

ALIGN TECHNOLOGY INC
Form 10-Q
October 30, 2014
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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, 2014
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 Accelerated filer
Non-accelerated filer (Do not check if a smaller reporting company) Smaller reporting company

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

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The number of shares outstanding of the registrant's Common Stock, \$0.0001 par value, as of October 24, 2014 was 80,289,814.

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PART I—FINANCIAL INFORMATION

ITEM 1 FINANCIAL STATEMENTS

ALIGN TECHNOLOGY, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per share data)

(unaudited)

| | Three Months Ended | | Nine Months Ended | |
|--|--------------------|-----------|-------------------|-----------|
| | September 30, | | September 30, | |
| | 2014 | 2013 | 2014 | 2013 |
| Net revenues | \$189,876 | \$164,506 | \$563,053 | \$481,914 |
| Cost of net revenues | 44,822 | 39,416 | 135,272 | 120,284 |
| Gross profit | 145,054 | 125,090 | 427,781 | 361,630 |
| Operating expenses: | | | | |
| Sales and marketing | 52,368 | 45,224 | 161,642 | 135,352 |
| General and administrative | 28,285 | 27,487 | 84,533 | 84,862 |
| Research and development | 12,854 | 10,915 | 39,523 | 33,113 |
| Impairment of goodwill | — | — | — | 40,693 |
| Impairment of long-lived assets | — | — | — | 26,320 |
| Total operating expenses | 93,507 | 83,626 | 285,698 | 320,340 |
| Income from operations | 51,547 | 41,464 | 142,083 | 41,290 |
| Interest and other income (expenses), net | (1,999 |) 449 | (1,491 |) (874 |
| Net income before provision for income taxes | 49,548 | 41,913 | 140,592 | 40,416 |
| Provision for income taxes | 11,301 | 7,376 | 34,301 | 18,542 |
| Net income | \$38,247 | \$34,537 | \$106,291 | \$21,874 |
| Net income per share: | | | | |
| Basic | \$0.47 | \$0.43 | \$1.31 | \$0.27 |
| Diluted | \$0.47 | \$0.42 | \$1.29 | \$0.26 |
| Shares used in computing net income per share: | | | | |
| Basic | 80,629 | 79,967 | 80,924 | 80,592 |
| Diluted | 82,014 | 81,848 | 82,443 | 82,549 |

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

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ALIGN TECHNOLOGY, INC.

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

(in thousands)

(unaudited)

| | Three Months Ended | | Nine Months Ended | |
|--|--------------------|----------|-------------------|----------|
| | September 30, | | September 30, | |
| | 2014 | 2013 | 2014 | 2013 |
| Net income | \$38,247 | \$34,537 | \$106,291 | \$21,874 |
| Net change in cumulative translation adjustment | (257 |) 171 | (155 |) 109 |
| Change in unrealized gains (losses) on available-for-sale securities, net of tax | (191 |) 203 | (81 |) 20 |
| Other comprehensive income (loss) | (448 |) 374 | (236 |) 129 |
| Comprehensive income | \$37,799 | \$34,911 | \$106,055 | \$22,003 |

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

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

| | September 30, 2014 (unaudited) | December 31, 2013 |
|--|--------------------------------------|----------------------|
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents | \$180,676 | \$242,953 |
| Marketable securities, short-term | 244,820 | 127,040 |
| Accounts receivable, net of allowances for doubtful accounts and returns of \$1,813 and \$1,733, respectively | 130,047 | 113,250 |
| Inventories | 15,983 | 13,968 |
| Prepaid expenses and other current assets | 44,146 | 47,465 |
| Total current assets | 615,672 | 544,676 |
| Marketable securities, long-term | 136,017 | 101,978 |
| Property, plant and equipment, net | 86,447 | 75,743 |
| Goodwill and intangible assets, net | 82,926 | 85,362 |
| Deferred tax assets | 19,714 | 15,766 |
| Other assets | 7,513 | 8,622 |
| Total assets | \$948,289 | \$832,147 |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current liabilities: | | |
| Accounts payable | \$24,517 | \$17,718 |
| Accrued liabilities | 86,600 | 80,345 |
| Deferred revenues | 87,443 | 77,275 |
| Total current liabilities | 198,560 | 175,338 |
| Other long-term liabilities | 27,273 | 22,839 |
| Total liabilities | 225,833 | 198,177 |
| Commitments and contingencies (Note 8) | | |
| Stockholders' equity: | | |
| Preferred stock, \$0.0001 par value (5,000 shares authorized; none issued) | — | — |
| Common stock, \$0.0001 par value (200,000 shares authorized; 80,516 and 80,583 issued and outstanding, respectively) | 8 | 8 |
| Additional paid-in capital | 775,523 | 729,578 |
| Accumulated other comprehensive income | 60 | 294 |
| Accumulated deficit | (53,135 |) (95,910) |
| Total stockholders' equity | 722,456 | 633,970 |
| Total liabilities and stockholders' equity | \$948,289 | \$832,147 |

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

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

| | Nine Months Ended September 30, | |
|---|------------------------------------|------------|
| | 2014 | 2013 |
| CASH FLOWS FROM OPERATING ACTIVITIES: | | |
| Net income | \$ 106,291 | \$ 21,874 |
| Adjustments to reconcile net income to net cash provided by operating activities: | | |
| Deferred taxes | 20,870 | 14,501 |
| Depreciation and amortization | 13,469 | 12,647 |
| Stock-based compensation | 29,348 | 21,265 |
| Excess tax benefit from share-based payment arrangements | (18,887 |) (21,849 |
| Impairment of goodwill | — | 40,693 |
| Impairment of long-lived assets | — | 26,320 |
| Other non-cash operating activities | 7,368 | 1,200 |
| Changes in assets and liabilities: | | |
| Accounts receivable | (24,930 |) (5,936 |
| Inventories | (2,033 |) 467 |
| Prepaid expenses and other assets | (2,349 |) 256 |
| Accounts payable | 3,788 | (318 |
| Accrued and other long-term liabilities | 12,402 | (671 |
| Deferred revenues | 9,957 | 8,415 |
| Net cash provided by operating activities | 155,294 | 118,864 |
| CASH FLOWS FROM INVESTING ACTIVITIES: | | |
| Acquisition, net of cash acquired | — | (7,652 |
| Purchase of property, plant and equipment | (16,957 |) (15,172 |
| Purchase of marketable securities | (350,611 |) (213,990 |
| Proceeds from maturities of marketable securities | 124,101 | 32,229 |
| Proceeds from sales of marketable securities | 72,276 | 6,943 |
| Other investing activities | (182 |) (2,347 |
| Net cash used in investing activities | (171,373 |) (199,989 |
| CASH FLOWS FROM FINANCING ACTIVITIES: | | |
| Proceeds from issuance of common stock | 17,373 | 28,291 |
| Common stock repurchases | (77,417 |) (95,105 |
| Excess tax benefit from share-based payment arrangements | 18,887 | 21,849 |
| Employees' taxes paid upon the vesting of restricted stock units | (5,761 |) (3,931 |
| Other financing activities | — | (6 |
| Net cash used in financing activities | (46,918 |) (48,902 |
| Effect of foreign exchange rate changes on cash and cash equivalents | 720 | (520 |
| Net decrease in cash and cash equivalents | (62,277 |) (130,547 |
| Cash and cash equivalents, beginning of the period | 242,953 | 306,386 |
| Cash and cash equivalents, end of the period | \$ 180,676 | \$ 175,839 |
| The accompanying notes are an integral part of these unaudited condensed consolidated financial statements. | | |

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ALIGN TECHNOLOGY, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(unaudited)

Note 1. Summary of Significant Accounting Policies

Basis of presentation

The accompanying unaudited Condensed Consolidated Financial Statements have been prepared by Align Technology, Inc. (“we”, “our”, or “Align”) in accordance with the rules and regulations of the Securities and Exchange Commission (“SEC”) and contain all adjustments, including normal recurring adjustments, necessary to present fairly our results of operations for the three and nine months ended September 30, 2014 and 2013, our comprehensive income for the three and nine months ended September 30, 2014 and 2013, our financial position as of September 30, 2014 and our cash flows for the nine months ended September 30, 2014 and 2013. The Condensed Consolidated Balance Sheet as of December 31, 2013 was derived from the December 31, 2013 audited financial statements. Net revenues by geographic area for prior period amounts in Note 13 have been reclassified to conform with the current period presentation. These reclassifications had no impact on our financial position for the three or nine months ended September 30, 2014 and 2013.

The results of operations for the three months ended September 30, 2014 are not necessarily indicative of the results that may be expected for the year ending December 31, 2014 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, 2013.

Use of estimates

The preparation of financial statements in conformity with generally accepted accounting principles (“GAAP”) 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, long-lived 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.

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) 2014-09, “Revenue from Contracts with Customers,” requiring an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers. The updated standard will replace most existing revenue recognition guidance in U.S. GAAP when it becomes effective and permits the use of either the retrospective or cumulative effect transition method. Early adoption is not permitted. The updated standard becomes effective for us in the first quarter of fiscal 2017. We have not yet selected a transition method and we are currently evaluating the effect that the updated standard will have on our consolidated financial statements and related disclosures.

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Note 2. Marketable Securities and Fair Value Measurements

As of September 30, 2014 and December 31, 2013, the estimated fair value of our short-term and long-term marketable securities, classified as available for sale, are as follows (in thousands):

Short-term

| September 30, 2014 | Amortized Cost | Gross Unrealized Gains | Gross Unrealized Losses | Fair Value |
|---|-------------------|------------------------------|-------------------------------|-------------|
| Commercial paper | \$44,840 | \$— | \$— | \$44,840 |
| Corporate bonds | 117,981 | 45 | (50) |) 117,976 |
| U.S. government agency bonds | 47,560 | 31 | (2) |) 47,589 |
| U.S. dollar dominated foreign corporate bonds | 911 | 2 | — | 913 |
| Municipal securities | 13,567 | 18 | — | 13,585 |
| U.S. government treasury bonds | 18,496 | 24 | — | 18,520 |
| Certificates of deposit | 1,397 | — | — | 1,397 |
| Total Marketable Securities, Short-Term | \$244,752 | \$120 | \$(52) |) \$244,820 |

Long-term

| September 30, 2014 | Amortized Cost | Gross Unrealized Gains | Gross Unrealized Losses | Fair Value |
|--|-------------------|------------------------------|-------------------------------|-------------|
| U.S. government agency bonds | \$28,887 | \$7 | \$(6) |) \$28,888 |
| Corporate bonds | 73,494 | 13 | (104) |) 73,403 |
| Municipal securities | 10,007 | 4 | (6) |) 10,005 |
| U.S. government treasury bonds | 11,298 | 1 | (4) |) 11,295 |
| Asset-backed securities | 12,439 | — | (13) |) 12,426 |
| Total Marketable Securities, Long-Term | \$136,125 | \$25 | \$(133) |) \$136,017 |

Short-term

| December 31, 2013 | Amortized Cost | Gross Unrealized Gains | Gross Unrealized Losses | Fair Value |
|---|-------------------|------------------------------|-------------------------------|-------------|
| Commercial paper | \$54,318 | \$10 | \$— | \$54,328 |
| Corporate bonds | 29,079 | 10 | (4) |) 29,085 |
| U.S. government agency bonds | 16,693 | 10 | — | 16,703 |
| U.S. dollar dominated foreign corporate bonds | 13,959 | 12 | — | 13,971 |
| Municipal securities | 7,006 | 11 | (3) |) 7,014 |
| Asset-backed securities | 5,937 | 2 | — | 5,939 |
| Total Marketable Securities, Short-Term | \$126,992 | \$55 | \$(7) |) \$127,040 |

Long-term

| December 31, 2013 | Amortized Cost | Gross Unrealized Gains | Gross Unrealized Losses | Fair Value |
|---|-------------------|------------------------------|-------------------------------|------------|
| U.S. government agency bonds | \$38,138 | \$1 | \$(21) |) \$38,118 |
| Corporate bonds | 23,308 | 14 | (9) |) 23,313 |
| U.S. dollar dominated foreign corporate bonds | 19,485 | 27 | (17) |) 19,495 |
| Municipal securities | 8,326 | 13 | (8) |) 8,331 |
| U.S. government treasury bonds | 6,916 | 3 | — | 6,919 |

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| | | | | |
|--|-----------|------|-------|-------------|
| Asset-backed securities | 5,800 | 4 | (2 |) 5,802 |
| Total Marketable Securities, Long-Term | \$101,973 | \$62 | \$(57 |) \$101,978 |

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For the three and nine months ended September 30, 2014 and 2013, realized gains were immaterial. Unrealized gains and losses for our available for sale securities as of September 30, 2014 and December 31, 2013 were also immaterial. Cash and cash equivalents are not included in the table above as the gross unrealized gains and losses are not material. We have no material short-term or long-term investments that have been in a continuous unrealized loss position for greater than twelve months as of September 30, 2014 and December 31, 2013. Amounts reclassified to earnings from accumulated other comprehensive income related to unrealized gain or losses were immaterial for the three and nine months ended September 30, 2014 and 2013.

Our fixed-income securities investment portfolio consists of corporate bonds, U.S. dollar dominated foreign corporate bonds, commercial paper, municipal securities, U.S. government agency bonds, U.S. government treasury bonds, certificates of deposit and asset-backed securities that have a maximum maturity of 27 months. The securities that we invest in are generally deemed to be low risk based on their credit ratings from the major rating agencies. The longer the duration of these securities, the more susceptible they are to changes in market interest rates and bond yields. As interest rates increase, those securities purchased at a lower yield show a mark-to-market unrealized loss. The unrealized losses are due primarily to changes in credit spreads and interest rates. We expect to realize the full value of all these investments upon maturity or sale. The weighted average remaining duration of these securities was approximately 11 months as of September 30, 2014 and December 31, 2013, respectively.

As the carrying value approximates the fair value for our short-term and long-term marketable securities shown in the tables above, the following table summarizes the fair value of our short-term and long-term marketable securities classified by maturity as of September 30, 2014 and December 31, 2013 (in thousands):

| | September 30, 2014 | December 31, 2013 |
|---|-----------------------|----------------------|
| Due in one year or less | \$244,820 | \$127,040 |
| Due in greater than one year | 136,017 | 101,978 |
| Total available for sale short-term and long-term marketable securities | \$380,837 | \$229,018 |

Fair Value Measurements

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

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

Our Level 1 assets consist of money market funds and U.S. government treasury bonds. We did not hold any Level 1 liabilities as of September 30, 2014 or December 31, 2013.

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, U.S. government agency bonds, asset-backed securities, municipal securities, U.S. dollar dominated foreign corporate bonds, certificates of deposit and our Israeli funds that are mainly invested in insurance policies. We obtain 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, 2014 or December 31, 2013.

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, 2014 or December 31, 2013.

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Non-Recurring Fair Value Measurements

During the nine months ended September 30, 2013, we recorded an impairment charge to our long-lived assets and goodwill of \$26.3 million and \$40.7 million, respectively, related to our Scanner and Services ("Scanner") reporting unit, formerly referred to as Scanner and CAD/CAM Services ("SCCS"), as an event occurred and circumstances changed that led us to perform an impairment analysis prior to our annual test which required us to determine the fair value of the Scanner reporting unit (Refer to Note 5). These fair value measurements were calculated using unobservable inputs, using the income approach which is classified as Level 3 within the fair value hierarchy. Inputs for the income approach includes the amount and timing of future cash flows based on our most recent operational budgets, strategic plans, terminal growth rates assumptions and other estimates.

Recurring Fair Value Measurements

The following tables summarize our financial assets measured at fair value on a recurring basis as of September 30, 2014 and December 31, 2013 (in thousands):

| Description | Balance as of September 30, 2014 | Quoted Prices in Active Markets for Identical Assets (Level 1) | Significant Other Observable Inputs (Level 2) |
|---|--|--|--|
| Cash equivalents: | | | |
| Money market funds | \$74,985 | \$74,985 | \$— |
| Commercial paper | 27,493 | — | 27,493 |
| Short-term investments: | | | |
| Commercial paper | 44,840 | — | 44,840 |
| Corporate bonds | 117,976 | — | 117,976 |
| U.S. government agency bonds | 47,589 | — | 47,589 |
| Municipal securities | 13,585 | — | 13,585 |
| U.S. dollar dominated foreign corporate bonds | 913 | — | 913 |
| U.S. government treasury bonds | 18,520 | 18,520 | — |
| Certificates of deposit | 1,397 | — | 1,397 |
| Long-term investments: | | | |
| Corporate bonds | 73,403 | — | 73,403 |
| U.S. government agency bonds | 28,888 | — | 28,888 |
| Asset-backed securities | 12,426 | — | 12,426 |
| Municipal securities | 10,005 | — | 10,005 |
| U.S. government treasury bonds | 11,295 | 11,295 | — |
| Other assets: | | | |
| Israeli funds | 2,371 | — | 2,371 |
| | \$485,686 | \$104,800 | \$380,886 |

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| Description | Balance as of December 31, 2013 | Quoted Prices in Active Markets for Identical Assets (Level 1) | Significant Other Observable Inputs (Level 2) |
|---|------------------------------------|--|--|
| Cash equivalents: | | | |
| Money market funds | \$ 143,540 | \$ 143,540 | \$— |
| Commercial paper | 15,398 | — | 15,398 |
| Short-term investments: | | | |
| Commercial paper | 54,328 | — | 54,328 |
| Corporate bonds | 29,085 | — | 29,085 |
| U.S. dollar denominated foreign corporate bonds | 13,971 | — | 13,971 |
| U.S. government agency bonds | 16,703 | — | 16,703 |
| Municipal securities | 7,014 | — | 7,014 |
| Asset-backed securities | 5,939 | — | 5,939 |
| Long-term investments: | | | |
| U.S. government agency bonds | 38,118 | — | 38,118 |
| Corporate bonds | 23,313 | — | 23,313 |
| U.S. dollar denominated foreign corporate bonds | 19,495 | — | 19,495 |
| Municipal securities | 8,331 | — | 8,331 |
| U.S. government treasury bonds | 6,919 | 6,919 | — |
| Asset-backed securities | 5,802 | — | 5,802 |
| Other assets: | | | |
| Israeli funds | 2,193 | — | 2,193 |
| | \$ 390,149 | \$ 150,459 | \$ 239,690 |

Note 3. Balance Sheet Components

Inventories

Inventories consist of the following (in thousands):

| | September 30, 2014 | December 31, 2013 |
|-------------------|-----------------------|----------------------|
| Raw materials | \$6,240 | \$5,172 |
| Work in process | 3,734 | 4,241 |
| Finished goods | 6,009 | 4,555 |
| Total Inventories | \$15,983 | \$13,968 |

Work in process includes costs to produce our clear aligner and intra-oral products. Finished goods primarily represent our intra-oral scanners and ancillary products that support our clear aligner products.

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Accrued liabilities

Accrued liabilities consist of the following (in thousands):

| | September 30, 2014 | December 31, 2013 |
|---------------------------------------|-----------------------|----------------------|
| Accrued payroll and benefits | \$39,265 | \$43,029 |
| Accrued sales rebates | 10,256 | 10,100 |
| Accrued sales tax and value added tax | 7,144 | 6,215 |
| Accrued sales and marketing expenses | 5,397 | 3,893 |
| Accrued accounts payable | 5,536 | 4,053 |
| Accrued warranty | 3,263 | 3,104 |
| Accrued professional fees | 1,605 | 1,892 |
| Accrued income taxes | 3,949 | 1,205 |
| Other accrued liabilities | 10,185 | 6,854 |
| Total Accrued Liabilities | \$86,600 | \$80,345 |

Warranty

We regularly review the accrued warranty balances and update these balances based on historical warranty trends. Actual warranty costs incurred have not materially differed from those accrued; however, future actual warranty costs could differ from the estimated amounts.

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.

Warranty accrual as of September 30, 2014 and 2013 consists of the following activity (in thousands):

| | Nine Months Ended September 30, | |
|---------------------------------|------------------------------------|----------|
| | 2014 | 2013 |
| Balance at beginning of period | \$3,104 | \$4,050 |
| Charged to cost of net revenues | 1,529 | 2,813 |
| Actual warranty expenditures | (1,370 |) (3,057 |
| Balance at end of period | \$3,263 | \$3,806 |

Note 4. Business Combinations

On April 30, 2013, we completed the acquisition of ICA Holdings Pty Limited ("ICA") upon the expiration of the distribution agreement between certain subsidiaries of ICA and Align Technology B.V., for a total cash consideration of approximately \$8.6 million, of which \$7.4 million was attributed to assets acquired, \$2.4 million in liabilities assumed and \$3.6 million to goodwill. Goodwill as a result of this acquisition represents the excess of the purchase

price over the fair value of the underlying net assets acquired and represents the knowledge and experience of the workforce in place. None of this goodwill will be deductible for tax purposes. Under the applicable accounting guidance, goodwill will not be amortized but will be tested for impairment on an annual basis or more frequently if certain indicators are present.

Pro forma results of operations for this acquisition have not been presented as it is not material to our results of operations, either individually or in aggregate, for the three or nine months ended September 30, 2013.

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Note 5. Goodwill and Long-lived Assets

Goodwill

The change in the carrying value of goodwill for the nine months ended September 30, 2014 by our reportable segments, which are also our reporting units, is as follows (in thousands):

| | |
|----------------------------------|---------------|
| | Clear Aligner |
| Balance as of December 31, 2013 | \$61,623 |
| Adjustments ¹ | (34) |
| Balance as of September 30, 2014 | \$61,589 |

¹ The adjustments to goodwill during the nine months ended September 30, 2014 were due to foreign currency translation.

The goodwill balance is entirely attributable to our Clear Aligner reporting unit. During the fourth quarter of fiscal 2013, we performed the annual goodwill impairment testing and found no impairment events as the fair value of our Clear Aligner reporting unit was significantly in excess of the carrying value.

Impairment of Goodwill in 2013

We evaluate our goodwill for impairment at least annually on November 30th or more frequently if indicators are present, an event occurs or circumstances change that suggest an impairment may exist and that it would more likely than not reduce the fair value of the reporting unit below its carrying amount. During March 2013, changes in the competitive environment for intra-oral scanners, including announcements from our competitors of new low-priced scanners targeted at orthodontists and general practitioner dentists in North America, that caused us to lower our expectations for growth and profitability for our Scanner reporting unit. As a result, we determined that goodwill related only to our Scanner reporting unit should be tested for impairment as of March 2013 due to these facts and circumstances which would more likely than not reduce the fair value of our Scanner reporting unit below its carrying amount. There was no triggering event related to our Clear Aligner goodwill.

We performed a step one analysis for our Scanner reporting unit which consists of a comparison of the fair value of the Scanner reporting unit against its carrying amount, including the goodwill allocated to it. In deriving the fair value of the Scanner reporting unit, we utilized the income approach which is classified as Level 3 within the fair value hierarchy. This approach provides an estimated fair value based on discounted expected future cash flows, which are based on management's estimates of revenue growth rates and operating margins, taking into consideration industry and market conditions. The discount rate used is based on a weighted average cost of capital adjusted for the relevant risk associated with the characteristics of the business and the projected cash flows.

As a result of our step one analysis, we concluded that the fair value of the Scanner reporting unit was less than its carrying value; therefore, we proceeded to step two of the goodwill impairment analysis. 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. This allocation process was performed only for the purposes of measuring the goodwill impairment and not to adjust the carrying values of the recognized tangible assets and liabilities. 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. We use a discounted cash flow ("DCF") approach, utilizing the harvest model, to estimate the fair value of a reporting unit which we believe is the most reliable indicator of fair value of this business, and is most consistent with the approach a market place participant would use. Based on our analysis, there was no implied goodwill for the Scanner reporting unit; therefore, we recorded a goodwill impairment charge of \$40.7 million in the three months ended March 31, 2013, which represents the remaining goodwill balance in the Scanner reporting unit. None of the goodwill impairment charge was deductible for tax purposes.

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Long-lived Assets

Impairment of Long-lived Assets in 2013

We amortize our intangible assets over their estimated useful lives. We evaluate long-lived assets, which includes property, plant and equipment and intangible assets, for impairment whenever events or changes in circumstances indicate the carrying value of an asset may not be recoverable. The carrying value is not recoverable if it exceeds the undiscounted cash flows resulting from the use of the asset and its eventual disposition. Our estimates of future cash flows attributable to our long-lived assets require significant judgment based on our historical and anticipated results and are subject to many factors. Factors we consider important which could trigger an impairment review include significant negative industry or economic trends, significant loss of customers and changes in the competitive environment of our intra-oral scanning business.

During March 2013, changes in the competitive environment for intra-oral scanners, including announcements from our competitors of new low-priced scanners targeted at orthodontists and general practitioner dentists in North America, that caused us to lower our expectations for growth and profitability for our Scanner reporting unit. As a result, we determined that the carrying value of the Scanner long-lived assets was not recoverable as compared to the value of the undiscounted cash flows of our revised projections for the asset group. In order to determine the impairment amount of our long-lived assets, we fair valued each key component of our long-lived assets within the asset group, which involved the use of significant estimates and assumptions including replacement costs, revenue growth rates, operating margins, and plant and equipment cost trends. We use a DCF approach, utilizing the harvest model, to estimate the fair value of a reporting unit which we believe is the most reliable indicator of fair value of this business, and is most consistent with the approach a market place participant would use. The estimation of fair value utilizing a DCF approach includes numerous uncertainties which require our significant judgment when making assumptions of expected growth rates and the selection of discount rates, as well as assumptions regarding general economic and business conditions, and the structure that would yield the highest economic value, among other factors. Key assumptions used in measuring the fair values of the Scanner reporting unit included the discount rate (based on the weighted-average cost of capital) and revenue growth. The fair value of Scanner's trademark was determined using a risk-adjusted DCF approach under the relief-from-royalty method. The royalty rate used was based on a consideration of market rates. The fair value of Scanner's finite-lived customer relationships was determined using a DCF approach under the multi-period excess earnings method. We determined our long-lived asset group within the Scanner reporting unit to be primarily finite-lived intangible assets, plant and equipment. Upon completion of this analysis, we recorded a total impairment charge of \$26.3 million in the three months ended March 31, 2013, of which \$19.3 million represented the impairment related to our Scanner intangible assets and \$7.0 million related to plant and equipment. There was no triggering event related to the Clear Aligner asset group.

Intangible assets arising either as a direct result from the Cadent Holdings, Inc. acquisition ("Cadent") or individually acquired are being amortized as follows (in thousands):

| | Weighted Average Amortization Period (in years) | Gross Carrying Amount as of September 30, 2014 | Accumulated Amortization | Accumulated Impairment Loss | Net Carrying Value as of September 30, 2014 |
|-------------------------|---|---|-----------------------------|-----------------------------------|--|
| Trademarks | 15 | \$7,100 | \$ (1,319) | \$(4,179) | \$1,602 |
| Existing technology | 13 | 12,600 | (2,873) | (4,328) | 5,399 |
| Customer relationships | 11 | 33,500 | (8,630) | (10,751) | 14,119 |
| Other | 8 | 285 | (68) | — | 217 |
| Total Intangible Assets | | \$53,485 | \$ (12,890) | \$(19,258) | \$21,337 |

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| | Weighted Average Amortization Period (in years) | Gross Carrying Amount as of December 31, 2013 | Accumulated Amortization | Accumulated Impairment Loss | Net Carrying Value as of December 31, 2013 |
|-------------------------|---|--|-----------------------------|-----------------------------------|--|
| Trademarks | 15 | \$7,100 | \$(1,100) | \$(4,179) | \$ 1,821 |
| Existing technology | 13 | 12,600 | (2,236) | (4,328) | 6,036 |
| Customer relationships | 11 | 33,500 | (7,112) | (10,751) | 15,637 |
| Other | 8 | 285 | (40) | — | 245 |
| Total Intangible Assets | | \$53,485 | \$(10,488) | \$(19,258) | \$ 23,739 |

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The total estimated annual future amortization expense for these acquired intangible assets as of September 30, 2014 is as follows (in thousands):

| | |
|---------------------------------|----------|
| Fiscal Year Ending December 31, | |
| Remainder of 2014 | \$649 |
| 2015 | 2,600 |
| 2016 | 2,600 |
| 2017 | 2,600 |
| 2018 | 2,600 |
| Thereafter | 10,288 |
| Total | \$21,337 |

Note 6. Credit Facilities

On March 22, 2013, we entered into a credit facility with Wells Fargo Bank. The credit facility provides for a \$50.0 million revolving line of credit, with a \$10.0 million letter of credit sublimit, and has a maturity date on March 22, 2016. The credit facility also requires us to maintain a minimum unrestricted cash balance of \$50.0 million and comply with specific financial conditions and performance requirements. The loan bears interest, at our option, at a fluctuating rate per annum equal to the daily one-month adjusted LIBOR rate plus a spread of 1.75% or an adjusted LIBOR rate (based on one, three, six or twelve-month interest periods) plus a spread of 1.75%. As of September 30, 2014, we had no outstanding borrowings under this credit facility and were in compliance with the conditions and performance requirements.

Note 7. Legal Proceedings

Securities Class Action Lawsuit

On November 28, 2012, plaintiff City of Dearborn Heights Act 345 Police & Fire Retirement System filed a lawsuit against Align, Thomas M. Prescott (“Mr. Prescott”), Align’s President and Chief Executive Officer, and Kenneth B. Arola (“Mr. Arola”), Align’s former Vice President, Finance and Chief Financial Officer, in the United States District Court for the Northern District of California on behalf of a purported class of purchasers of our common stock (the “Securities Action”). On July 11, 2013, an amended complaint was filed, which named the same defendants, on behalf of a purported class of purchasers of our common stock between January 31, 2012 and October 17, 2012. The amended complaint alleged that Align, Mr. Prescott and Mr. Arola violated Section 10(b) of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder, and that Mr. Prescott and Mr. Arola violated Section 20(a) of the Securities Exchange Act of 1934. Specifically, the amended complaint alleged that during the purported class period defendants failed to take an appropriate goodwill impairment charge related to the April 29, 2011 acquisition of Cadent Holdings, Inc. in the fourth quarter of 2011, the first quarter of 2012 or the second quarter of 2012, which rendered our financial statements and projections of future earnings materially false and misleading and in violation of U.S. GAAP. The amended complaint sought monetary damages in an unspecified amount, costs and attorneys’ fees. On December 9, 2013, the court granted defendants’ motion to dismiss with leave for plaintiff to file a second amended complaint. Plaintiff filed a second amended complaint on January 8, 2014 on behalf of the same purported class. The second amended complaint states the same claims as the amended complaint. On August 22, 2014, the court granted our motion to dismiss without leave to amend. On September 22, 2014, Plaintiff filed a notice of appeal to the Ninth Circuit Court of Appeals. Align intends to vigorously defend itself against these allegations. Align is currently unable to predict the outcome of this amended complaint and therefore cannot determine the likelihood of loss nor estimate a range of possible loss, if any.

Shareholder Derivative Lawsuit

On February 1, 2013, plaintiff Gary Udis filed a shareholder derivative lawsuit against several of Align's current and former officers and directors in the Superior Court of California, County of Santa Clara. The complaint alleges that our reported income and earnings were materially overstated because of a failure to timely write down goodwill related to the April 29, 2011 acquisition of Cadent Holdings, Inc., and that defendants made allegedly false statements concerning our forecasts. The complaint asserts various state law causes of action, including claims of breach of fiduciary duty, unjust enrichment, and insider trading, among others. The complaint seeks unspecified damages on behalf of Align, which is named solely as nominal defendant against whom no recovery is sought. The complaint also seeks an order directing Align to reform and improve its corporate governance and internal procedures, and seeks restitution in an unspecified amount, costs, and attorneys' fees. On July 8, 2013, an Order was entered staying this derivative lawsuit until an initial ruling on our first motion to dismiss the Securities Action. On January 15, 2014, an Order was entered staying this derivative lawsuit until an initial ruling on our second motion to dismiss the Securities

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Action. On October 14, 2014, an Order was entered staying this derivative lawsuit until a ruling by the Ninth Circuit in the Securities Action discussed above. Align is currently unable to predict the outcome of this complaint and therefore cannot determine the likelihood of loss nor estimate a range of possible losses.

In addition, in the course of Align's operations, Align is 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 Align's view of these matters may change in the future as litigation and events related thereto unfold; Align currently does not believe that these matters, individually or in the aggregate, will materially affect Align's financial position, results of operations or cash flows.

Note 8. Commitments and Contingencies

Operating Leases

As of September 30, 2014, minimum future lease payments for non-cancelable operating leases are as follows (in thousands):

| | |
|-------------------------------------|------------------|
| Fiscal Year Ending December 31, | Operating leases |
| Remainder of 2014 | \$2,282 |
| 2015 | 8,480 |
| 2016 | 7,690 |
| 2017 | 4,346 |
| 2018 | 1,490 |
| Thereafter | 437 |
| Total minimum future lease payments | \$24,725 |

Off-balance Sheet Arrangements

As of September 30, 2014, we had no off-balance sheet arrangements that have, or are reasonably likely to have, a current or future material effect on our consolidated financial condition, results of operations, liquidity, capital expenditures or capital resources.

Indemnification Provisions

In the normal course of business to facilitate transactions in our services and products, we indemnify certain parties: customers, vendors, lessors and other parties with respect to certain matters, including, but not limited to, services to be provided by us and intellectual property infringement claims made by third parties. In addition, we have entered into indemnification agreements with our directors and our executive officers that will require us, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. Several of these agreements limit the time within which an indemnification claim can be made and the amount of the claim.

It is not possible to make a reasonable estimate of the maximum potential amount under these indemnification agreements due to the unique facts and circumstances involved in each particular agreement. Additionally, we have a limited history of prior indemnification claims and the payments we have made under such agreements have not had a material adverse effect on our results of operations, cash flows or financial position. However, to the extent that valid indemnification claims arise in the future, future payments by us could be significant and could have a material adverse effect on our results of operations or cash flows in a particular period. As of September 30, 2014, we did not

have any material indemnification claims that were probable or reasonably possible.

Note 9. Stock-based Compensation

Summary of stock-based compensation expense

As of September 30, 2014, we had a total reserve of 23,283,379 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.

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Stock-based compensation 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 related to all of our stock-based awards and employee stock purchases for the three and nine months ended September 30, 2014 and 2013 is as follows (in thousands):

| | Three Months Ended | | Nine Months Ended | |
|--------------------------------|--------------------|---------|-------------------|----------|
| | September 30, | | September 30, | |
| | 2014 | 2013 | 2014 | 2013 |
| Cost of net revenues | \$867 | \$664 | \$2,648 | \$1,881 |
| Sales and marketing | 2,837 | 2,215 | 8,615 | 5,238 |
| General and administrative | 4,544 | 3,687 | 13,133 | 11,170 |
| Research and development | 1,662 | 1,024 | 4,952 | 2,976 |
| Total stock-based compensation | \$9,910 | \$7,590 | \$29,348 | \$21,265 |

Options

Activity for the nine months ended September 30, 2014 under the stock option plans is 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, 2013 | 1,321 | \$ 16.08 | | |
| Granted | — | — | | |
| Exercised | (598 |) 16.88 | | |
| Cancelled or expired | (4 |) 18.33 | | |
| Outstanding as of September 30, 2014 | 719 | \$ 15.40 | 3.10 | \$26,098 |
| Vested and expected to vest at September 30, 2014 | 719 | \$ 15.39 | 3.10 | \$26,085 |
| Exercisable at September 30, 2014 | 692 | \$ 15.12 | 3.09 | \$25,294 |

There were no stock options granted during the three and nine months ended September 30, 2014 and 2013.

As of September 30, 2014, the total unamortized compensation cost related to stock options, net of estimated forfeitures, is \$0.3 million, which we expect to recognize over a weighted average period of 0.5 years.

Restricted Stock Units (“RSU”)

A summary of the RSU activity for the nine months ended September 30, 2014 is as follows (in thousands, except years):

| | Number of Shares Underlying RSU | Weighted Average Grant Date Fair Value | Weighted Remaining Contractual Period (in years) | Aggregate Intrinsic Value |
|--|------------------------------------|--|--|---------------------------------|
|--|------------------------------------|--|--|---------------------------------|

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| | | | | |
|------------------------------------|-------|---------|------|-----------|
| Nonvested as of December 31, 2013 | 2,044 | \$36.68 | | |
| Granted | 958 | 53.71 | | |
| Vested and released | (639) |) 28.59 | | |
| Forfeited | (144) |) 36.84 | | |
| Nonvested as of September 30, 2014 | 2,219 | \$41.93 | 1.51 | \$114,662 |

As of September 30, 2014, the total unamortized compensation cost related to RSU, net of estimated forfeitures, was \$68.4 million, which we expect to recognize over a weighted average period of 2.5 years.

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We have granted market-performance based restricted stock units ("MSU") 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 MSU 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 MSU initially granted.

The following table summarizes the MSU activity for the nine months ended September 30, 2014 (in thousands, except years):

| | Number of Shares Underlying MSU | Weighted Average Grant Date Fair Value | Weighted Average Remaining Contractual Period (in years) | Aggregate Intrinsic Value |
|------------------------------------|------------------------------------|--|--|---------------------------------|
| Nonvested as of December 31, 2013 | 307 | \$31.96 | | |
| Granted | 243 | 50.46 | | |
| Vested and released | (52 |) 22.41 | | |
| Forfeited | — | — | | |
| Nonvested as of September 30, 2014 | 498 | \$42.00 | 1.63 | \$25,711 |

As of September 30, 2014, the total unamortized compensation costs related to the MSU, net of estimated forfeitures, was \$11.1 million, which we expect to recognize over a weighted average period of 1.6 years.

Employee Stock Purchase Plan ("ESPP")

In May 2010, our stockholders approved the 2010 Employee Stock Purchase Plan ("2010 Purchase Plan") which will continue until terminated by either the Board of Directors 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, 2014, there remains 1,363,827 shares available for purchase under the 2010 Purchase Plan.

The fair value of the option component of the 2010 Purchase Plan shares was estimated at the grant date using the Black-Scholes option pricing model with the following weighted average assumptions:

| | Three Months Ended September 30, | | Nine Months Ended September 30, | | |
|---|-------------------------------------|---------|------------------------------------|---------|---|
| | 2014 | 2013 | 2014 | 2013 | |
| ESPP: | | | | | |
| Expected term (in years) | 1.3 | 1.2 | 1.2 | 1.2 | |
| Expected volatility | 35.8 | % 37.3 | % 38.8 | % 44.9 | % |
| Risk-free interest rate | 0.24 | % 0.20 | % 0.20 | % 0.20 | % |
| Expected dividends | — | — | — | — | |
| Weighted average fair value at grant date | \$16.44 | \$13.84 | \$17.15 | \$11.70 | |

As of September 30, 2014, the total unamortized compensation cost related to employee purchases was \$1.3 million, which we expect to recognize over a weighted average period of 0.6 year.

Note 10. Common Stock Repurchase

On April 23, 2014, we announced that our Board of Directors had authorized a stock repurchase program pursuant to which we may purchase up to \$300.0 million of our common stock over the next three years, with \$100.0 million of that amount authorized to be purchased over the first twelve months. Any purchases under this stock repurchase

program may be made, from time-to-time, pursuant to open market purchases (including pursuant to Rule 10b5-1 plans), privately-negotiated transactions, accelerated stock repurchases, block trades or derivative contracts or otherwise in accordance with applicable federal securities laws, including Rule 10b-18 of the Securities Exchange Act of 1934.

As part of our \$300.0 million stock repurchase program, we entered into an accelerated share repurchase agreement ("ASR") with Goldman, Sachs & Co. on April 28, 2014 to repurchase \$70.0 million of our common stock. We paid \$70.0 million on April 29, 2014 and received an initial delivery of approximately 1.0 million shares. The ASR was completed on July 29, 2014 with a final delivery of approximately 0.4 million shares. We received a total of approximately 1.4 million shares under the ASR for an

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average purchase price per share of \$51.46, which all shares were retired. The final number of shares repurchased was based on our volume-weighted average stock price during the term of the transaction, less an agreed upon discount. During the three months ended September 30, 2014, we repurchased on the open market approximately 0.1 million shares of our common stock at an average price of \$54.22 per share, including commissions, for an aggregate purchase price of approximately \$7.4 million. All repurchased shares were retired. As of September 30, 2014, we have \$222.6 million remaining under the April 2014 stock repurchase program, \$22.6 million of which we expect to purchase over the next six months.

Note 11. Accounting for Income Taxes

Our provision for income taxes was \$11.3 million and \$7.4 million for the three months ended September 30, 2014 and 2013, respectively. This represents effective tax rates of 22.8% and 17.6%, respectively. The increase in our provision for income taxes was primarily due to higher pre-tax income, which was partially offset by a jurisdictional shift in forecasted earnings from the U.S. to lower-tax non-U.S. jurisdictions.

Our provision for income taxes was \$34.3 million and \$18.5 million for the nine months ended September 30, 2014 and 2013, respectively. This represents effective tax rates of 24.4% and 45.9%, respectively. Our provision for income taxes reflects a negative impact from a \$1.8 million adjustment related to prior years, offset by a jurisdictional shift in forecasted earnings from the U.S. to lower-tax non-U.S. jurisdictions. The effective tax rate for the nine months ended September 30, 2013 reflects a non-deductible goodwill impairment charge of \$40.7 million recorded during the three months ended March 31, 2013.

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.

As of September 30, 2014, we maintained a valuation allowance of \$35.4 million against deferred tax assets primarily related to foreign net operating loss carryforwards and capital loss carryforwards. These net operating and capital loss carryforwards would result in an income tax benefit if we were to conclude it is more likely than not that the related deferred tax assets will be realized.

During the three months ended September 30, 2014, the change in our gross unrecognized tax benefits was not material. The total amount of gross unrecognized tax benefits was \$31.1 million as of September 30, 2014, all of which would impact our effective tax rate if recognized. We have elected to recognize interest and penalties related to unrecognized tax benefits as a component of income taxes. The change in accrued interest and penalties during the three months ended September 30, 2014 was not material. We do not expect any significant changes to the amount of unrecognized tax benefit within the next twelve months.

During the first quarter of 2014, we adopted ASU 2013-11, "Presentation of an Unrecognized Tax Benefit when a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists (a consensus of the FASB Emerging Issues Task Force)." The adoption of this standard had the effect of reducing our accruals for uncertain tax positions by \$8.4 million, with an offsetting reduction in our long term deferred tax assets, but had no effect on net income.

We are subject to taxation in the U.S. and various states and foreign jurisdictions. All of our tax years will be open to examination by the U.S. federal and most state tax authorities due to our net operating loss and overall credit carryforward position. With few exceptions, we are no longer subject to examination by foreign tax authorities for years before 2006.

In June 2009, the Costa Rica Ministry of Foreign Trade, an agency of the Government of Costa Rica, granted a twelve year extension of certain income tax incentives, which were previously granted in 2002. The incentive tax rates will

expire in various years beginning in 2017. Under these incentives, all of the income in Costa Rica during these twelve year incentive periods is subject to reduced rate of Costa Rica income tax. In order to receive the benefit of these incentives, we must hire specified numbers of employees and maintain certain 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. The Costa Rica corporate income tax rate that would apply, absent the incentives, is 30% for 2014. As a result of these incentives, our income taxes were reduced by \$22.8 million and \$18.0 million for the nine months ended September 30, 2014 and 2013, respectively, representing a benefit to diluted net income per share of \$0.28 and \$0.22 in 2014 and 2013, respectively. For the three months ended September 30, 2014 and 2013, income taxes were reduced by \$7.7 million and \$6.1 million, respectively, representing a benefit to diluted net income per share of \$0.09 and \$0.08, respectively.

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Note 12. Net Income Per Share

Basic net income per share is computed using the weighted average number of shares of common stock outstanding during the period. Diluted net income per share is computed using the weighted average number of shares of common stock, adjusted for any dilutive effect of potential common stock. Potential common stock, computed using the treasury stock method, includes stock options, RSU, MSU and ESPP.

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

| | Three Months Ended, September 30, | | Nine Months Ended, September 30, | |
|---|--------------------------------------|----------|-------------------------------------|----------|
| | 2014 | 2013 | 2014 | 2013 |
| Numerator: | | | | |
| Net income | \$38,247 | \$34,537 | \$106,291 | \$21,874 |
| Denominator: | | | | |
| Weighted-average common shares outstanding, basic | 80,629 | 79,967 | 80,924 | 80,592 |
| Dilutive effect of potential common stock | 1,385 | 1,881 | 1,519 | 1,957 |
| Total shares, diluted | 82,014 | 81,848 | 82,443 | 82,549 |
| Net income per share, basic | \$0.47 | \$0.43 | \$1.31 | \$0.27 |
| Net income per share, diluted | \$0.47 | \$0.42 | \$1.29 | \$0.26 |

For the three and nine months ended September 30, 2014 and September 30, 2013, the anti-dilutive effect from stock options, RSU, MSU and ESPP was not material.

Note 13. Segments and Geographical Information

Segment Information

Operating segments are defined as components of an enterprise for 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 CODM 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 Scanner 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 Scanner 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 scanner and OrthoCAD services.

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These reportable operating segments are based on how our CODM views and evaluates our operations as well as allocation of resources. The following information relates to these segments (in thousands):

| | For the Three Months Ended September 30, | | For the Nine Months Ended September 30, | |
|----------------------------------|---|------------|--|------------|
| | 2014 | 2013 | 2014 | 2013 |
| Net Revenues | | | | |
| Clear Aligner | | | | |
| Invisalign Full Products | \$ 147,583 | \$ 125,169 | \$ 432,874 | \$ 361,328 |
| Invisalign Express/Lite Products | 19,205 | 17,702 | 59,308 | 52,943 |
| Invisalign non-case revenues | 11,350 | 10,679 | 33,930 | 34,154 |
| Scanner | | | | |
| Scanners and Services | 11,738 | 10,956 | 36,941 | 33,489 |
| Total net revenues | \$ 189,876 | \$ 164,506 | \$ 563,053 | \$ 481,914 |
| Gross profit | | | | |
| Clear Aligner | \$ 141,117 | \$ 122,663 | \$ 415,903 | \$ 352,114 |
| Scanners and Services | 3,937 | 2,427 | 11,878 | 9,516 |
| Total gross profit | \$ 145,054 | \$ 125,090 | \$ 427,781 | \$ 361,630 |

Geographical Information

Net revenues are presented below by geographic area (in thousands):

| | For the Three Months Ended September 30, | | For the Nine Months Ended September 30, | |
|------------------------------|---|------------|--|------------|
| | 2014 | 2013 | 2014 | 2013 |
| Net revenues: ⁽¹⁾ | | | | |
| U.S. | \$ 134,244 | \$ 123,904 | \$ 396,837 | \$ 365,596 |
| the Netherlands | 35,878 | 26,494 | 118,401 | 86,049 |
| Other international | 19,754 | 14,108 | 47,815 | 30,269 |
| Total net revenues | \$ 189,876 | \$ 164,506 | \$ 563,053 | \$ 481,914 |

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

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

| | September 30, 2014 | December 31, 2013 |
|-----------------------------------|-----------------------|----------------------|
| Long-lived assets: ⁽²⁾ | | |
| United States | \$ 72,616 | \$ 61,439 |
| Mexico | 6,266 | 6,291 |
| the Netherlands | 1,067 | 1,630 |
| Other International | 6,498 | 6,383 |
| Total long-lived assets | \$ 86,447 | \$ 75,743 |

⁽²⁾ Long-lived assets are attributed to countries based on entity that owns the asset.

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 that 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 scanner and services business, our expectations to increase our investment in manufacturing capacity, our expectations regarding the continued expansion of our international markets, the anticipated number of new doctors trained, the effectiveness of our new training course and its impact on volumes, our expectations regarding our stock repurchase program, 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.

Overview

Align Technology, Inc. is a global medical device company that advanced 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 Services ("Scanner"), known as the iTero intra-oral scanners and OrthoCAD services (which we previously referred to as Scanner and CAD/CAM Services ("SCCS")).

We received FDA clearance in 1998 and began our first commercial sales of Invisalign to U.S. orthodontists 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 Europe Middle East and Africa ("EMEA"), and introduced a full range of treatment options including Invisalign Express 10, Invisalign Teen, Invisalign Assist, and Vivera Retainers. By 2011, we launched 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 2013, we launched SmartTrack, the next generation of Invisalign clear aligner material, which became the new standard aligner material for Invisalign products in North America, Europe and other international markets where we have obtained regulatory approval. Most recently, in February 2014, we launched Invisalign G5 innovations, specifically designed for treatment of deep bite malocclusion as well as ClinCheck Pro, the next generation Invisalign treatment software tool, designed to help Invisalign providers achieve their treatment goals. We also sell iTero intra-oral scanners and provide computer-aided design and computer-aided manufacturing ("CAD/CAM") services. 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. In late 2012, we commercially launched the Invisalign Outcome Simulator, the first Invisalign chair-side application powered by the iTero scanner. The interactive application provides dentists and orthodontists an enhanced platform for patient education and is designed to increase treatment acceptance by helping patients visualize the benefits possible with Invisalign treatment. In January 2014, we announced that the 3M™ True Definition scanner was qualified for use with Invisalign case submissions. This qualification enables Invisalign providers with a True Definition scanner to submit a digital impression in place of a traditional PVS impression as part of the Invisalign case submission process. The 3M True Definition scanner is currently the

only third-party scanner that has been qualified for use with Invisalign treatment. We continue to believe in an open systems approach to digital impressions, and are committed to working with other intra-oral scanning companies interested in developing interoperability for use with Invisalign treatment.

The Invisalign System is offered in more than 80 countries and has been used to treat more than 2.8 million patients. Our iTero intra-oral scanner, which is primarily sold in North America, provides dental professionals with an open choice to send digital impressions to any laboratory-based CAD/CAM system or to any of the more than 2,300 dental labs worldwide.

Our goal is to establish Invisalign clear aligners as the standard method for treating malocclusion and to establish the iTero intra-oral scanner as the preferred scanning device for 3D digital scans, ultimately driving increased product adoption by dental professionals. We intend to achieve this by continued focus and execution of our strategic growth drivers set forth in the Business Strategy section in our Annual Report on Form 10-K.

The successful execution of our business strategy and our results in 2014 and beyond may be affected by a number of other factors, which are updated below:

New Products, Feature Enhancements and Technology Innovation. Product innovation drives greater treatment predictability and clinical applicability, and ease of use for our customers, which supports adoption of Invisalign in their practices. Increasing applicability and treating more complex cases requires that we move away from individual features to more comprehensive solutions so that Invisalign providers can more predictably treat the whole case, such as with Invisalign G5 for deep bite treatment. Launched in February 2014, Invisalign G5 was engineered to help doctors achieve even better clinical outcomes when treating patients with deep bites - a prevalent orthodontic problem. In North America, in February 2014, we also launched ClinCheck Pro, the next generation Invisalign treatment software tool, designed to provide more precise control over final tooth position and to help Invisalign providers achieve their treatment goals. We intend to launch ClinCheck Pro in our other country markets in the first quarter of 2015. We believe that over the long-term, clinical solutions and treatment tools will increase adoption of Invisalign; however, it is difficult to predict the rate of adoption which may vary by region and channel.

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, also known as "utilization rates". Our quarterly utilization rates for the previous 9 quarters are as follows:

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

Total utilization in the third quarter of 2014 was 4.4 cases per doctor, up slightly from 4.3 cases in the third quarter of 2013 driven primarily by North America orthodontist and International customers. Utilization among our North American orthodontist customers increased to 8.8 cases per doctor in the third quarter of 2014 from 8.4 cases in the third quarter of 2013, while our International doctor utilization increased to 4.3 cases in the third quarter of 2014 from 4.1 cases in the third quarter of 2013. This increase in North America orthodontist utilization reflects improvements in product and technology, which continues to strengthen our doctors' clinical confidence in the use of Invisalign such that they now utilize Invisalign more often and on more complex cases, including their teenage patients. Increased International utilization reflects growth in both the EMEA and Asia Pacific regions driven by go-to-market and sales coverage investments, improving clinical education and support as well as ongoing technology innovation. Year over year utilization for our North American GP customers decreased to 2.8 cases per doctor in the third quarter of 2014 from 2.9 cases in the third quarter of 2013. 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 due to a variety of factors, including as a result of seasonal trends in our business.

Seasonal Trends. In North America, summer is typically the busiest season for orthodontists with practices that have a high percentage of adolescent and teenage patients as many parents want to get their teenagers started in treatment before the start of the school year; however, many GPs are on vacation during this time and, therefore, tend to start fewer cases. Internationally, sales of Invisalign treatment are often weaker in the summer months due to our customers and their patients being on holiday. The fourth quarter is often a slower period for North American Orthodontists as fewer teenagers start orthodontic treatment once the school year has started. As such, we expect North American Orthodontists to be down sequentially in the fourth quarter. Offsetting this trend, our fourth quarter has historically been a stronger quarter for our international doctors and North American GPs as they rebound from a seasonally slower summer quarter. We expect volume for both international and North American GPs to be up sequentially in the fourth quarter. Consequently, we expect that our Invisalign volume in the fourth quarter of 2014 will be up slightly compared to the third quarter.

Number of new Invisalign doctors trained. We continue to expand our Invisalign customer base through the training of new doctors. In 2013, Invisalign growth was driven primarily by increased utilization by our orthodontist customers as well as by the continued expansion of our customer base as we trained a total of 8,065 new Invisalign doctors. GPs are one of the keys to driving growth in the adult segment, and, in 2014, we launched a new CE I training course, now called Invisalign Fundamentals, designed to improve practice integration and increase utilization for newly trained doctors. We have implemented this new Invisalign Fundamentals program across North America and will look for opportunities to adjust our international training programs as we work to help our GP practices worldwide more successfully adopt Invisalign into their practices. We believe that this new training approach will increase the number of doctors submitting cases 90-days post-training, as well as the number of cases submitted per doctor.

International Clear Aligner. We will continue to focus our efforts towards increasing adoption of our products by dental professionals in our direct international markets. On a year over year basis, international volume increased 27.8%, driven primarily by growth in Europe as well as by strong performance in the Asia Pacific region. In 2014, we are continuing to expand in our existing markets through targeted investments in sales coverage and professional marketing and education programs, along with consumer marketing in selected country markets. In addition, given the significant long term potential this extensive geography represents and the support we can now provide by utilizing our direct coverage model in Europe, beginning in February 2014, we began the transition of a small number of countries into direct sales regions. We continued the transition of additional smaller countries during the current quarter which will continue through February 2015. We expect to leverage our existing infrastructure and resources to bring sales coverage and customer support to these countries, most of which are adjacent to our directly covered European countries. Due to the small volume of business from our EMEA distributor, we do not anticipate that this transition will have a material effect on our financial results in the next several years.

Foreign exchange rates. Although the U.S. dollar is our reporting currency, a portion of our net revenues and income are generated in foreign currencies. Net revenues and income 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 exchange rates against the U.S. dollar will continue to affect the reported amount of net revenues and income in our consolidated financial statements. In the third quarter of 2014, our net revenues were negatively impacted by \$0.8 million and we incurred other foreign currency translation net losses of \$2.1 million in Interest and Other Income (Expense) net, due to current fluctuations of the Euro to the U.S. Dollar.

Medical Device Excise Tax. During March 2014, Align had extensive discussions with the IRS and they informed us that our aligners are not subject to the medical device excise tax ("MDET") which we had been paying and expensing in general and administrative expenses in the consolidated statements of operations since January 1, 2013; however, our scanners are still subject to the MDET. As a result of these discussions, beginning in March 2014, we ceased expensing and paying the MDET for aligners, which reduced our first quarter general and administrative expense by approximately \$0.5 million. In June 2014, we received a \$1.2 million refund for MDET paid in 2014 related to our aligners which reduced general and administrative expenses for the three months ended June 30, 2014. In the current quarter, MDET expense was lower by approximately \$1.6 million compared to the same quarter in the prior year. Additionally, we are in process of claiming a \$6.8 million refund of MDET paid in 2013 related to our aligners; however, because this claim is subject to review and approval by the IRS, we have not recorded a receivable as the outcome of the audit is uncertain. Any future changes in the applicability of the MDET as it applies to us or refunds of amounts previously paid will be recorded as an additional expense or a credit to the consolidated statement of operations in the period in which it becomes probable and reasonably estimable.

Stock Repurchase Authorization. On April 23, 2014, we announced that our Board of Directors had authorized a stock repurchase program pursuant to which we may purchase up to \$300.0 million of our common stock over the next three years, with \$100.0 million of that amount authorized to be purchased over the first twelve months. Any purchases under this stock repurchase program may be made, from time-to-time, pursuant to open market purchases (including pursuant to Rule 10b5-1 plans), privately-negotiated transactions, accelerated stock repurchases, block trades or derivative contracts or otherwise in accordance with applicable federal securities laws, including Rule 10b-18 of the Securities Exchange Act of 1934. The program does not obligate Align to acquire any particular amount of common stock and depending on market conditions or other factors these purchases may be commenced or suspended at any time, or from time-to-time without prior notice. The authorization or continuance of any repurchases under stock repurchase programs is contingent on a variety of factors, including our financial condition, results of operations, business requirements, and our Board of Directors' continuing determination that such stock repurchases are in the best interests of our stockholders and in compliance with all laws and applicable agreements. Additionally, there can be no assurance that our stock repurchase program will have a beneficial impact on our stock price. As of September 30, 2014, there is approximately \$222.6 million remaining under the April 2014 stock repurchase program. Accelerated Stock Repurchase Agreement. As part of our \$300.0 million stock repurchase program, we entered into an accelerated share repurchase agreement ("ASR") with Goldman, Sachs & Co. on April 28, 2014 to repurchase \$70.0 million of our common stock. We paid \$70.0 million on April 29, 2014 and received an initial delivery of approximately 1.0 million shares based on the then current market price, which were retired. The ASR was completed on July 29, 2014 with a final delivery of approximately 0.4 million shares. Under the ASR, we received a total of approximately 1.4 million shares of our common stock for an average purchase price per share of \$51.46. The final number of shares repurchased was based on our volume-weighted average stock price during the term of the transaction, less an agreed upon discount.

Results of Operations

Net revenues by Reportable Segment

We group our operations into two reportable segments: Clear Aligner segment and Scanner segment.

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

Our Scanner 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 scanner and OrthoCAD services.

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Net revenues for our Clear Aligner segment by region and product and our Scanner segment by region for the three and nine months ended September 30, 2014 and 2013 is as follows (in millions).

| | For the Three Months Ended, September 30, | | | | For the Nine Months Ended, September 30, | | | | |
|----------------------------------|--|----------------|---------------|-------------|---|----------------|---------------|-------------|----------|
| | 2014 | 2013 | Net Change | % Change | 2014 | 2013 | Net Change | % Change | |
| Clear Aligner: | | | | | | | | | |
| Region | | | | | | | | | |
| North America | \$113.3 | \$103.9 | \$9.4 | 9.0 | % \$332.9 | \$303.2 | \$29.7 | 9.8 | % |
| International | 53.4 | 38.9 | 14.5 | 37.3 | % 159.3 | 111.0 | 48.3 | 43.5 | % |
| Invisalign non-case net revenues | 11.4 | 10.7 | 0.7 | 6.5 | % 33.9 | 34.2 | (0.3) | (0.9) | % |
| Total Clear Aligner net revenues | \$178.1 | \$153.5 | \$24.6 | 16.0 | % \$526.1 | \$448.4 | \$77.7 | 17.3 | % |
| Product | | | | | | | | | |
| Invisalign Full Products | \$147.6 | \$125.1 | \$22.5 | 18.0 | % \$432.9 | \$361.2 | \$71.7 | 19.9 | % |
| Invisalign Express Products | 19.2 | 17.7 | 1.5 | 8.5 | % 59.3 | 53.0 | 6.3 | 11.9 | % |
| Invisalign non-case net revenues | 11.3 | 10.7 | 0.6 | 5.6 | % 33.9 | 34.2 | (0.3) | (0.9) | % |
| Total Clear Aligner net revenues | \$178.1 | \$153.5 | \$24.6 | 16.0 | % \$526.1 | \$448.4 | \$77.7 | 17.3 | % |
| Scanner: | | | | | | | | | |
| Region | | | | | | | | | |
| North America | \$11.6 | \$10.9 | \$0.7 | 6.4 | % \$36.6 | \$33.2 | \$3.4 | 10.2 | % |
| International | 0.1 | 0.1 | — | — | % 0.3 | 0.3 | — | — | % |
| Total Scanner net revenues | \$11.7 | \$11.0 | \$0.7 | 6.4 | % \$36.9 | \$33.5 | \$3.4 | 10.1 | % |
| Total net revenues | \$189.9 | \$164.5 | \$25.4 | 15.4 | % \$563.1 | \$481.9 | \$81.2 | 16.8 | % |

Changes and percentages are based on actual values. Certain tables may not sum or recalculate due to rounding.

Clear Aligner Case Volume by Region and Product

Case volume data which represents Invisalign case shipments by region and product, for the three and nine months ended September 30, 2014 and 2013 is as follows (in thousands).

| Region | For the Three Months Ended, September 30, | | | | For the Nine Months Ended, September 30, | | | | |
|----------------------------------|--|-------|---------------|-------------|---|-------|---------------|-------------|---|
| | 2014 | 2013 | Net Change | % Change | 2014 | 2013 | Net Change | % Change | |
| North American Invisalign | 85.4 | 80.1 | 5.3 | 6.6 | % 251.7 | 233.6 | 18.1 | 7.7 | % |
| International Invisalign | 34.2 | 26.8 | 7.4 | 27.6 | % 99.4 | 77.6 | 21.8 | 28.1 | % |
| Total Invisalign case volume | 119.6 | 106.9 | 12.7 | 11.9 | % 351.1 | 311.2 | 39.9 | 12.8 | % |
| Product | | | | | | | | | |
| Invisalign Full Product Group | 99.4 | 87.7 | 11.7 | 13.3 | % 290.3 | 251.8 | 38.5 | 15.3 | % |
| Invisalign Express Product Group | 20.2 | 19.2 | 1.0 | 5.2 | % 60.8 | 59.4 | 1.4 | 2.4 | % |
| Total Invisalign case volume | 119.6 | 106.9 | 12.7 | 11.9 | % 351.1 | 311.2 | 39.9 | 12.8 | % |

Changes and percentages are based on actual values. Certain tables may not sum or recalculate due to rounding.

Total net revenues increased by \$25.4 million and \$81.2 million for the three and nine months ended September 30, 2014, respectively, as compared to the same period in 2013 primarily as a result of Invisalign case volume growth across all regions and most products.

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Clear Aligner

In the three months ended September 30, 2014, Clear Aligner North America net revenues increased by \$9.4 million or 9.0% compared to the same period in 2013 primarily due to Invisalign case volume growth of approximately \$6.8 million across all channels and most products and, to a lesser extent, higher average selling prices ("ASP") which contributed approximately \$2.6 million to the increase in net revenues. The increase in ASP was primarily a result of increased mid-course correction revenue in the current period compared to the same period in the prior year.

In the nine months ended September 30, 2014, Clear Aligner North America net revenues increased by \$29.7 million or 9.8% compared to the same period in 2013 mainly due to Invisalign case volume growth of \$23.3 million and, to a lesser extent, higher ASP which contributed approximately \$6.4 million to the increase in net revenues. The increase in ASP was a result of a product mix shift towards higher priced Invisalign full products as well as increased mid-course correction revenue in the current period compared to the same period in the prior year.

In the three months ended September 30, 2014, Clear Aligner international net revenues increased by \$14.5 million or 37.3% compared to the same period in 2013 primarily driven by Invisalign case volume growth of \$10.8 million across all products and higher ASP which contributed approximately \$3.6 million to the increase in net revenues. The increase in ASP was a result of a product mix shift towards higher priced Invisalign full products in the current period compared to the same period in the prior year as well as a favorable impact from foreign exchange rates.

In the nine months ended September 30, 2014, Clear Aligner international net revenues increased by \$48.3 million or 43.5% compared to the same period in 2013 mainly due to Invisalign case volume growth of \$31.5 million and, to a lesser extent, higher ASP which contributed approximately \$16.7 million to increase in net revenues. The increase in ASP was primarily due to the impact from acquiring our distributor in the Asia Pacific region on April 30, 2013 as we now recognize direct sales of Invisalign products sold in that region at our full ASP rather than the discounted ASP under the distributor agreement, as well as favorable impact from foreign exchange rates.

Invisalign non-case net revenues, consisting of training fees and ancillary product revenues, increased by \$0.7 million or 6.5% for the three months ended September 30, 2014 compared to the same period in 2013 primarily due to increased Vivera volume both in North America and international.

Invisalign non-case net revenue decreased by \$0.3 million or 0.9% for the nine months ended September 30, 2014 compared to the same period in 2013 primarily due to the consolidation of our Vivera product shipments in North America from four shipments per year to one shipment in 2013, offset in part by increased Vivera volume both in North America and International for the nine months ended September 30, 2014.

Scanner and Services

Scanner and Services net revenues increased \$0.7 million or 6.4% for the three months ended September 30, 2014 compared to the same period in 2013. The increase was primarily due to an increase in the volume of services resulting from a larger installed base of scanners. This increase was offset in part by a decrease in scanner revenue which was primarily due to a decrease in the number of scanners recognized.

Scanner and Services net revenues increased \$3.4 million or 10.1% for the nine months ended September 30, 2014 compared to the same period in 2013. The increase was primarily due to an increase in both scanner revenue as well as service revenue. The increase in scanner revenue was primarily due to an increase in the number of scanners recognized offset in part by lower scanner ASP as a result of promotional discounts as well as permanent price reductions. Additionally, scanner revenues for the nine months ended September 30, 2013 included a release of \$1.4 million of revenue previously reserved for the iTero upgrade program which was completed in the first quarter of

2013. The increase in services revenue was primarily due to an increase in the volume of services resulting from a larger installed base of scanners.

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

| | Three Months Ended September 30, | | | Nine Months Ended September 30, | | |
|----------------------------|----------------------------------|---------|----------|---------------------------------|---------|--------|
| | 2014 | 2013 | Change | 2014 | 2013 | Change |
| Clear Aligner | | | | | | |
| Cost of net revenues | \$37.0 | \$30.9 | \$6.1 | \$110.2 | \$96.3 | \$13.9 |
| % of net segment revenues | 20.8 | % 20.1 | % | 20.9 | % 21.5 | % |
| Gross profit | \$141.1 | \$122.7 | \$18.4 | \$415.9 | \$352.1 | \$63.8 |
| Gross margin % | 79.2 | % 79.9 | % | 79.1 | % 78.5 | % |
| Scanner | | | | | | |
| Cost of net revenues | \$7.8 | \$8.5 | \$(0.7) | \$25.1 | \$24.0 | \$1.1 |
| % of net segment revenues | 66.5 | % 77.8 | % | 67.8 | % 71.6 | % |
| Gross profit | \$3.9 | \$2.4 | \$1.5 | \$11.9 | \$9.5 | \$2.4 |
| Gross margin % | 33.5 | % 22.2 | % | 32.2 | % 28.4 | % |
| Total cost of net revenues | \$44.8 | \$39.4 | \$5.4 | \$135.3 | \$120.3 | \$15.0 |
| % of net revenues | 23.6 | % 24.0 | % | 24.0 | % 25.0 | % |
| Gross profit | \$145.1 | \$125.1 | \$20.0 | \$427.8 | \$361.6 | \$66.2 |
| Gross margin % | 76.4 | % 76.0 | % | 76.0 | % 75.0 | % |

Changes and percentages are based on actual values. Certain tables may not sum or recalculate due to rounding.

Cost of net revenues for our Clear Aligner and Scanner segments 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.

Clear Aligner

Gross margin decreased for the three months ended September 30, 2014 compared to the same period in 2013 as we experienced lower warranty costs in the prior year period corresponding with the change in our mid-course correction policy in June 2013. These were partially offset by a higher ASP.

Gross margin increased for the nine months ended September 30, 2014 compared to the same period in 2013 due to higher ASP. This was partially offset by increased costs from higher volumes from mid-course corrections.

Scanner

Gross margin increased for the three months ended September 30, 2014 compared to the same period in 2013 due to a product mix shift to lower cost products along with lower inventory reserves.

Gross margin increased for the nine months ended September 30, 2014 compared to the same period in 2013 due to increased absorption of manufacturing spend from higher production volumes and lower costs related to the discontinuation of OrthoCAD iQ services. This was partially offset by a lower ASP from price reductions.

Sales and marketing (in millions):

| | Three Months Ended September 30, | | | Nine Months Ended September 30, | | |
|--|----------------------------------|------|--------|---------------------------------|------|--------|
| | 2014 | 2013 | Change | 2014 | 2013 | Change |

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| | | | | | | |
|---------------------|--------|--------|-------|---------|---------|--------|
| Sales and marketing | \$52.4 | \$45.2 | \$7.2 | \$161.6 | \$135.4 | \$26.2 |
| % of net revenues | 27.6 | % 27.5 | % | 28.7 | % 28.1 | % |

Changes and percentages are based on actual values. Certain tables may not sum or recalculate due to rounding.

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

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Sales and marketing expense for the three months ended September 30, 2014 increased compared to the same period in 2013 primarily due to higher compensation related costs of \$2.3 million due to increased headcount as well as higher salaries and higher stock-based compensation. In addition, advertising, public relations and training costs increased due to increased advertising production, social media campaigns and increased customer training and study clubs.

Sales and marketing expense for the nine months ended September 30, 2014 increased compared to the same period in 2013 primarily due to higher compensation costs of \$14.4 million due to increased headcount, including additional employees as a result of the acquisition of our APAC distributor on April 30, 2013, as well as higher salaries and higher stock-based compensation. In addition, we incurred higher advertising, trade show, public relations, and marketing expenses primarily due to increased advertising production and marketing campaigns, travel, trade shows, and events costs including our Europe and APAC Summit events and higher social media campaigns.

General and administrative (in millions):

| | Three Months Ended September 30, | | | Nine Months Ended September 30, | | |
|----------------------------|----------------------------------|--------|--------|---------------------------------|--------|---------|
| | 2014 | 2013 | Change | 2014 | 2013 | Change |
| General and administrative | \$28.3 | \$27.5 | \$0.8 | \$84.5 | \$84.9 | \$(0.4) |
| % of net revenues | 14.9 | % 16.7 | % | 15.0 | % 17.6 | % |

Changes and percentages are based on actual values. Certain tables may not sum or recalculate due to rounding.

General and administrative expense primarily includes administrative personnel compensation costs including stock-based compensation, outside consulting services, legal expenses, depreciation and amortization expense, the medical device excise tax ("MDET") and allocations of corporate overhead expenses including facilities and IT.

General and administrative expense was relatively consistent for the three months ended September 30, 2014 compared to the same period in 2013. Compensation related expenses increased due to higher stock-based compensation as well as increases in credit card processing fees and consulting expenses; however, these increases were offset in part by a decrease in MDET expense of \$1.6 million. As previously noted, in March 2014, the IRS informed us that our aligners are not subject to the MDET, which we had been paying and expensing in general and administrative expenses in the consolidated statements of operations since January 1, 2013; however, our scanners are still subject to the MDET. There is no expense in the current year period for MDET related to our aligners. Additionally, we are in process of claiming a \$6.8 million refund of MDET paid in 2013 related to our aligners; however, because this claim is subject to review and approval by the IRS, we have not recorded a receivable as the outcome of the audit is uncertain. Any future changes in the applicability of the MDET as it applies to us or refunds of amounts previously paid will be recorded as an additional expense or a credit to the consolidated statement of operations in the period in which it becomes probable and reasonably estimable.

General and administrative expense for the nine months ended September 30, 2014 decreased slightly compared to the same period in 2013 primarily related to lower MDET of \$5.0 million as our aligners are no longer subject to the tax in 2014 in relation to our aligners as well as lower outside litigation costs. These decreases were partially offset by higher compensation related expenses due to higher stock-based compensation and higher salaries along with higher credit card processing fees.

Research and development (in millions):

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| | Three Months Ended September | | | Nine Months Ended September | | |
|--------------------------|------------------------------|--------|--------|-----------------------------|--------|--------|
| | 30, 2014 | 2013 | Change | 30, 2014 | 2013 | Change |
| Research and development | \$12.9 | \$10.9 | \$2.0 | \$39.5 | \$33.1 | \$6.4 |
| % of net revenues | 6.8 | % 6.6 | % | 7.0 | % 6.9 | % |

Changes and percentages are based on actual values. Certain tables may not sum or recalculate due to rounding. 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, corporate allocations, facility and facility related costs and stock-based compensation expense.

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Research and development expense for the three and nine months ended September 30, 2014 increased compared to the same periods in 2013 almost entirely due to higher compensation costs as a result of higher bonuses and stock-based compensation as well as additional headcount and increased salaries.

Impairment of goodwill (in millions):

| | Three Months Ended September 30, | | | Nine Months Ended September 30, | | |
|------------------------|----------------------------------|------|--------|---------------------------------|--------|-----------|
| | 2014 | 2013 | Change | 2014 | 2013 | Change |
| Impairment of goodwill | \$— | \$— | \$— | \$— | \$40.7 | \$(40.7) |
| % of net revenues | — | % — | % | — | % 8.4 | % |

Changes and percentages are based on actual values. Certain tables may not sum or recalculate due to rounding.

There was no impairment of goodwill charge recorded in the three or nine months ended September 30, 2014.

In the first quarter of 2013, we determined that the goodwill for our Scanner reporting unit should be tested for impairment between annual tests since an event occurred or circumstances changed that would more likely than not reduce the fair value of our Scanner reporting unit below its carrying amount. As a result of our analysis, we recorded a goodwill impairment charge of \$40.7 million in the first quarter of 2013, none of which was deductible for tax purposes. Refer to Note 5 for details of the impairment analysis.

Impairment of long-lived assets (in millions):

| | Three Months Ended September 30, | | | Nine Months Ended September 30, | | |
|---------------------------------|----------------------------------|------|--------|---------------------------------|--------|-----------|
| | 2014 | 2013 | Change | 2014 | 2013 | Change |
| Impairment of long-lived assets | \$— | \$— | \$— | — | \$26.3 | \$(26.3) |
| % of net revenues | — | % — | % | — | % 5.5 | % |

Changes and percentages are based on actual values. Certain tables may not sum or recalculate due to rounding.

There was no impairment of long-lived assets charge recorded in the three or nine months ended September 30, 2014.

We recorded \$26.3 million related to the impairment of long-lived assets during the first quarter of 2013 as a result of changes in the competitive environment of our intra-oral scanners, which included announcements of new low-priced scanners targeted at orthodontists and general practitioner dentists in North America, which caused us to lower our expectations for growth and profitability for our Scanner reporting unit. Therefore, we determined that the carrying value of the long-lived assets was not recoverable and recorded an impairment charge of \$26.3 million. Refer to Note 5 for details of the impairment analysis.

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

| | Three Months Ended September 30, | | | Nine Months Ended September 30, | | |
|--|----------------------------------|-------|----------|---------------------------------|--------|----------|
| | 2014 | 2013 | Change | 2014 | 2013 | Change |
| Interest and other income (expense), net | \$(2.0) | \$0.5 | \$(2.5) | (1.5) | (0.9) | \$(0.6) |

Changes and percentages are based on actual values. Certain tables may not sum or recalculate due to rounding.

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

Interest and other income (expense), net for the three and nine months ended September 30, 2014 decreased compared to the same periods in 2013 due to higher foreign exchange losses in the current year periods primarily as a result of the strengthening of the U.S. dollar to the Euro.

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Income tax (in millions):

| | Three Months Ended September 30, | | | Nine Months Ended September 30, | | |
|----------------------------|----------------------------------|--------|--------|---------------------------------|--------|--------|
| | 2014 | 2013 | Change | 2014 | 2013 | Change |
| Provision for income taxes | \$11.3 | \$7.4 | \$3.9 | \$34.3 | \$18.5 | \$15.8 |
| Effective tax rates | 22.8 | % 17.6 | % | 24.4 | % 45.9 | % |

Our provision for income taxes was \$11.3 million and \$7.4 million for the three months ended September 30, 2014 and 2013, respectively. This represents effective tax rates of 22.8% and 17.6%, respectively. The increase in our provision for income taxes was primarily due to higher pre-tax income, which was partially offset by a jurisdictional shift in forecasted earnings from the U.S. to lower-tax non-U.S. jurisdictions.

Our provision for income taxes was \$34.3 million and \$18.5 million for the nine months ended September 30, 2014 and 2013, respectively. This represents effective tax rates of 24.4% and 45.9%, respectively. Our provision for income taxes reflects a negative impact from a \$1.8 million adjustment related to prior years, offset by a jurisdictional shift in forecasted earnings from the U.S. to lower-tax non-U.S. jurisdictions. The effective tax rate for the nine months ended September 30, 2013 reflects a non-deductible goodwill impairment charge of \$40.7 million recorded during the three months ended March 31, 2013.

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.

As of September 30, 2014, we maintained a valuation allowance of \$35.4 million against deferred tax assets primarily related to foreign net operating loss carryforwards and capital loss carryforwards. These net operating and capital loss carryforwards would result in an income tax benefit if we were to conclude it is more likely than not that the related deferred tax assets will be realized.

During the three months ended September 30, 2014, the change in our gross unrecognized tax benefits was not material. The total amount of gross unrecognized tax benefits was \$31.1 million as of September 30, 2014, all of which would impact our effective tax rate if recognized. We have elected to recognize interest and penalties related to unrecognized tax benefits as a component of income taxes. The change in accrued interest and penalties during the three months ended September 30, 2014 was not material. We do not expect any significant changes to the amount of unrecognized tax benefit within the next twelve months.

During the first quarter of 2014, we adopted ASU 2013-11, "Presentation of an Unrecognized Tax Benefit when a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists (a consensus of the FASB Emerging Issues Task Force)." The adoption of this standard had the effect of reducing our accruals for uncertain tax positions by \$8.4 million, with an offsetting reduction in our long term deferred tax assets, but had no effect on net income.

We are subject to taxation in the U.S. and various states and foreign jurisdictions. All of our tax years will be open to examination by the U.S. federal and most state tax authorities due to our net operating loss and overall credit carryforward position. With few exceptions, we are no longer subject to examination by foreign tax authorities for years before 2006.

Liquidity and Capital Resources

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We fund our operations from product sales and the proceeds from the sale of our common stock. As of September 30, 2014 and December 31, 2013, we had the following cash, cash equivalents, and short-term and long-term marketable securities (in thousands):

| | September 30, 2014 | December 31, 2013 |
|---|--------------------------|----------------------|
| Cash and cash equivalents | \$180,676 | \$242,953 |
| Marketable securities, short-term | 244,820 | 127,040 |
| Marketable securities, long-term | 136,017 | 101,978 |
| Total cash, cash equivalents and short-term and long-term marketable securities | \$561,513 | \$471,971 |

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Cash flows (in thousands):

| | Nine Months Ended September 30, | |
|--|------------------------------------|--------------|
| | 2014 | 2013 |
| Net cash flow provided by (used in): | | |
| Operating activities | \$155,294 | \$118,864 |
| Investing activities | (171,373) | (199,989) |
| Financing activities | (46,918) | (48,902) |
| Effect of exchange rate changes on cash and cash equivalents | 720 | (520) |
| Net decrease in cash and cash equivalents | \$(62,277) | \$(130,547) |

As of September 30, 2014, we had \$561.5 million of cash, cash equivalents and short-term and long-term marketable securities. Cash equivalents and marketable securities are comprised of money market funds and debt instruments which include commercial paper, corporate bonds, U.S. government agency bonds, U.S. dollar dominated foreign corporate bonds, U.S. government treasury bonds, municipal securities and asset-backed securities.

As of September 30, 2014, approximately \$298.6 million of cash, cash equivalents and short-term and long-term marketable securities 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. The costs to repatriate our foreign earnings to the U.S. would likely be material; however, our intent is to permanently reinvest our earnings from foreign operations, and our current plans do not require us to repatriate them to fund our U.S. operations as we generate sufficient domestic operating cash flow and have access to external funding under our current revolving line of credit.

On April 23, 2014, we announced that our Board of Directors had authorized a stock repurchase program pursuant to which we may purchase up to \$300.0 million of our common stock over the next three years, with \$100.0 million of that amount authorized to be purchased over the next twelve months. Any purchases under this stock repurchase program may be made, from time-to-time, pursuant to open market purchases (including pursuant to Rule 10b5-1 plans), privately-negotiated transactions, accelerated stock repurchases, block trades or derivative contracts or otherwise in accordance with applicable federal securities laws, including Rule 10b-18 of the Securities Exchange Act of 1934. As part of this repurchase program, on April 28, 2014, we entered into an accelerated share repurchase agreement ("ASR") with Goldman, Sachs & Co. to repurchase \$70.0 million of our common stock. Under the terms of the ASR, we agreed to repurchase in total \$70.0 million of our common stock and received an initial delivery of approximately 1.0 million shares based on the then current market price, which were retired. The ASR was completed on July 29, 2014 with a final delivery of approximately 0.4 million shares. We received a total of 1.4 million shares under the ASR for an average purchase price per share of \$51.46. The final number of shares repurchased was based on our volume-weighted average stock price during the term of the transaction, less an agreed upon discount. In addition, during the three months ended September 30, 2014, we repurchased on the open market approximately 0.1 million shares of our common stock at an average price of \$54.22 per share, including commissions, for an aggregate purchase price of approximately \$7.4 million. All repurchased shares were retired. We have \$222.6 million remaining under the April 2014 stock repurchase program, \$22.6 million of which we expect to purchase over the next six months. We expect to finance future stock repurchases with current cash on hand.

On March 22, 2013, we entered into a credit facility with Wells Fargo Bank. The credit facility provides for a \$50.0 million revolving line of credit, with a \$10.0 million letter of credit sublimit, and has a maturity date on March 22, 2016. The credit facility also requires us to maintain a minimum unrestricted cash balance of \$50.0 million and comply with specific financial conditions and performance requirements. The loan bears interest, at our option, at a fluctuating rate per annum equal to the daily one-month adjusted LIBOR rate plus a spread of 1.75% or an adjusted LIBOR rate (based on one, three, six or twelve-month interest periods) plus a spread of 1.75%. As of September 30, 2014, we had no outstanding borrowings under this credit facility and were in compliance with the conditions and

performance requirements.

We believe that our current cash and cash equivalents and marketable securities combined with our positive cash flows from operations will be sufficient to fund our operations and stock repurchases 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.

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Operating Activities

For the nine months ended September 30, 2014, cash flows from operations of \$155.3 million resulted primarily from our net income of approximately \$106.3 million as well as the following:

Significant non-cash activities:

• stock-based compensation of \$29.3 million related to equity incentive compensation awards granted to our employees, deferred taxes of \$20.9 million, and
• depreciation and amortization of property, plant and equipment and intangibles of \$13.5 million, offset in part by excess tax benefits from our share-based compensation arrangements of \$18.9 million.

Significant changes in working capital:

• an increase of \$24.9 million in accounts receivable which is a result of the increase in net revenues,
• an increase of \$12.4 million in accrued and long term liabilities due to timing of payments and activities, and
• an increase of \$10.0 million in deferred revenues corresponding to the increases in revenues.

Investing Activities

Net cash used in investing activities was \$171.4 million for the nine months ended September 30, 2014 primarily consisting of purchases of marketable securities of \$350.6 million, and property, plant and equipment purchases of \$17.0 million. These outflows were partially offset by \$196.4 million of maturities and sales of our marketable securities.

For the remainder of 2014, we expect to spend an additional \$20.0 million to \$25.0 million on capital expenditures for estimated total capital expenditures of \$37.0 million to \$42.0 million for 2014 primarily for additional manufacturing capacity and infrastructure. Although we believe our current investment portfolio has little risk of impairment, we cannot predict future market conditions or market liquidity and can provide no assurance that our investment portfolio will remain unimpaired.

Financing Activities

Net cash used in financing activities was \$46.9 million for the nine months ended September 30, 2014 primarily resulting from \$77.4 million for the repurchase of our common stock and \$5.8 million related to payroll taxes paid for vesting of restricted stock units through share withholdings. These outflows were offset in part by \$17.4 million in proceeds from issuance of common stock and \$18.9 million from excess tax benefits from our share-based compensation arrangements.

Contractual Obligations

Our contractual obligations have not significantly changed since December 31, 2013 as disclosed in our Annual Report on Form 10-K. We believe that our current cash, cash equivalents and short-term marketable securities 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 and need more funds beyond those available under our credit facility, 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.

Off-Balance Sheet Arrangements

As of September 30, 2014, we had no off-balance sheet arrangements that have, or are reasonably likely to have, a current or future material effect on our consolidated financial condition, results of operations, liquidity, capital expenditures or capital resources.

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Indemnification Provisions

In the normal course of business to facilitate transactions in our services and products, we indemnify certain parties: customers, vendors, lessors and other parties with respect to certain matters, including, but not limited to, services to be provided by us and intellectual property infringement claims made by third parties. In addition, we have entered into indemnification agreements with our directors and certain of our officers that will require us, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. Several of these agreements limit the time within which an indemnification claim can be made and the amount of the claim.

It is not possible to make a reasonable estimate of the maximum potential amount under these indemnification agreements due to the unique facts and circumstances involved in each particular agreement. Additionally, we have a limited history of prior indemnification claims and the payments we have made under such agreements have not had a material adverse effect on our results of operations, cash flows, or financial position. However, to the extent that valid indemnification claims arise in the future, future payments by us could be significant and could have a material adverse effect on our results of operations or cash flows in a particular period. As of September 30, 2014, we did not have any material indemnification claims that were probable or reasonably possible.

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, 2013:

- Revenue recognition;
- Stock-based compensation expense;
- Goodwill and finite-lived acquire assets,
- Impairment of goodwill, finite-lived acquire assets and long-lived assets, and
- Accounting for income taxes.

Recent Accounting Pronouncements

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

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

For quantitative and qualitative disclosures about market risk affecting us, see Item 7A, "Quantitative and Qualitative Disclosures About Market Risk," in our Annual Report on Form 10-K for the year ended December 31, 2013, which is incorporated herein by reference. Our exposure to market risk has not changed materially since December 31, 2013.

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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, 2014, to provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our Chief Executive Officer and our Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure, and that such information is recorded, processed, summarized and reported within the time periods specified in the SEC rules and forms.

Changes in internal control over financial reporting.

There were no changes in our internal control over financial reporting that occurred during the period covered by this report that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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PART II—OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

Securities Class Action Lawsuit

On November 28, 2012, plaintiff City of Dearborn Heights Act 345 Police & Fire Retirement System filed a lawsuit against Align, Thomas M. Prescott (“Mr. Prescott”), Align’s President and Chief Executive Officer, and Kenneth B. Arola (“Mr. Arola”), Align’s former Vice President, Finance and Chief Financial Officer, in the United States District Court for the Northern District of California on behalf of a purported class of purchasers of our common stock (the “Securities Action”). On July 11, 2013, an amended complaint was filed, which named the same defendants, on behalf of a purported class of purchasers of our common stock between January 31, 2012 and October 17, 2012. The amended complaint alleged that Align, Mr. Prescott and Mr. Arola violated Section 10(b) of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder, and that Mr. Prescott and Mr. Arola violated Section 20(a) of the Securities Exchange Act of 1934. Specifically, the amended complaint alleged that during the purported class period defendants failed to take an appropriate goodwill impairment charge related to the April 29, 2011 acquisition of Cadent Holdings, Inc. in the fourth quarter of 2011, the first quarter of 2012 or the second quarter of 2012, which rendered our financial statements and projections of future earnings materially false and misleading and in violation of U.S. GAAP. The amended complaint sought monetary damages in an unspecified amount, costs and attorneys’ fees. On December 9, 2013, the court granted defendants’ motion to dismiss with leave for plaintiff to file a second amended complaint. Plaintiff filed a second amended complaint on January 8, 2014 on behalf of the same purported class. The second amended complaint states the same claims as the amended complaint. On August 22, 2014, the court granted our motion to dismiss without leave to amend. On September 22, 2014, Plaintiff filed a notice of appeal to the Ninth Circuit Court of Appeals. Align intends to vigorously defend itself against these allegations. Align is currently unable to predict the outcome of this amended complaint and therefore cannot determine the likelihood of loss nor estimate a range of possible loss, if any.

Shareholder Derivative Lawsuit

On February 1, 2013, plaintiff Gary Udis filed a shareholder derivative lawsuit against several of Align’s current and former officers and directors in the Superior Court of California, County of Santa Clara. The complaint alleges that our reported income and earnings were materially overstated because of a failure to timely write down goodwill related to the April 29, 2011 acquisition of Cadent Holdings, Inc., and that defendants made allegedly false statements concerning our forecasts. The complaint asserts various state law causes of action, including claims of breach of fiduciary duty, unjust enrichment, and insider trading, among others. The complaint seeks unspecified damages on behalf of Align, which is named solely as nominal defendant against whom no recovery is sought. The complaint also seeks an order directing Align to reform and improve its corporate governance and internal procedures, and seeks restitution in an unspecified amount, costs, and attorneys’ fees. On July 8, 2013, an Order was entered staying this derivative lawsuit until an initial ruling on our first motion to dismiss the Securities Action. On January 15, 2014, an Order was entered staying this derivative lawsuit until an initial ruling on our second motion to dismiss the Securities Action. On October 14, 2014, an Order was entered staying this derivative lawsuit until a ruling by the Ninth Circuit in the Securities Action discussed above. Align is currently unable to predict the outcome of this complaint and therefore cannot determine the likelihood of loss nor estimate a range of possible losses.

In addition, in the course of Align's operations, Align is 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 Align's

view of these matters may change in the future as litigation and events related thereto unfold; Align currently does not believe that these matters, individually or in the aggregate, will materially affect Align's financial position, results of operations or cash flows.

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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 income.

We expect that net revenues from the sale of the Invisalign System, primarily Invisalign Full and Invisalign Teen, 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 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 which may decrease our net revenues.

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; if we expand our discount programs in the future or participation in these programs increases; if our product mix shifts to lower priced

products or products that have a higher percentage of deferred revenue our average selling prices would be adversely affected and our net revenues, gross profit, gross margin and net income may be reduced. Furthermore, although the U.S. dollar is our reporting currency, a portion of our net revenues and net income are generated in foreign currencies. Net revenues and net income generated by subsidiaries operating outside of the U.S. 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 net income in our consolidated financial statements.

As we continue to grow, we are subject to growth related risks, including risks related to excess or constrained capacity 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

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be unable to manage such growth effectively. Any such failure could have a material adverse impact on our business, operations and prospects.

Because we cannot 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 never achieve the anticipated benefits from our acquisitions which may have an adverse effect on our business.

We acquired Cadent Holdings, Inc. in April 2011 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 Invisalign treatment by integrating 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 completed the acquisition of our Asia Pacific distributor on April 30, 2013.

We may experience difficulties in achieving the anticipated financial or strategic benefits of these acquisitions. 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;
- continued changes in the competitive environment, including recent announcements from competitors of new lower-priced scanners which we expect will lengthen the customer evaluation process and may result in price reductions and/or loss of sales;
- difficulty dealing with tax, employment, logistics, and other related issues unique to international operations in Israel and the Asia Pacific region;
- possible impairment of relationships with employees and customers as a result of the integration;
- possible inconsistencies in standards, controls, procedures and policies among the acquired businesses and Align, which may make it more difficult to implement and harmonize worldwide 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, further impairment of goodwill, impairment 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.

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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 U.S. economy and global economies;
- changes in relationships with our distributors;
- changes in the timing of receipt of Invisalign 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 or availability of raw materials;
- 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.

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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 Invisalign. 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 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.

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

Our key production steps are performed in operations located outside of the U.S. At our facility in San Jose, 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 Moscow, Russia. In addition, our customer-care, accounts receivable, credit and collections and customer event registration organizations are located at our facility in San Jose, Costa Rica. We also have operations in Israel where the design and wand assembly and our intra-oral scanner are manufactured. 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, including any travel restrictions to or from our facilities located in Moscow, Russia and Israel;
- fluctuations in currency exchange rates;
- increased income taxes, and other restrictions and limitations, if we were to decide to repatriate any of our foreign cash balances back to the U.S.;
- 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. We cannot predict the effect on us of any future armed conflict, political instability or violence in these regions. In addition, some of our employees in Israel are obligated to perform annual reserve duty in the Israeli military and are subject to being called for additional active duty under emergency circumstances. We cannot predict the full impact of these conditions on us in the future, particularly if emergency circumstances or an escalation in the political situation occurs. If many of our employees are called for active duty, our operations in Israel and our business may not be able to function at full capacity;
- acts of terrorism and acts of war;
- geopolitical risks around the Ukraine and the possibility of additional sanctions against Russia which continue to bring uncertainty to this region;
- interruptions and limitations in telecommunication services;
- product or material transportation delays or disruption, including as a result of increased levels of violence, acts of terrorism, acts of war or 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.

We earn an increasingly larger portion of our total revenues from international sales and face risks attendant to those operations.

We earn an increasingly larger portion of our total revenues from international sales generated through our foreign direct and indirect operations. As a result of these sales operations, we face a variety of risks, including:

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• local political and economic instability;

the engagement of activities by our employees, contractors, partners and agents, especially in countries with developing economies, that are prohibited by international and local trade and labor laws and other laws prohibiting corrupt payments to government officials, including the Foreign Corrupt Practices Act, the UK Bribery Act of 2010 and export control laws, in spite of our policies and procedures designed to ensure compliance with these laws;

although it is our intention to permanently reinvest earnings outside the U.S., restrictions on the transfer of funds held by our foreign subsidiaries, including with respect to restrictions on our ability to repatriate foreign cash to the U.S at favorable tax rates;

• fluctuations in currency exchange rates; and

• increased expense of developing, testing and making localized versions of our products.

Any of these factors, either individually or in combination, could materially impact our international operations and adversely affect our business as a whole.

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 income 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 locations in Costa Rica and Mexico are in earthquake zones and may be subject to other natural disasters. If there is a major earthquake or any other natural disaster in a region where one of these facilities is located, our ability to create ClinCheck treatment plans, respond to customer inquiries or manufacture and ship our aligners could be compromised which could result in our customers experiencing a significant delay in receiving their completed aligners and a decrease in service levels for a period of time. In addition, our headquarters facility in California 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 U.S. 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. The expiration of key certain patents commencing in 2017 owned by us may result in additional competition. 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 income (loss) and stock price. We cannot assure you that we will be able to compete successfully against our current or future

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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. We are in the process of implementing a multi-year, company-wide program to transform certain business processes or extend established processes, including the transition to a single enterprise resource planning ("ERP") software system to perform various functions. The implementation of additional functionality to the ERP system entails certain risks, including difficulties with changes in business processes that could disrupt our operations, such as our ability to track orders and timely ship products, manage our supply chain and aggregate financial and operational data. During transitions we must continue to rely on legacy information systems, which may be costly or inefficient, while the implementation of new initiatives may not achieve the anticipated benefits and may divert management's attention from other operational activities, negatively affect employee morale, or have other unintended consequences. Additionally, if we are not able to accurately forecast expenses and capitalized costs related to the project, this may have an adverse impact on our financial condition and operating results.

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.

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. Software applications frequently contain errors or defects, especially when they are first introduced or when new versions are released. The discovery of a defect or error or the incompatibility with the computer operating system and hardware configurations of customers in a new upgraded version or the failure of our primary information systems may result in the following consequences, among others: loss of revenue or delay in market acceptance, damage to our reputation or increased service costs, any of which could have a material adverse

effect on our business, financial condition or results of operations.

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

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.

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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, 2014, we had issued 341 U.S. patents, 132 pending U.S. patent applications, and 251 foreign issued patents, and 130 pending foreign patent applications.

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

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

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

Pursuant to the Sarbanes-Oxley Act of 2002 and the rules and regulations promulgated by the SEC, we are required to furnish in our Form 10-K 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 believe our internal control over financial reporting is currently 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. 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.

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

We are highly dependent on the key employees in our clinical engineering, technology development, sales, 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. During 2013 and early 2014, we announced the appointment of four executive officers, including a new Chief Financial Officer. With these new appointments, there is the risk of uncertainty and instability relating to transition the duties and responsibilities to new key executives in an orderly, effective and efficient manner. 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 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 the vast majority 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.

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We depend on a single contract manufacturer and supplier of parts used in our iTero scanner 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 iTero scanner. 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, 2014, our North American sales organization consisted of approximately 280 people. Internationally, we had approximately 160 people engaged in direct sales and sales support as of September 30, 2014. We do not have any long-term employment contracts with the members of our direct sales force. The loss of the services provided by these key personnel may harm our business. If we are unable to retain our direct sales force personnel or replace them with individuals of equivalent technical expertise and qualifications, or if we are unable to successfully instill such technical expertise or if we fail to establish and maintain 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 considered 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;
complaint handling and corrective actions;

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advertising and promotion; and
product sales and distribution.

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

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

If any of these events were to occur, they could harm our business. We must comply with facility registration and product listing requirements of the FDA and adhere to applicable Quality System regulations. The FDA enforces its Quality System regulations through periodic unannounced inspections. Our failure 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.

In addition, as part of the Dodd-Frank Wall Street Reform and Consumer Protection Act, the SEC adopted disclosure requirements regarding the use of certain minerals, known as conflict minerals, which are mined from the Democratic Republic of Congo and adjoining countries, as well as procedures regarding a manufacturer's efforts to identify and discourage the sourcing of such minerals and metals produced from those minerals. Additional reporting obligations are being considered by the European Union. The implementation of the existing U.S. requirements and any additional requirements in Europe could affect the sourcing and availability of metals used in the manufacture of a limited number of parts (if any) contained in our products. For example, the implementation of these disclosure requirements may decrease the number of suppliers capable of supplying our needs for certain metals, thereby negatively affecting our ability to obtain products in sufficient quantities or at competitive prices. Our material sourcing is broad based and multi-tiered, and we may be unable to conclusively verify the origins for all metals used in our products. We may suffer financial and reputational harm if customers require, and we are unable to deliver, certification that our products are conflict free. Regardless, we will incur additional costs associated with compliance with these disclosure requirements, including time-consuming and costly efforts to determine the source of any conflict minerals used in our products.

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 passed health care reform legislation that President Obama signed into law in March 2010. This 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. Effective January 1, 2013, as a medical device manufacturer, we were required to pay an excise tax on the price for which we sell our medical devices in the U.S. This Medical Device Excise Tax ("MDET") applies to most medical devices, including our products, which could have a material, negative impact on our results of operations and our cash flows.

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During March 2014, Align had extensive discussions with the IRS and they informed us that our aligners are not subject to the MDET; however, our scanners are still subject to the MDET. As a result of these discussions, beginning in March 2014, we ceased expensing and paying the MDET for aligners, which reduced our general and administrative expense for the nine months ended September 30, 2014 by approximately \$5.0 million compared to the prior year period. The excise tax expense was \$5.3 million for the nine months ended September 30, 2013; however, MDET for the nine months ended September 30, 2014 was reduced to \$0.3 million due to the changes noted above. Additionally, we are in process of claiming a \$6.8 million refund of MDET paid in 2013 related to our aligners; however, because this claim is subject to review and approval by the IRS, we have not recorded a receivable as the outcome of the audit is undeterminable. Any future changes in the applicability of the MDET as it applies to us or refunds of amounts previously paid will be recorded as an additional expense or a credit to the consolidated statement of operations in the period in which it becomes probable and reasonably estimable. The MDET is included in general and administrative expenses in the consolidated statements of operations.

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 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.

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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.

If our goodwill or long-lived 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 asset group 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 qualitative and quantitative analysis used to test goodwill are dependent upon various assumptions and reflect management's best estimates. Changes in certain assumptions including revenue growth rates, discount rates, earnings multiples and future cash flows may cause a change in circumstances indicating that the carrying value of goodwill or the asset group may be impaired. 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 asset group are determined.

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.

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, 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

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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 a 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 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 first quarter of 2013, we incurred a \$40.7 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 various income tax incentives, which were previously granted in 2002. The incentive tax rates will expire in various years beginning in 2017. Under these incentives, all of the income in Costa Rica during these twelve year incentive periods is subject to reduced rates of Costa Rica income tax. In order to receive the benefit of these incentives, we must hire specified numbers of employees and maintain certain 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. The Costa Rica corporate income tax rate that would apply, absent the incentives, is 30% for 2014. As a result of these incentives, our income taxes were reduced by \$22.8 million and \$18.0 million for nine months ended September 30, 2014 and 2013, respectively, representing a benefit to diluted net income per share of \$0.28 and \$0.22 in 2014 and 2013, respectively. For the three months ended September 30, 2014 and 2013, the income taxes was reduced by \$7.7 million and \$6.1 million, respectively, representing a benefit to diluted net income per share of \$0.09 and \$0.08, respectively. Our subsidiary in Israel is under audit by the local tax authorities for calendar years 2006 through 2012.

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, 2014:

| Period | Total Number of | Average Price Paid | Total Number of Shares | Approximate Dollar Value of |
|--------|--------------------|-----------------------|---------------------------|--------------------------------|
|--------|--------------------|-----------------------|---------------------------|--------------------------------|

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| | Shares Repurchased | per Share | Repurchased as Part of Publicly Announced Program ⁽¹⁾ | Shares that May Yet Be Repurchased Under the Program ⁽¹⁾ |
|---|-----------------------|-----------|--|---|
| July 1, 2014 through July 31, 2014 | 363,625 | \$57.75 | 363,625 | ⁽²⁾ \$230,000,000 |
| August 1, 2014 through August 31, 2014 | 53,400 | \$54.40 | 53,400 | \$227,094,862 |
| September 1, 2014 through September 30, 2014 | 83,400 | \$54.10 | 83,400 | \$222,583,243 |

⁽¹⁾ On April 23, 2014, we announced that our Board of Directors had authorized a stock repurchase program pursuant to which we may purchase up to \$300.0 million of our common stock over the next three years, with \$100.0 million of that amount authorized to be purchased over the first twelve months. Any purchases under this stock repurchase program may be made, from time-to-time, pursuant to open market purchases (including pursuant to Rule 10b5-1 plans), privately-negotiated transactions, accelerated

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stock repurchases, block trades or derivative contracts or otherwise in accordance with applicable federal securities laws, including Rule 10b-18 of the Securities Exchange Act of 1934.

(2) As part of our \$300.0 million stock repurchase program, we entered into an accelerated share repurchase agreement ("ASR") with Goldman, Sachs & Co. on April 28, 2014 to repurchase \$70.0 million of our common stock. Under the terms of the ASR, we agreed to repurchase in total \$70.0 million of our common stock, with an initial delivery of approximately 1.0 million shares based on the then current market price. The ASR was completed on July 29, 2014 with a final delivery of approximately 0.4 million shares. We received a total of 1.4 million shares under the ASR for an average purchase price per share of \$51.46. The final number of shares repurchased was based on our volume-weighted average stock price during the term of the transaction, less an agreed upon discount.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None

ITEM 6. EXHIBITS

(a) Exhibits:

| Exhibit Number | Description | Filing | Date | Exhibit Number | Filed here with |
|----------------|--|--------|------|----------------|-----------------|
| 10.29 | Fixed Dollar Accelerated Repurchase Transaction Agreement dated April 28, 2014 between Goldman, Sachs & Co. and registrant | | | | * |
| 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 | | | | | * |

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SIGNATURES

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

ALIGN TECHNOLOGY, INC.

October 30, 2014

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

By: /S/ DAVID L. WHITE
David L. White
Chief Financial Officer

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| 101.PRE | XBRL Taxonomy Extension Presentation Linkbase Document | | | | * |