tax rate was 108.3% and 26.5% for the three months ended September 30, 2012 and 2011, respectively, and 27.6% and 27.2% for the nine months ended September, 2012 and 2011, respectively.

The effective tax rate for the three months ended September 30, 2012 increased compared to the same period in 2011 primarily as a result of the non-deductible goodwill impairment charge of \$24.7 million recorded during the third quarter of 2012.

Our effective tax rate for the three months ended September 30, 2012, excluding the effect of this non-deductible goodwill impairment charge, would have been 15.6% which is still lower compared to the same period in 2011 due to a discrete income tax benefit recorded during the current quarter in order to adjust taxes provided for the prior year U.S. tax return.

Our effective tax rate for the nine months ended September 30, 2012 differs from the statutory federal income tax rate of 35% due to non-deductible expenses and certain foreign earnings, primarily Costa Rica, which are subject to a lower tax rate.

We exercise significant judgment in regards to estimates of future market growth, forecasted earnings and projected taxable income, in determining the provision for income taxes, and for purposes of assessing our ability to utilize any future benefit from deferred tax assets (“DTAs”).

Our valuation allowance of \$20.2 million is mostly related to capital loss and foreign net operating loss carryforwards as of September 30, 2012 because we cannot forecast sufficient future capital gains or foreign source income to realize these DTAs. These capital loss carryforwards and net operating losses 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.

Table of Contents

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, 2012 and December 31, 2011, we had the following cash and cash equivalents, and short-term and long-term investments (in thousands):

	September 30 , 2012	December 31, 2011
Cash and cash equivalents	\$304,907	\$240,675
Marketable securities, short-term	23,142	7,395
Marketable securities, long-term	20,802	—
Total	\$348,851	\$248,070

Cash flows (in thousands):

	Nine Months Ended 2012	September 30, 2011
Net cash flow provided by (used in) :		
Operating activities	\$83,020	\$82,491
Investing activities	(65,648) (199,297
Financing activities	46,819	24,389
Effects of exchange rate changes on cash and cash equivalents	41	(18
Net increase (decrease) in cash and cash equivalents	\$64,232	\$(92,435

As of September 30, 2012 we had \$348.9 million of cash, cash equivalents, and marketable securities. Cash equivalents and marketable securities are comprised of money market funds and debt instruments which include commercial paper, corporate bonds, and foreign bonds.

As of September 30, 2012, approximately \$110.5 million of cash was held by our foreign subsidiaries. Amounts held by foreign subsidiaries are generally subject to U.S. income taxation on repatriation to the U.S. Such earnings that are intended to be permanently reinvested outside of the U.S. are not subject to U.S. income taxation.

Operating Activities

For the nine months ended September 30, 2012, cash flows from operations of \$83.0 million resulted primarily from our net profit of approximately \$49.1 million and the following reasons:

Non-cash activities

- Deferred taxes were \$13.2 million primarily due to the utilization of our deferred tax assets.
- Depreciation, amortization, and the amortization of intangibles were \$12.5 million including the impact of the acquired assets and intangible assets resulting from the Cadent acquisition as well as the additional fixed assets that were placed into service in our new Juarez facility during the first half of 2012.
- Stock-based compensation expense was \$15.5 million related to equity incentive compensation granted to employees.
- Excess tax benefit from our share-based payments were \$18.1 million.
- Impairment of goodwill was \$24.7 million
- Other non-cash activities were \$0.9 million.

Changes in working capital

32

Table of Contents

Accounts receivable increased by \$15.5 million due to the increase in net revenues during the first three quarters of 2012 as well as higher days sales outstanding due to slower customer payments in September 2012, reducing our cash inflows from operating activities.

Inventories increased by \$5.7 million which was primarily due to increased production volumes for our intra-oral scanner products in preparation for the move into our new facility in Israel, reducing our cash inflow from operating activities.

Prepaid expenses and other assets increased \$1.6 million primarily due to the timing of software license and insurance policy renewals, reducing our cash inflow from operations

Accounts payable decreased by \$3.9 million during the first three quarters of 2012, reducing our cash inflow from operating activities.

Accrued and other long-term liabilities decreased by \$0.7 million primarily due to the payments of our incentive compensation during the first quarter of 2012 partially offset by the increase of our long-term income tax payable, reducing our cash inflow from operating activities.

Deferred revenues increased by \$12.7 million primarily due to higher sales during the first half of 2012, increasing our cash inflow from operating activities.

For the nine months ended September 30, 2011, cash flows from operations of approximately \$82.5 million resulted primarily from our net profit of approximately \$46.3 million adjusted for the following:

Non-cash activities

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

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.

Excess tax benefit from our share-based payments were approximately \$6.0 million.

Other non-cash activities 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.

Investing Activities

Net cash used in investing activities was \$65.6 million for the nine months ended September 30, 2012 primarily consisted of our purchase of marketable securities of \$53.9 million and property and equipment purchases of \$31.5 million. These costs were partially offset by \$17.4 million of maturities of our marketable securities and the release of \$2.5 million of funds we hold related to unclaimed merger consideration for the acquisition of Cadent on April 29, 2011.

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.

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.

Table of Contents

Financing Activities

Net cash provided by financing activities was \$46.8 million for the nine months ended September 30, 2012 primarily resulting from \$40.2 million in proceeds from the issuance of our common stock and \$18.1 million from excess tax benefit from our share-based arrangements. These costs were partially offset by \$9.8 million of common stock repurchases and \$1.8 million of taxes paid for our employees' vesting of restricted stock units.

Net cash provided by financing activities was \$24.4 million for the nine months ended September 30, 2011 primarily resulting from \$20.0 million in proceeds from the issuance of our common stock and \$6.0 million from excess tax benefit from our share-based arrangements. These cost were partially offset by \$1.5 million of taxes paid on the vesting of restricted stock units related to our employee stock plan.

Revision of Prior Period Financial Statements

In connection with the preparation of our consolidated financial statements for the third quarter of 2012, we determined that we had not correctly recognized the excess tax benefits related to stock-based awards in the first, second, and third quarters of 2011 and the first quarter of 2012.

In accordance with Staff Accounting Bulletin (SAB) No. 99, "Materiality", and SAB No. 108, "Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements", we evaluated the materiality of the errors from qualitative and quantitative perspectives, and evaluated the quantified errors under both the iron curtain and the roll-over methods. We concluded that the errors were not material to the financial statements for the first, second and third quarters of 2011 and the first quarter of 2012. We have revised the presentation of the statement of cash flows for the third quarter of 2011 and we will revise the presentation of the first quarter of 2012 statement of cash flows in future periods.

The following tables summarize the effects of the revision on our Condensed Consolidated Balance Sheets and Condensed Consolidated Statement of Cash Flows. The revision did not impact our Condensed Consolidated Statement of Operations for any of the applicable periods.

Balance Sheets

	March 31, 2011 (in thousands)		
	Previously Reported	Adjustment	As Revised
Balance Sheet:			
Deferred tax assets	\$38,024	\$2,068	\$40,092
Total assets	496,982	2,068	499,050
Additional paid-in capital	563,878	2,068	565,946
Total stockholders' equity	402,105	2,068	404,173
	June 30, 2011 (in thousands)		
	Previously Reported	Adjustment	As Revised
Balance Sheet:			
Deferred tax assets	\$28,546	\$5,374	\$33,920
Total assets	547,049	5,374	552,423
Additional paid-in capital	580,274	5,374	585,648
Total stockholders' equity	429,782	5,374	435,156

Table of Contents

	September 30, 2011 (in thousands)		
	Previously Reported	Adjustment	As Revised
Balance Sheet:			
Deferred tax assets	\$22,945	\$5,988	\$28,933
Total assets	585,920	5,988	591,908
Additional paid-in capital	588,501	5,988	594,489
Total stockholders' equity	456,876	5,988	462,864
	March 31, 2012 (in thousands)		
	Previously Reported	Adjustment	As Revised
Balance Sheet:			
Deferred tax assets	\$17,612	\$8,043	\$25,655
Total assets	670,436	8,043	678,479
Additional paid-in capital	619,991	8,043	628,034
Total stockholders' equity	523,022	8,043	531,065
Cash flows			
	Three Months Ended March 31, 2011 (in thousands)		
	Previously Reported	Adjustment	As Revised
Statement of Cash Flows			
Net cash provided by operating activities	\$17,248	\$(2,068)	\$15,180
Net cash provided by financing activities	3,749	2,068	5,817
Net increase cash and cash equivalents	13,944	—	13,944
	Six Months Ended June 30, 2011 (in thousands)		
	Previously Reported	Adjustment	As Revised
Statement of Cash Flows			
Net cash provided by operating activities	\$46,944	\$(5,374)	\$41,570
Net cash provided by financing activities	15,128	5,374	20,502
Net increase (decrease) cash and cash equivalents	(126,057)	—	(126,057)
	Nine Months Ended September 30, 2011 (in thousands)		
	Previously Reported	Adjustment	As Revised
Statement of Cash Flows			
Net cash provided by operating activities	\$88,479	\$(5,988)	\$82,491
Net cash provided by financing activities	18,401	5,988	24,389
Net increase (decrease) cash and cash equivalents	(92,435)	—	(92,435)

Table of Contents

	Three Months Ended March 31, 2012		
	(in thousands)		
	Previously Reported	Adjustment	As Revised
Statement of Cash Flows			
Net cash provided by operating activities	\$15,424	\$(8,043)	\$7,381
Net cash provided by financing activities	6,248	8,043	14,291
Net increase (decrease) in cash and cash equivalents	(16,314)) —	(16,314)

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 subject to market conditions, share price and other considerations. Purchases under the stock repurchase program may be made from time to time in the open market. As of September 30, 2012, there remains approximately \$132.5 million available under our existing stock repurchase authorization.

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 and Estimates

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, net 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, impairment of goodwill and income taxes. We use authoritative pronouncements, historical experience and other assumptions as the basis for making estimates. Actual results could differ from those estimates.

We believe the following critical accounting policies reflect our most significant estimates, judgments and assumptions used in the preparation of our consolidated financial statements. These critical accounting policies and related disclosures appear in our Annual Report on Form 10-K for the year ended December 31, 2011.

Revenue recognition;

Stock-based compensation expense;

Long-lived assets, including finite-lived purchased intangible assets;

Deferred tax valuation allowance;

Goodwill; and

Impairment of goodwill, finite-lived purchased intangible assets and long-lived assets

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

36

Table of Contents

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, 2011, which is incorporated herein by reference. Our exposure to market risk has not changed materially since December 31, 2011.

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, 2012 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 noted below, there have been no changes in our internal control over financial reporting during the nine months ending September 30, 2012 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 the Notes to our Condensed Consolidated Financial Statements for additional information regarding this acquisition. We are in the process of implementing our internal control structure over the acquired operations, and expect that this effort will be completed in fiscal 2012.

Table of Contents

PART II—OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

In the course of our operations, we are involved in a variety of claims, suits, investigations, and proceedings, including actions with respect to intellectual property claims, patent infringement claims, government investigations, labor and employment claims, breach of contract claims, tax, and other matters. Regardless of the outcome, these proceedings can have an adverse impact on us because of defense costs, diversion of management resources, and other factors. Although the results of complex legal proceedings are difficult to predict and our view of these matters may change in the future as litigation and events related thereto unfold; we currently do not believe that these matters, individually or in the aggregate, will materially affect our financial position, results of operations or cash flows.

ITEM 1A. RISK FACTORS

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

We expect that net revenues from the sale of the Invisalign system will continue to account for the vast majority of our total net 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 U.S. 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 treatment, which currently accounts for the vast majority of our net 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 treatment as both an alternative to braces and as a clinical method for treatment of malocclusion, but a number of dental professionals believe that Invisalign treatment 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 the Invisalign system 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 net revenues, gross margin and net profits (losses) may be

Table of Contents

reduced. Furthermore, although the U.S. dollar is our reporting currency, a portion of our net revenues and profits are generated in foreign currencies. Net 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 net 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 opened a new manufacturing facility in Juarez, Mexico at the end of 2011. We plan to transition aligner fabrication from our current facilities into this new facility during 2012. We completed the transition of virtually all our scanner distribution, repair and CAD/CAM services from our New Jersey facility to this facility in Juarez, Mexico in the third quarter of 2012. In addition, in October 2012, we transitioned our intra-oral scanner research and development and manufacturing operations in Or Yehuda, Israel into a new, larger facility in the same city. Our ability to plan, construct and equip additional manufacturing facilities is subject to significant risk and uncertainty, including risks inherent in the establishment of a new manufacturing facility, such as:

Hiring and retaining employees;

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 transition into this new 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. In addition, if product demand decreases or we fail to forecast demand accurately, we could be required to write off inventory or record excess capacity charges, which would lower our gross margin. 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 intra-oral scanner-related activities based in Carlstadt, New Jersey with our existing manufacturing and shared services organizations. We completed this consolidation in 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:

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failure to successfully coordinate and phase the relocation of these CAD/CAM services and intra-oral scanner customer care may cause our customers to experience decrease in service levels which could negatively impact the utilization of each scanner and total service revenue;

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

Table of Contents

the timely and successful transition; and

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

In the course of creating a more integrated business, we have recently experienced lower service levels in our scanner and CAD/CAM services business negatively impacting our customer facing functions such as, customer service and technical support. Any or all of these problems could result in reduced scanner sales and has resulted in reduced flow of services from ongoing CAD/CAM services and our operating results, statement of operations and cash flows may be adversely affected.

We may never achieve the anticipated benefits from our 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 iRecord and OrthoCAD iCast in addition to their intra-oral scanning technology. This acquisition is expected to strengthen our ability to drive adoption of the Invisalign system 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;
- 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
- 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 net 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.

Table of Contents

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 or significantly fluctuate. 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 relationships with our distributors;
- 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 intra-oral 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 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;
- major changes in available technology or the preferences of customers may cause our current product offerings to become less competitive or obsolete;
- aggressive price competition from competitors;
- costs and expenditures in connection with litigation;
- the timing of new product introductions by us and our competitors, as well as customer order deferrals in anticipation of enhancements or new products;
- 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 net revenues, production and other operating costs; and
- investments in research and development to develop new products and enhancements.

Table of Contents

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 net 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 net 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 with the Invisalign system. 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 net revenues to decline.

A disruption in the operations of our primary freight carrier or higher shipping costs could cause a decline in our net 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 net 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 net revenues, our gross margin and financial results could be adversely affected.

Table of Contents

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, intra-oral 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 net 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

Table of Contents

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.

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 net 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, net 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

Table of Contents

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.

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, 2012, we had issued 276 U.S. patents, 137 pending U.S. patent applications, and 215 issued foreign patents, and 139 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

Table of Contents

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 a 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 April 2011, we completed the acquisition of Cadent and are in the process of implementing our internal control structure over the acquired operations. 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. 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.

If our goodwill or amortizable intangible assets become impaired, we may be required to record a significant charge to earnings.

Under Generally Accepted Accounting Principles in the United States (“U.S. 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. The revenue growth rates, discount rates, earnings multiples and future cash flows are critical assumptions used to determine these fair values. Slower revenue 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. For instance, during the third quarter of 2012, we determined that sufficient indicators of potential impairment existed to require an interim goodwill impairment analysis for our Scanner and CAD/CAM Services reporting unit. These indicators included the termination of the exclusive distribution arrangement with Straumann for iTero intra-oral scanners in Europe, as well as their non-exclusive distribution arrangement for iTero intra-oral scanners in North America, together with market conditions and business trends within the Scanner and CAD/CAM Services reporting unit which led to lower expectations of profitability and growth rates than our previous estimates.

As a result, we performed a goodwill impairment test as of September 30, 2012 for our Scanner and CAD/CAM Services reporting unit and concluded that the goodwill within this reporting unit was impaired. Based on our preliminary analysis, the implied fair value of goodwill was substantially lower than the carrying value of the goodwill for the SCCS reporting unit by an estimated \$24.7 million which we recorded as impairment to goodwill in the third quarter of 2012. As of September 30, 2012, the remaining amount of goodwill associated with our SCCS reporting unit is \$52.6 million. In the fourth quarter of 2012, we expect to finalize the analysis and, if necessary, record any change from our original estimate.

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 intra-oral 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

Table of Contents

successfully instill such technical expertise in newly hired personnel or accurately predict the number of such personnel needed, our net 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 intra-oral scanners. We maintain single supply relationships for many of these machines and materials technologies. In particular, our CT scanning and stereolithography equipment used in our aligner manufacturing and many of the critical components for the optics of our scanners are provided by single suppliers. We are also committed to purchasing all of our resin and polymer, the primary raw materials used in our manufacturing process for clear aligners, 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.

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, 2012, our North American sales organization consisted of approximately 200 people. Internationally, we had approximately 80 people engaged in sales and sales support as of September 30, 2012. 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

Table of Contents

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 net 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 net 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;
- 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

Table of Contents

regulations through periodic unannounced inspections. Our failure to take satisfactory corrective action in response to an adverse inspection or the failure to comply with applicable manufacturing regulations could result in enforcement action, and we may be required to find alternative manufacturers, which could be a long and costly process. 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 in the U.S.. 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.

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

Table of Contents

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 net 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.

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

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

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

We prepare our consolidated financial statements in conformity with U.S. GAAP. 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; 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.

50

Table of Contents

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, non-deductible goodwill impairments, changing interpretations of existing tax laws or regulations, changes in the relative proportions of revenues and income before taxes in the various jurisdictions in which we operate that have differing statutory tax rates, the future levels of tax benefits of stock option deductions relating to incentive stock options and employee stock purchase plans, settlement of income tax audits, and changes in overall levels of pretax earnings. During the third quarter of 2012, we incurred a \$24.7 million impairment of goodwill which was not deductible for tax purposes. 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 2012. As a result of these incentives, income taxes were reduced by \$17.0 million through the third quarter of 2012. 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. Our subsidiary in Israel is under audit by the local tax authority for calendar years 2006 through 2009.

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

Following is a summary of stock repurchases for the three months ended September 30, 2012 (1):

Period

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	Total Number of Shares Repurchased	Average Price Paid per Share	Total Number of Shares Repurchased as Part of Publicly Announced Program	Approximate Dollar Value of Shares that May Yet Be Repurchased Under the Program
July 1, 2012 to September 30, 2012	213,000	\$34.15	213,000	\$ 132,452,259

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 subject to market conditions, share price and other considerations. Purchases under the stock repurchase program may be made from time to time in the open market. During the third quarter of 2012, we repurchased approximately 0.2 million shares of common stock at an average price of \$34.15 per share for an aggregate purchase price of approximately \$7.3 million including commissions. The common stock repurchases

Table of Contents

reduced additional paid-in capital by approximately \$1.9 million and increased accumulated deficit by \$5.4 million. All repurchased shares were retired.

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

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

Effective November 8, 2012, we entered into an amended and restated employment agreement with Timothy A. Mack, our Sr. Vice President, Business Development (the “Amended Mack Agreement”). The Amended Mack Agreement will replace and supersede, in all respects, the employment agreement with Mr. Mack signed as of March 29, 2011 (the “Original Mack Agreement”). The Original Mack Agreement was amended to, among other things, provide for a commuting allowance equal to \$155,000 for the twelve month period commencing June 8, 2012 until June 8, 2013, and provide that arbitration will be administered by Judicial Arbitration & Mediation Services, Inc. (JAMS). All remaining terms and conditions of the Amended Agreements are substantially the same as those set forth in the Original Mack Agreement. A copy of the Amended Mack Agreement is attached hereto as Exhibit 10.1.

Effective November 8, 2012, we entered into an amended and restated employment agreement (the “Amended Prescott Agreement”) with Thomas M. Prescott, our President and Chief Executive Officer. The Amended Prescott Agreement will replace and supersede, in all respects, the amended and restated employment agreement with Mr. Prescott signed as of April 5, 2007 (the “Prior Prescott Agreement”). The Amended Prescott Agreement was amended to, among other things, conform such agreement to the final Regulations promulgated under IRC Section 409A, to provide that arbitration will be administered by Judicial Arbitration & Mediation Services, Inc. (JAMS) and to make certain other non-substantive changes that are not inconsistent with the terms and conditions currently contained in the Prior Prescott Agreement. All remaining terms and conditions of the Amended Prescott Agreement are substantially the same as those set forth in the Prior Prescott Agreement. A copy of the Amended Prescott Agreement is attached hereto as Exhibit 10.2.

Effective November 8, 2012, we also entered into an amended and restated employment agreement with each of its other named executive officers (collectively, the “Amended EMC Agreements”) Kenneth B. Arola, Vice President, Finance and Chief Financial Officer, Len M. Hedge, Sr. Vice President, Business Operations and Dana C. Cambra, Vice President, Research & Development and Information Technology (each an “Executive” and collectively, the “Executives”). The Amended EMC Agreements will replace and supersede, in all respects, the amended and restated employment agreement between Executives and Align that were entered into on the following dates: December 14, 2007 (Mr. Arola), May 15, 2008 (Mr. Hedge) and June 16, 2008 (Mr. Cambra) (collectively, the “Prior EMC Agreements”). The Amended EMC Agreements were each amended to, among other things, conform such agreement to the final Regulations promulgated under IRC Section 409A, to provide that arbitration will be administered by Judicial Arbitration & Mediation Services, Inc. (JAMS) and to make certain other non-substantive changes that are not inconsistent with the terms and conditions currently contained in the Prior EMC Agreements. All remaining terms and conditions of the Amended EMC Agreements are substantially the same as those set forth in the Prior EMC Agreements. A copy of the Form of Amended EMC Agreement is attached hereto as Exhibit 10.3.

ITEM 6. EXHIBITS

(a) Exhibits:

52

Table of Contents

Exhibit Number	Description	Filing	Date	Exhibit Number	Filed here with
10.1	Amended and Restated Employment Agreement between the Company and Tim Mack				*
10.2	Amended and Restated Employment Agreement between the Company and Thomas M. Prescott				*
10.3	Form of Amended and Restated Employment Agreement between the Company and each of its other Named Executive Officers (Messrs. Arola, Hedge and Cambra)				*
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				*

Table of Contents

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 9, 2012

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

Table of Contents

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