

ALIGN TECHNOLOGY INC
Form 10-Q
October 29, 2015
Table of Contents

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2015
OR

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

For the transition period from _____ to _____
Commission file number: 0-32259

ALIGN TECHNOLOGY, INC.
(Exact name of registrant as specified in its charter)

| | |
|---|--|
| Delaware (State or other jurisdiction of incorporation or organization) 2560 Orchard Parkway San Jose, California 95131 (Address of principal executive offices) (408) 470-1000 (Registrant's telephone number, including area code) | 94-3267295 (I.R.S. Employer Identification Number) |
|---|--|

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

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

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

| | | | |
|---|-------------------------------------|---------------------------|--------------------------|
| Large accelerated filer | <input checked="" type="checkbox"/> | Accelerated filer | <input type="checkbox"/> |
| Non-accelerated filer | <input type="checkbox"/> | Smaller reporting company | <input type="checkbox"/> |
| o (Do not check if a smaller reporting company) | | | |

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

Edgar Filing: ALIGN TECHNOLOGY INC - Form 10-Q

The number of shares outstanding of the registrant's Common Stock, \$0.0001 par value, as of October 23, 2015 was 79,490,148.

Table of Contents

ALIGN TECHNOLOGY, INC.

INDEX

| | | |
|----------|--|-----------|
| PART I | <u>FINANCIAL INFORMATION</u> | <u>3</u> |
| ITEM 1. | <u>FINANCIAL STATEMENTS (UNAUDITED):</u> | <u>3</u> |
| | <u>CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS</u> | <u>3</u> |
| | <u>CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME</u> | <u>4</u> |
| | <u>CONDENSED CONSOLIDATED BALANCE SHEETS</u> | <u>5</u> |
| | <u>CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS</u> | <u>6</u> |
| | <u>NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS</u> | <u>7</u> |
| ITEM 2. | <u>MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS</u> | <u>21</u> |
| ITEM 3. | <u>QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK</u> | <u>34</u> |
| ITEM 4. | <u>CONTROLS AND PROCEDURES</u> | <u>35</u> |
| PART II | <u>OTHER INFORMATION</u> | <u>36</u> |
| ITEM 1. | <u>LEGAL PROCEEDINGS</u> | <u>36</u> |
| ITEM 1A. | <u>RISK FACTORS</u> | <u>37</u> |
| ITEM 2. | <u>UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS</u> | <u>51</u> |
| ITEM 3. | <u>DEFAULTS UPON SENIOR SECURITIES</u> | <u>51</u> |
| ITEM 4. | <u>MINE SAFETY DISCLOSURES</u> | <u>51</u> |
| ITEM 5. | <u>OTHER INFORMATION</u> | <u>51</u> |
| ITEM 6. | <u>EXHIBITS</u> | <u>51</u> |
| | <u>SIGNATURES</u> | <u>53</u> |

Invisalign, Align, the Invisalign logo, ClinCheck, Invisalign Assist, Invisalign Teen, Viverra, SmartForce, SmartTrack, SmartStage, Power Ridge, iTero, iTero Element, Orthocad, iCast and iRecord, among others, are trademarks and/or service marks of Align Technology, Inc. or one of its subsidiaries or affiliated companies and may be registered in the United States and/or other countries.

Table of Contents

PART I—FINANCIAL INFORMATION

ITEM 1 FINANCIAL STATEMENTS

ALIGN TECHNOLOGY, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per share data)

(unaudited)

| | Three Months Ended | | Nine Months Ended | |
|--|--------------------|-----------|-------------------|-----------|
| | September 30, | | September 30, | |
| | 2015 | 2014 | 2015 | 2014 |
| Net revenues | \$207,636 | \$189,876 | \$615,210 | \$563,053 |
| Cost of net revenues | 50,060 | 44,822 | 147,910 | 135,272 |
| Gross profit | 157,576 | 145,054 | 467,300 | 427,781 |
| Operating expenses: | | | | |
| Selling, general and administrative | 101,751 | 80,653 | 290,657 | 246,175 |
| Research and development | 17,779 | 12,854 | 47,348 | 39,523 |
| Total operating expenses | 119,530 | 93,507 | 338,005 | 285,698 |
| Income from operations | 38,046 | 51,547 | 129,295 | 142,083 |
| Interest and other income (expenses), net | (1,568) |) (1,999) |) (2,846) |) (1,491) |
| Net income before provision for income taxes | 36,478 | 49,548 | 126,449 | 140,592 |
| Provision for income taxes | 8,862 | 11,301 | 31,306 | 34,301 |
| Net income | \$27,616 | \$38,247 | \$95,143 | \$106,291 |
| Net income per share: | | | | |
| Basic | \$0.35 | \$0.47 | \$1.19 | \$1.31 |
| Diluted | \$0.34 | \$0.47 | \$1.17 | \$1.29 |
| Shares used in computing net income per share: | | | | |
| Basic | 79,808 | 80,629 | 80,173 | 80,924 |
| Diluted | 81,092 | 82,014 | 81,576 | 82,443 |

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

Table of Contents

ALIGN TECHNOLOGY, INC.

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

(in thousands)

(unaudited)

| | Three Months Ended | | Nine Months Ended | |
|--|--------------------|----------|-------------------|-----------|
| | September 30, | | September 30, | |
| | 2015 | 2014 | 2015 | 2014 |
| Net income | \$27,616 | \$38,247 | \$95,143 | \$106,291 |
| Net change in cumulative translation adjustment | 114 | (257) |) (95 |) (155 |
| Change in unrealized gains (losses) on available-for-sale securities, net of tax | 98 | (191) |) 260 | (81 |
| Other comprehensive income (loss) | 212 | (448) |) 165 | (236 |
| Comprehensive income | \$27,828 | \$37,799 | \$95,308 | \$106,055 |

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

Table of Contents

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

| | September 30, 2015 (unaudited) | December 31, 2014 |
|--|--------------------------------------|----------------------|
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 174,040 | \$ 199,871 |
| Marketable securities, short-term | 310,715 | 254,787 |
| Accounts receivable, net of allowances for doubtful accounts and returns of \$1,803 and \$1,563, respectively | 148,395 | 129,751 |
| Inventories | 18,939 | 15,928 |
| Prepaid expenses and other current assets | 29,554 | 19,770 |
| Deferred tax assets | 30,090 | 37,053 |
| Total current assets | 711,733 | 657,160 |
| Marketable securities, long-term | 145,246 | 147,892 |
| Property, plant and equipment, net | 120,738 | 90,125 |
| Goodwill and intangible assets, net | 79,715 | 82,056 |
| Deferred tax assets | 14,542 | 3,099 |
| Other assets | 7,588 | 7,665 |
| Total assets | \$ 1,079,562 | \$ 987,997 |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current liabilities: | | |
| Accounts payable | \$ 32,599 | \$ 23,247 |
| Accrued liabilities | 95,914 | 87,880 |
| Deferred revenues | 115,998 | 90,684 |
| Total current liabilities | 244,511 | 201,811 |
| Income tax payable | 34,916 | 30,483 |
| Other long-term liabilities | 1,876 | 2,932 |
| Total liabilities | 281,303 | 235,226 |
| Commitments and contingencies (Note 6 and 7) | | |
| Stockholders' equity: | | |
| Preferred stock, \$0.0001 par value (5,000 shares authorized; none issued) | — | — |
| Common stock, \$0.0001 par value (200,000 shares authorized; 79,564 and 80,205 issued and outstanding, respectively) | 8 | 8 |
| Additional paid-in capital | 810,116 | 783,410 |
| Accumulated other comprehensive income (loss), net | 25 | (140) |
| Accumulated deficit | (11,890) | (30,507) |
| Total stockholders' equity | 798,259 | 752,771 |
| Total liabilities and stockholders' equity | \$ 1,079,562 | \$ 987,997 |
| The accompanying notes are an integral part of these unaudited condensed consolidated financial statements. | | |

Table of Contents

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

| | Nine Months Ended September 30, | |
|---|------------------------------------|-----------|
| | 2015 | 2014 |
| CASH FLOWS FROM OPERATING ACTIVITIES: | | |
| Net income | \$95,143 | \$106,291 |
| Adjustments to reconcile net income to net cash provided by operating activities: | | |
| Deferred taxes | 4,017 | 20,870 |
| Depreciation and amortization | 13,141 | 13,469 |
| Stock-based compensation | 39,135 | 29,348 |
| Excess tax benefit from share-based payment arrangements | (8,663) | (18,887) |
| Other non-cash operating activities | 9,252 | 7,368 |
| Changes in assets and liabilities: | | |
| Accounts receivable | (27,123) | (24,930) |
| Inventories | (3,033) | (2,033) |
| Prepaid expenses and other assets | (2,529) | (2,349) |
| Accounts payable | 4,408 | 3,788 |
| Accrued and other long-term liabilities | 6,712 | 12,402 |
| Deferred revenues | 28,182 | 9,957 |
| Net cash provided by operating activities | 158,642 | 155,294 |
| CASH FLOWS FROM INVESTING ACTIVITIES: | | |
| Purchase of property, plant and equipment | (36,663) | (16,957) |
| Purchase of marketable securities | (306,938) | (350,611) |
| Proceeds from maturities of marketable securities | 238,412 | 124,101 |
| Proceeds from sales of marketable securities | 12,518 | 72,276 |
| Other investing activities | 46 | (182) |
| Net cash used in investing activities | (92,625) | (171,373) |
| CASH FLOWS FROM FINANCING ACTIVITIES: | | |
| Proceeds from issuance of common stock | 10,559 | 17,373 |
| Common stock repurchases | (90,603) | (77,417) |
| Excess tax benefit from share-based payment arrangements | 8,663 | 18,887 |
| Employees' taxes paid upon the vesting of restricted stock units | (17,574) | (5,761) |
| Net cash used in financing activities | (88,955) | (46,918) |
| Effect of foreign exchange rate changes on cash and cash equivalents | (2,893) | 720 |
| Net decrease in cash and cash equivalents | (25,831) | (62,277) |
| Cash and cash equivalents, beginning of the period | 199,871 | 242,953 |
| Cash and cash equivalents, end of the period | \$174,040 | \$180,676 |

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

Table of Contents

ALIGN TECHNOLOGY, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(unaudited)

Note 1. Summary of Significant Accounting Policies

Basis of presentation

The accompanying unaudited Condensed Consolidated Financial Statements have been prepared by Align Technology, Inc. (“we”, “our”, or “Align”) in accordance with the rules and regulations of the Securities and Exchange Commission (“SEC”) and contain all adjustments, including normal recurring adjustments, necessary to present fairly our results of operations for the three and nine months ended September 30, 2015 and 2014, our comprehensive income for the three and nine months ended September 30, 2015 and 2014, our financial position as of September 30, 2015 and our cash flows for the nine months ended September 30, 2015 and 2014. The Condensed Consolidated Balance Sheet as of December 31, 2014 was derived from the December 31, 2014 audited financial statements. Net revenues by geographic area for prior period amounts in Note 12 have been reclassified to conform with the current period presentation. These reclassifications had no impact on our financial position for the three and nine months ended September 30, 2015 and 2014.

The results of operations for the three and nine months ended September 30, 2015 are not necessarily indicative of the results that may be expected for the year ending December 31, 2015 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, 2014.

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, revenue recognition, 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.

Revenue Recognition

In July 2015, we launched a new product policy called "Additional Aligners at No Charge" that addressed one of our customers' top complaints. Previously, we charged customers for additional aligners ordered beyond those covered by the initial treatment plan. With this product policy change, we no longer distinguish between mid-course corrections and case refinements and allow doctors to order additional aligners to address either treatment need at no charge. As part of this change, we also grandfathered over one million open cases under this product policy change. These changes were effective for all new Invisalign Full, Teen, and Assist treatments shipped worldwide after July 18, 2015 as well as any open Invisalign Full, Teen and Assist cases as of that date.

We concluded that additional aligners is a separate unit of accounting in our treatment plans, similar to case refinement and mid-course correction. We determined the best estimated selling price (“BESP”) of additional aligners

based on a cost and margin analysis, as well as other inputs based on our historical pricing practices. Further, we will continue to allocate revenue to each unit in our treatment plan based on the unit's relative selling price based on BESP and recognize the revenue upon the delivery of each unit in the treatment plan. We regularly review our estimates of selling price and maintain internal controls over the establishment and update of these estimates.

Derivative Financial Instruments

In September 2015, we entered into foreign currency forward contracts to minimize the short-term impact of foreign currency exchange rate fluctuations on cash and certain trade and intercompany receivables and payables. These forward contracts are not designated as hedging instruments and do not subject us to material balance sheet risk due to fluctuations in foreign currency exchange rates. The gains and losses on these forward contracts are intended to offset the gains and losses in the underlying foreign currency denominated monetary assets and liabilities being economically hedged. We do not enter into foreign currency forward contracts for trading or speculative purposes. These instruments are marked to market through earnings every period and generally

Table of Contents

are one month in original maturity. The net gain or loss from the settlement of these foreign currency forward contracts is recorded in Interest and other income (expense), net in the consolidated statements of operations.

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. In July 2015, the FASB voted to defer the effective date for annual reporting periods beginning after December 15, 2017 (including interim reporting periods within those periods) and permitted early adoption of the standard, but not before the original effective date of December 15, 2016. We expect the updated standard to become effective for us in the first quarter of fiscal 2018. 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.

In April 2015, the FASB issued ASU No. 2015-05, "Customer's Accounting for Fees Paid in a Cloud Computing Arrangement." providing guidance to entities about whether a cloud computing arrangement includes a software license. If a cloud computing arrangement includes a software license, the entity should account for the software license element of the arrangement consistent with the acquisition of other software licenses. If a cloud computing arrangement does not include a software license, the entity should account for the arrangement as a service contract. The new guidance does not change the accounting for an entity's accounting for service contracts. The updated standard becomes effective for interim and annual reporting periods beginning after December 15, 2015. We are currently evaluating the effect that the updated standard will have on our consolidated financial statements and related disclosures.

Note 2. Marketable Securities and Fair Value Measurements

As of September 30, 2015 and December 31, 2014, 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, 2015 | Amortized Cost | Gross Unrealized Gains | Gross Unrealized Losses | Fair Value |
|---|-------------------|------------------------------|-------------------------------|-------------|
| Commercial paper | \$35,938 | \$— | \$— | \$35,938 |
| Corporate bonds | 176,901 | 45 | (84) |) 176,862 |
| Municipal securities | 11,694 | 4 | — | 11,698 |
| U.S. government agency bonds | 58,003 | 36 | — | 58,039 |
| U.S. government treasury bonds | 27,649 | 17 | — | 27,666 |
| U.S. dollar dominated foreign corporate bonds | 513 | — | (1) |) 512 |
| Total Marketable Securities, Short-Term | \$310,698 | \$102 | \$(85) |) \$310,715 |

Long-term

| September 30, 2015 | Amortized Cost | Gross Unrealized Gains | Gross Unrealized Losses | Fair Value |
|---|-------------------|------------------------------|-------------------------------|------------|
| U.S. government agency bonds | \$37,733 | \$43 | \$— | \$37,776 |
| Corporate bonds | 54,808 | 28 | (121) |) 54,715 |
| U.S. dollar dominated foreign corporate bonds | — | — | — | — |

Edgar Filing: ALIGN TECHNOLOGY INC - Form 10-Q

| | | | | |
|--|-----------|-------|--------|-------------|
| U.S. government treasury bonds | 38,741 | 84 | — | 38,825 |
| Municipal securities | 7,372 | 17 | — | 7,389 |
| Asset-backed securities | 6,544 | — | (3 |) 6,541 |
| Total Marketable Securities, Long-Term | \$145,198 | \$172 | \$(124 |) \$145,246 |

8

Table of Contents

Short-term

| December 31, 2014 | Amortized Cost | Gross Unrealized Gains | Gross Unrealized Losses | Fair Value |
|---|-------------------|------------------------------|-------------------------------|-------------|
| Commercial paper | \$33,998 | \$— | \$— | \$33,998 |
| Corporate bonds | 152,055 | 27 | (116) |) 151,966 |
| U.S. dollar dominated foreign corporate bonds | 901 | — | — | 901 |
| Municipal securities | 9,147 | 13 | — | 9,160 |
| U.S. government agency bonds | 41,574 | 14 | (1) |) 41,587 |
| U.S. government treasury bonds | 15,770 | 7 | — | 15,777 |
| Certificates of Deposits | 1,398 | — | — | 1,398 |
| Total Marketable Securities, Short-Term | \$254,843 | \$61 | \$(117) |) \$254,787 |

Long-term

| December 31, 2014 | Amortized Cost | Gross Unrealized Gains | Gross Unrealized Losses | Fair Value |
|---|-------------------|------------------------------|-------------------------------|-------------|
| U.S. government agency bonds | \$48,233 | \$12 | \$(28) |) \$48,217 |
| Corporate bonds | 57,195 | 6 | (112) |) 57,089 |
| U.S. dollar dominated foreign corporate bonds | 523 | — | (2) |) 521 |
| U.S. government treasury bonds | 20,814 | 5 | (6) |) 20,813 |
| Municipal securities | 9,552 | 5 | (6) |) 9,551 |
| Asset-backed securities | 11,713 | — | (12) |) 11,701 |
| Total Marketable Securities, Long-Term | \$148,030 | \$28 | \$(166) |) \$147,892 |

For the three and nine months ended September 30, 2015 and 2014, realized gains were immaterial. Unrealized gains and losses for our available for sale securities as of September 30, 2015 and December 31, 2014 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, 2015 and December 31, 2014. 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, 2015 and 2014.

Our fixed-income securities investment portfolio consists of corporate bonds, certificates of deposits, U.S. dollar dominated foreign corporate bonds, commercial paper, municipal securities, U.S. government agency bonds, U.S. government treasury bonds 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 10 and 11 months as of September 30, 2015 and December 31, 2014, 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, 2015 and December 31, 2014 (in thousands):

| | September 30, 2015 | December 31, 2014 |
|---|-----------------------|----------------------|
| Due in one year or less | \$310,715 | \$254,787 |
| Due in greater than one year | 145,246 | 147,892 |
| Total available for sale short-term and long-term marketable securities | \$455,961 | \$402,679 |

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

9

Table of Contents

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.

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, certificates of deposits, U.S. government agency bonds, asset-backed securities, municipal securities, U.S. dollar dominated foreign corporate bonds and our Israeli funds that are mainly invested in insurance policies and foreign currency forward contracts. 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. The foreign currency forward contracts are valued using observable inputs such as quotations on forward foreign exchange rates.

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.

Recurring Fair Value Measurements

The following tables summarize our financial assets measured at fair value on a recurring basis as of September 30, 2015 and December 31, 2014 (in thousands):

| Description | Balance as of September 30, 2015 | Quoted Prices in Active Markets for Identical Assets (Level 1) | Significant Other Observable Inputs (Level 2) |
|---|--|--|--|
| Cash equivalents: | | | |
| Money market funds | \$71,090 | \$71,090 | \$— |
| Commercial paper | 48,711 | — | 48,711 |
| Corporate bonds | 400 | — | 400 |
| Short-term investments: | | | |
| Commercial paper | 35,938 | — | 35,938 |
| Corporate bonds | 176,862 | — | 176,862 |
| Municipal securities | 11,698 | — | 11,698 |
| U.S. government agency bonds | 58,039 | — | 58,039 |
| U.S. government treasury bonds | 27,666 | 27,666 | — |
| U.S. dollar dominated foreign corporate bonds | 512 | — | 512 |
| Long-term investments: | | | |
| U.S. government agency bonds | 37,776 | — | 37,776 |
| Corporate bonds | 54,715 | — | 54,715 |

Edgar Filing: ALIGN TECHNOLOGY INC - Form 10-Q

| | | | |
|---|-----------|-----------|-----------|
| U.S. dollar dominated foreign corporate bonds | — | — | — |
| U.S. government treasury bonds | 38,825 | 38,825 | — |
| Municipal securities | 7,389 | — | 7,389 |
| Asset-backed securities | 6,541 | — | 6,541 |
| Prepaid expenses and other current assets: | | | |
| Israeli funds | 2,338 | — | 2,338 |
| | \$578,500 | \$137,581 | \$440,919 |

Table of Contents

| Description | Balance as of December 31, 2014 | Quoted Prices in Active Markets for Identical Assets (Level 1) | Significant Other Observable Inputs (Level 2) |
|---|------------------------------------|--|--|
| Cash equivalents: | | | |
| Money market funds | \$ 80,786 | \$80,786 | \$— |
| Commercial paper | 21,997 | — | 21,997 |
| Corporate bonds | 1,745 | — | 1,745 |
| Short-term investments: | | | |
| Commercial paper | 33,998 | — | 33,998 |
| Corporate bonds | 151,966 | — | 151,966 |
| U.S. dollar denominated foreign corporate bonds | 901 | — | 901 |
| Municipal securities | 9,160 | — | 9,160 |
| U.S. government agency bonds | 41,587 | — | 41,587 |
| U.S. government treasury bonds | 15,777 | 15,777 | — |
| Certificates of Deposits | 1,398 | — | 1,398 |
| Long-term investments: | | | |
| U.S. government agency bonds | 48,217 | — | 48,217 |
| Corporate bonds | 57,089 | — | 57,089 |
| U.S. dollar denominated foreign corporate bonds | 521 | — | 521 |
| U.S. government treasury bonds | 20,813 | 20,813 | — |
| Municipal securities | 9,551 | — | 9,551 |
| Asset-backed securities | 11,701 | — | 11,701 |
| Prepaid expenses and other current assets: | | | |
| Israeli funds | 2,307 | — | 2,307 |
| | \$ 509,514 | \$ 117,376 | \$ 392,138 |

Derivative Financial Instruments

In September 2015, we began entering into foreign currency forward contracts to minimize the short-term impact of foreign currency exchange rate fluctuations on cash and certain trade and intercompany receivables and payables. These instruments are classified within level 2 of the fair value hierarchy and are included in prepaid expenses and other current assets. The net loss on these forward contracts was immaterial for the three and nine months ended September 30, 2015. As of September 30, 2015, the fair value of foreign exchange forward contracts outstanding was a loss of \$0.1 million.

The following table presents the gross notional value of all our foreign exchange forward contracts outstanding as of September 30, 2015 (in thousands):

| | As of September 30, 2015 | |
|-----------|-----------------------------|---|
| | Local Currency Amount | Notional Contract Amount (USD) |
| US dollar | \$ 31,600 | \$31,600 |
| Euro | €14,600 | 16,428 |

Edgar Filing: ALIGN TECHNOLOGY INC - Form 10-Q

| | | |
|-------------------|------------|----------|
| Japanese yen | ¥1,680,000 | 14,018 |
| Australian dollar | A\$5,200 | 3,657 |
| Hong Kong dollar | HK\$27,000 | 3,494 |
| Singapore dollar | S\$2,600 | 1,817 |
| | | \$71,014 |

11

Table of Contents

Note 3. Balance Sheet Components

Inventories

Inventories consist of the following (in thousands):

| | September 30, 2015 | December 31, 2014 |
|-------------------|-----------------------|----------------------|
| Raw materials | \$9,690 | \$8,143 |
| Work in process | 6,659 | 2,970 |
| Finished goods | 2,590 | 4,815 |
| Total Inventories | \$18,939 | \$15,928 |

Work in process includes costs to produce our clear aligner and intra-oral products. The increase in work in process from December 30, 2014 to September 30, 2015 is due to the production ramp up of iTero Element scanners, which began shipping late in the third quarter of 2015. Finished goods primarily represent our intra-oral scanners and ancillary products that support our clear aligner products.

Accrued liabilities

Accrued liabilities consist of the following (in thousands):

| | September 30, 2015 | December 31, 2014 |
|---------------------------------------|-----------------------|----------------------|
| Accrued payroll and benefits | \$48,150 | \$44,610 |
| Accrued sales rebates | 7,172 | 11,110 |
| Accrued sales and marketing expenses | 6,006 | 5,979 |
| Accrued accounts payable | 8,582 | 5,736 |
| Accrued sales tax and value added tax | 5,650 | 5,456 |
| Accrued professional fees | 3,841 | 2,494 |
| Accrued warranty | 2,711 | 3,148 |
| Accrued income taxes | 2,400 | 2,027 |
| Other accrued liabilities | 11,402 | 7,320 |
| Total Accrued Liabilities | \$95,914 | \$87,880 |

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, 2015 and 2014 consists of the following activity (in thousands):

12

Table of Contents

| | Nine Months Ended September 30, | |
|---------------------------------|------------------------------------|----------|
| | 2015 | 2014 |
| Balance at beginning of period | \$3,148 | \$3,104 |
| Charged to cost of net revenues | 1,308 | 1,529 |
| Actual warranty expenditures | (1,745 |) (1,370 |
| Balance at end of period | \$2,711 | \$3,263 |

Note 4. Goodwill and Long-lived Assets

Goodwill

On April 29, 2011, we acquired Cadent Holdings, Inc. (“Cadent”). In connection with the acquisition, we allocated approximately \$58.0 million of goodwill to our Clear Aligner reporting unit based on the expected relative synergies generated by the acquisition. On April 30, 2013, we acquired ICA Holdings Pty Limited in a purchase business combination of which \$3.6 million was recorded to goodwill, which was attributed to our Clear Aligner reporting unit.

The change in the carrying value of goodwill for the nine months ended September 30, 2015, all attributable to our Clear Aligner reporting unit, is as follows (in thousands):

| | |
|----------------------------------|---------------------------|
| Balance as of December 31, 2014 | Clear Aligner \$61,369 |
| Adjustments ¹ | (391 |
| Balance as of September 30, 2015 | \$60,978 |

¹ The adjustments to goodwill during the nine months ended September 30, 2015 were due to foreign currency translation.

During the fourth quarter of fiscal 2014, 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.

Acquired intangible assets, arising either as a direct result from the Cadent acquisition or individually acquired, are being amortized as follows (in thousands):

| | Weighted Average Amortization Period (in years) | Gross Carrying Amount as of September 30, 2015 | Accumulated Amortization | Accumulated Impairment Loss | Net Carrying Value as of September 30, 2015 |
|-------------------------|---|---|-----------------------------|-----------------------------------|--|
| Trademarks | 15 | \$7,100 | \$ (1,457 |) \$ (4,179 |) \$ 1,464 |
| Existing technology | 13 | 12,600 | (3,437 |) (4,328 |) 4,835 |
| Customer relationships | 11 | 33,500 | (10,492 |) (10,751 |) 12,257 |
| Other | 8 | 285 | (104 |) — | 181 |
| Total Intangible Assets | | \$53,485 | \$ (15,490 |) \$ (19,258 |) \$ 18,737 |

| | Weighted Average Amortization Period (in years) | Gross Carrying Amount as of December 31, 2014 | Accumulated Amortization | Accumulated Impairment Loss | Net Carrying Value as of December 31, 2014 |
|------------|---|--|-----------------------------|-----------------------------------|--|
| Trademarks | 15 | \$7,100 | \$ (1,354 |) \$ (4,179 |) \$ 1,567 |

Edgar Filing: ALIGN TECHNOLOGY INC - Form 10-Q

| | | | | | |
|-------------------------|----|----------|-----------|-------------|-------------|
| Existing technology | 13 | 12,600 | (3,015 |) (4,328 |) 5,257 |
| Customer relationships | 11 | 33,500 | (9,095 |) (10,751 |) 13,654 |
| Other | 8 | 285 | (76 |) — | 209 |
| Total Intangible Assets | | \$53,485 | \$(13,540 |) \$(19,258 |) \$ 20,687 |

13

Table of Contents

The total estimated annual future amortization expense for these acquired intangible assets as of September 30, 2015 is as follows (in thousands):

| | |
|---------------------------------|----------|
| Fiscal Year Ending December 31, | |
| Remainder of 2015 | \$650 |
| 2016 | 2,600 |
| 2017 | 2,600 |
| 2018 | 2,600 |
| 2019 | 2,592 |
| Thereafter | 7,695 |
| Total | \$18,737 |

Note 5. Credit Facilities

On March 22, 2013, we entered into a credit facility, which 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, 2015, we had no outstanding borrowings under this credit facility; however, we were not in compliance with certain negative covenants. As a result, on October 15, 2015, we received a waiver for our non-compliance and also amended the credit facility in regards to these negative covenants.

Note 6. 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 former 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

Table of Contents

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.

Note 7. Commitments and Contingencies

Operating Leases

As of September 30, 2015, minimum future lease payments for non-cancelable operating leases are as follows (in thousands):

| | |
|-------------------------------------|------------------|
| Fiscal Year Ending December 31, | Operating leases |
| Remainder of 2015 | \$2,594 |
| 2016 | 9,982 |
| 2017 | 5,952 |
| 2018 | 2,409 |
| 2019 | 529 |
| Thereafter | 438 |
| Total minimum future lease payments | \$21,904 |

Off-balance Sheet Arrangements

As of September 30, 2015, 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, 2015, we did not have any material indemnification claims that were probable or reasonably possible.

Table of Contents

Note 8. Stock-based Compensation

Summary of stock-based compensation expense

As of September 30, 2015, the 2005 Incentive Plan (as amended) has a total reserve of 23,283,379 shares of which 5,371,675 shares are available for issuance.

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, 2015 and 2014 is as follows (in thousands):

| | Three Months Ended | | Nine Months Ended | |
|-------------------------------------|--------------------|---------|-------------------|----------|
| | September 30, | | September 30, | |
| | 2015 | 2014 | 2015 | 2014 |
| Cost of net revenues | \$984 | \$867 | \$2,929 | \$2,648 |
| Selling, general and administrative | 11,564 | 7,381 | 30,106 | 21,748 |
| Research and development | 2,113 | 1,662 | 6,100 | 4,952 |
| Total stock-based compensation | \$14,661 | \$9,910 | \$39,135 | \$29,348 |

Options

Activity for the nine months ended September 30, 2015 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, 2014 | 668 | \$ 15.57 | | |
| Granted | — | — | | |
| Exercised | (129 |) 16.47 | | |
| Cancelled or expired | — | — | | |
| Outstanding as of September 30, 2015 | 539 | \$ 15.36 | 2.28 | \$22,300 |
| Vested and expected to vest at September 30, 2015 | 539 | \$ 15.36 | 2.28 | \$22,300 |
| Exercisable at September 30, 2015 | 539 | \$ 15.36 | 2.28 | \$22,300 |

There were no stock options granted during the nine months ended September 30, 2015 and 2014. All compensation costs relating to stock options have been recognized as of September 30, 2015.

Restricted Stock Units (“RSU”)

A summary of the RSU activity for the nine months ended September 30, 2015 is as follows (in thousands, except years):

| Number of Shares Underlying RSU | Weighted Average Grant | Weighted Remaining | Aggregate Intrinsic |
|------------------------------------|---------------------------|-----------------------|------------------------|
|------------------------------------|---------------------------|-----------------------|------------------------|

Edgar Filing: ALIGN TECHNOLOGY INC - Form 10-Q

| | | Date Fair Value | Contractual Period (in years) | Value |
|------------------------------------|-------|-----------------|-------------------------------------|-----------|
| Nonvested as of December 31, 2014 | 2,124 | \$42.08 | | |
| Granted | 835 | 57.72 | | |
| Vested and released | (661 |) 36.77 | | |
| Forfeited | (80 |) 47.48 | | |
| Nonvested as of September 30, 2015 | 2,218 | \$49.39 | 1.34 | \$125,883 |

Table of Contents

As of September 30, 2015, the total unamortized compensation cost related to RSU, net of estimated forfeitures, was \$75.0 million, which we expect to recognize over a weighted average period of 2.3 years.

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, 2015 (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, 2014 | 498 | \$42.00 | | |
| Granted | 289 | 61.73 | | |
| Vested and released | (162 |) 30.28 | | |
| Forfeited | (14 |) 53.69 | | |
| Nonvested as of September 30, 2015 | 611 | \$51.41 | 1.55 | \$34,689 |

As of September 30, 2015, the total unamortized compensation costs related to the MSU, net of estimated forfeitures, was \$16.2 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, 2015, there remains 1,133,749 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, | | |
|---|-------------------------------------|---------|------------------------------------|---------|---|
| | 2015 | 2014 | 2015 | 2014 | |
| Expected term (in years) | 1.2 | 1.3 | 1.2 | 1.2 | |
| Expected volatility | 27.9 | % 35.8 | % 31.1 | % 38.8 | % |
| Risk-free interest rate | 0.41 | % 0.24 | % 0.29 | % 0.20 | % |
| Expected dividends | — | — | — | — | |
| Weighted average fair value at grant date | \$17.10 | \$16.44 | \$16.19 | \$17.15 | |

As of September 30, 2015, the total unamortized compensation cost related to employee purchases was \$2.8 million, which we expect to recognize over a weighted average period of 0.8 year.

Note 9. 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

authorized over the first 12 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, on April 28, 2014, we entered into an accelerated share repurchase agreement ("2014 ASR") to repurchase \$70.0 million of our common stock which was completed in July 2014. We received a total of approximately 1.4 million shares under the 2014 ASR for an average purchase price per share of \$51.46, which all shares

Table of Contents

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 2014, we repurchased on the open market approximately 0.6 million shares of our common stock at an average price of \$50.93 per share, including commissions, for an aggregate purchase price of approximately \$28.2 million. In the first quarter of 2015, we repurchased on the open market approximately 0.03 million shares of our common stock at an average price of \$57.49 per share, including commission for an aggregate purchase price of approximately \$1.8 million. All repurchased shares were retired.

In January 2015, our Board of Directors authorized the repurchase of the next \$100.0 million under the repurchase program which we anticipate completing within twelve months. On April 28, 2015, we entered into an accelerated share purchase agreement ("2015 ASR") to repurchase \$70.0 million of our common stock. Under the terms of the 2015 ASR, we paid \$70.0 million on April 29, 2015 and received an initial delivery of approximately 0.8 million shares. The 2015 ASR was completed on July 23, 2015 with a final delivery of approximately 0.3 million shares. We received a total of approximately 1.2 million shares under the 2015 ASR for an average share price of \$60.52, 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, 2015, we repurchased on the open market approximately 0.3 million shares of our common stock at an average price of \$57.04 per share, including commissions, for an aggregate purchase price of approximately \$18.8 million. All repurchased shares were retired. As of September 30, 2015, we have \$111.2 million remaining under the April 2014 stock repurchase program, \$11.2 million of which we expect to purchase within the next six months.

Note 10. Accounting for Income Taxes

Our provision for income taxes was \$8.9 million and \$11.3 million for the three months ended September 30, 2015 and 2014, respectively. This represents effective tax rates of 24.3% and 22.8%, respectively. Our effective tax rates differ from the statutory federal income tax rate of 35% due to certain foreign earnings, primarily from Costa Rica, which are subject to a lower tax rate, state income tax expense, the tax impact of certain stock-based compensation charges and unrecognized tax benefits. The increase in the effective rate for the three months ended September 30, 2015 compared to the three months ended September 30, 2014 reflects a jurisdictional shift in forecasted earnings from lower tax non-U.S. jurisdictions to the U.S.

Our provision for income taxes was \$31.3 million and \$34.3 million for the nine months ended September 30, 2015 and 2014, respectively. This represents effective tax rates of 24.8% and 24.4%, respectively. The increase in the effective rate for the nine months ended September 30, 2015 compared to the nine months ended September 30, 2014 reflects a jurisdictional shift in forecasted earnings from lower tax non-U.S. jurisdictions to the U.S., offset by a negative impact in prior year from a \$1.8 million adjustment which related to prior periods.

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, 2015, we maintained a valuation allowance of \$32.8 million against deferred tax assets primarily related to Israel and California operating loss carryforwards and Australia 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.

Edgar Filing: ALIGN TECHNOLOGY INC - Form 10-Q

Our total gross unrecognized tax benefits was \$37.8 million and \$33.1 million as of September 30, 2015 and December 31, 2014, respectively, 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 and nine months ended September 30, 2015 was not material. We do not expect any significant changes to the amount of unrecognized tax benefit within the next twelve months.

We file U.S. federal, U.S. state, and non-U.S. income tax returns. Our major tax jurisdictions are U.S. federal and the State of California. For U.S. federal and state tax returns, we are no longer subject to tax examinations for years before 2000. With few exceptions, we are no longer subject to examination by foreign tax authorities for years before 2007. We are currently under audit by the California Franchise Tax Board for fiscal year 2011, 2012 and 2013.

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

Table of Contents

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 2015 and 2014. Income taxes were reduced by \$8.2 million and \$7.7 million for the three months ended September 30, 2015 and 2014, respectively, representing a benefit to diluted net income per share of \$0.10 and \$0.09 in 2015 and 2014, respectively. As a result of these incentives, our income taxes were reduced by \$24.6 million and \$22.8 million for the nine months ended September 30, 2015 and 2014, respectively, representing a benefit to diluted net income per share of \$0.30 and \$0.28 in 2015 and 2014, respectively.

Note 11. 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 RSU, MSU, stock options 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, | |
|---|--------------------------------------|----------|-------------------------------------|-----------|
| | 2015 | 2014 | 2015 | 2014 |
| Numerator: | | | | |
| Net income | \$27,616 | \$38,247 | \$95,143 | \$106,291 |
| Denominator: | | | | |
| Weighted-average common shares outstanding, basic | 79,808 | 80,629 | 80,173 | 80,924 |
| Dilutive effect of potential common stock | 1,284 | 1,385 | 1,403 | 1,519 |
| Total shares, diluted | 81,092 | 82,014 | 81,576 | 82,443 |
| Net income per share, basic | \$0.35 | \$0.47 | \$1.19 | \$1.31 |
| Net income per share, diluted | \$0.34 | \$0.47 | \$1.17 | \$1.29 |

For the three and nine months ended September 30, 2015 and 2014, the anti-dilutive effect from RSU, MSU and ESPP was not material.

Note 12. 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 and Services segment.

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

Our Scanner and Services ("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.

Table of Contents

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, | |
|--------------------|---|-----------|--|-----------|
| | 2015 | 2014 | 2015 | 2014 |
| Net Revenues | | | | |
| Clear Aligner | \$198,292 | \$178,138 | \$586,138 | \$526,112 |
| Scanner | 9,344 | 11,738 | 29,072 | 36,941 |
| Total net revenues | \$207,636 | \$189,876 | \$615,210 | \$563,053 |
| Gross profit | | | | |
| Clear Aligner | \$156,205 | \$141,117 | \$461,502 | \$415,903 |
| Scanner | 1,371 | 3,937 | 5,798 | 11,878 |
| Total gross profit | \$157,576 | \$145,054 | \$467,300 | \$427,781 |

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, | |
|------------------------------|---|-----------|--|-----------|
| | 2015 | 2014 | 2015 | 2014 |
| Net revenues: ⁽¹⁾ | | | | |
| U.S. | \$143,933 | \$134,244 | \$429,005 | \$396,837 |
| the Netherlands | 37,427 | 34,538 | 118,295 | 113,828 |
| Other international | 26,276 | 21,094 | 67,910 | 52,388 |
| Total net revenues | \$207,636 | \$189,876 | \$615,210 | \$563,053 |

⁽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, 2015 | December 31, 2014 |
|-----------------------------------|-----------------------|----------------------|
| Long-lived assets: ⁽²⁾ | | |
| United States | \$97,789 | \$76,511 |
| Mexico | 14,655 | 6,229 |
| Other International | 8,294 | 7,385 |
| Total long-lived assets | \$120,738 | \$90,125 |

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

Table of Contents

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

In addition to historical information, this quarterly report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. These statements include, among other things, our expectations regarding the anticipated impact that our new products and product enhancements will have on doctor utilization and our market share, our expectation that the policy simplification “Additional Aligners at No Charge” will help increase Invisalign utilization and volume as well as the expected impact this policy change will have on Invisalign Clear Aligner net revenues in the fourth quarter of 2015 and beyond, 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 (“Scanner”) 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 expected date our iTero Element Intraoral Scanner will be available, 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 intraoral scanners and OrthoCAD services.

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. Over the last several years’ we have continued to build upon our technology and expertise to deliver enhanced clinical innovations aimed at helping our customers treat some of the most challenging cases. These innovations, both launched in early 2014, include Invisalign G5,

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. Most recently, we began the initial commercialization of Invisalign G6 clinical innovations for first premolar extraction during the first quarter of 2015.

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 March 2015, we announced our next generation iTero Element Intraoral Scanner which features a more compact footprint, enhanced wand and multi-touch display and is engineered to enable faster scan speeds for more efficient, real-time clinical evaluation.

We believe in an open systems approach to our technologies and are committed to working with other intra-oral scanning companies interested in developing interoperability for use 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. In March 2015, we announced that the Sirona CEREC Omnicam with the new CEREC Ortho software 1.1 was qualified for use with Invisalign case submissions. The new CEREC Ortho software was available in select markets in the summer of 2015. The 3M True Definition scanner and Sirona CEREC Omnicam scanner are the only third-party scanners that have been qualified for use with Invisalign treatment.

The Invisalign System is offered in more than 90 countries and has been used to treat more than 3.4 million patients. Our iTero intraoral 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 3,160 dental labs worldwide.

Our goal is to establish Invisalign clear aligners as the standard method for treating malocclusion and to establish the iTero intraoral 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 2015 and beyond may be affected by a number of other factors including:

Additional Aligners at No Charge. In July 2015, we launched a new product policy called "Additional Aligners at No Charge" that addresses one of our customers' top complaints. Previously, we charged customers for additional aligners ordered beyond those covered by the initial treatment plan. With this product policy change, we no longer distinguish between mid-course corrections and case refinements and allow doctors to order additional aligners to address either treatment need at no charge, subject to certain requirements. These changes were effective for all new Invisalign Full, Teen, and Assist treatments shipped worldwide after July 18, 2015 as well as any open Invisalign Full, Teen and Assist cases as of that date. We expect this product policy change will result in a significant improvement in customer satisfaction and loyalty, which we believe will help increase Invisalign utilization and volume over time.

Based on this new product policy, beginning in the third quarter of 2015, we deferred more revenue as a result of providing free additional aligners for eligible treatments. Additionally, since we grandfathered over 1 million open cases, we will recognize lower revenues as additional aligners are shipped. We expect lower recognitions for at least the next two years until these cases complete. In the third quarter of 2015, the new product policy decreased Clear Aligner net revenues by approximately \$7.0 million and reduced operating margin by 2.6% and diluted earnings per share by \$0.06 per share. We expect a decrease in Clear Aligner net revenues by approximately \$7.0 million to \$8.0 million in the fourth quarter of 2015, and by approximately \$25.0 million to \$30.0 million in fiscal year 2016.

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 and Internationally in the first quarter of 2015, we 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. Invisalign G6 clinical innovations for premolar extraction became available to Invisalign-trained providers beginning in the first quarter of 2015 with limited commercialization. Full commercialization of Invisalign G6 in Europe, Middle East and Africa ("EMEA"), Asia

Pacific, and Latin America geographies will occur throughout 2015 and in North America in early 2016. Invisalign G6 is engineered to improve clinical outcomes for orthodontic treatment of severe crowding and bimaxillary

protrusion. Most recently, in March 2015, we announced the next generation iTero Element Intraoral Scanner with improved imaging technology that is designed to enable significantly faster scan speed, accuracy, intuitive operation, and visualization capabilities. We began shipping the iTero Element Intraoral Scanner in September 2015 and expect to ramp up our production over the next few quarters accordingly; however, if we are unable to scale production of our iTero Element scanner to meet customer demand, our financial results may be negatively impacted. We believe that over the long-term, clinical solutions and treatment tools will increase adoption of Invisalign and increase sales of our intraoral scanners; 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 2015 increased to 4.7 cases per doctor compared to 4.4 in the third quarter of 2014. Utilization among our North American orthodontist customers reached an all time high of 9.9 cases per doctor in the third quarter of 2015 compared to 8.8 in the third quarter of 2014. International doctor utilization increased to 4.6 in the third quarter of 2015 from 4.3 in the third quarter of 2014. North American GP doctor utilization increased slightly to 2.9 in the third quarter of 2015 from 2.8 in the third quarter of 2014. The 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. We expect that over the long-term our utilization rates will gradually improve as a result of advancements in product and technology, which continue to strengthen our doctors' clinical confidence in the use of Invisalign, along with the implementation of our Go-To-Market strategy (as discussed below); however, we expect that our utilization rates may fluctuate from period to period due to a variety of factors, including seasonal trends in our business along with adoption rates of new products and features.

Seasonal Trends. The fourth quarter is often a slower period for North American Orthodontists compared to the third quarter; however, we expect North American Orthodontists volume to be up sequentially in the fourth quarter. Offsetting this trend, our fourth quarter has historically been a stronger quarter for EMEA and a seasonally slower-to-flat quarter for APAC. As a result, we expect international volumes to also be up sequentially in the fourth quarter.

Consequently, we expect that our Invisalign volume in the fourth quarter of 2015 will be up 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 2014, Invisalign growth was driven primarily by increased utilization by our North American orthodontist doctors and International doctors as well as by the continued expansion of our customer base as we trained a total of 9,440 new Invisalign doctors, of which 56% were trained internationally. GPs are one of the keys to driving growth in the adult segment, and, in 2014, we launched Invisalign Fundamentals, a new training course, designed to improve practice integration and increase utilization for newly trained doctors. The Invisalign Fundamentals program has been implemented across North America, and we 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, together with our go-to market strategy which includes dedicated focus, pre-and post training, has the potential to increase the number of doctors submitting cases 90-days post-training, as well as the number of cases submitted per doctor. During the third quarter of 2015, we trained 2,260 new Invisalign doctors.

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 35.1% driven primarily due to strong performance in the Asia Pacific region as well as growth in Europe. In 2015, 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. We expect international revenues to continue to grow at a faster rate than North America for the foreseeable future due to our continued investment in international market expansion, the size of the market opportunity, and our relatively low market penetration in this region. In addition, as we plan for further international expansion over the next several years, we must provide better support to our customers in these regions and be geographically closer to their practices. Accordingly, we intend to make further investments in our manufacturing over the next few years to enhance our regional capabilities.

Go-To-Market Evolution. In order to provide more comprehensive sales and service coverage, in 2015, we implemented an updated go-to-market strategy with an expanded team and new structure in North America. In order to ensure our North America sales and marketing team can increase time in-office and help each practice become more successful, we have added approximately 50 sales team members in 2015, the majority of which were in place as of the end of the first quarter. We also continue to invest in our sales force in EMEA and Asia Pacific in order to support the growth in these regions. We believe that these investments in a refined go-to-market strategy and the strategic deployment of more people will improve adoption and utilization of Invisalign by our customers.

Increase in Invisalign Selling Price. We have historically invested in research and development and continuous product innovation. In order to continue and even accelerate this product innovation cycle, we increased our prices by approximately 3% on Invisalign Full and Invisalign Teen products. In North America, the increase of \$50 per treatment was effective April 1, 2015, and internationally, the price increase of €50 per treatment was effective July 1, 2015. The prices for Invisalign Assist, Invisalign Express 10 and Invisalign Express 5/Lite products remained unchanged.

Operating Expenses. We expect operating expenses to increase in 2015 compared to 2014 due in part to: the increase in North American sales force coverage discussed above, as well as additions to our sales force in EMEA and Asia Pacific regions, infrastructure investments, including a project to implement a new enterprise resource planning system which we started in late 2014 with expected "go-live" for various modules and subsidiaries throughout 2016; and investments in new products and markets.

We believe that these investments will position us to increase our revenue and continue to grow our market share.

Investments to Increase Manufacturing Capacity. In February 2015, in order to expand our various clear aligner operating activities to support additional growth, we purchased another facility in Juarez, Mexico. We began

manufacturing aligners in this second facility in September 2015 while continuing to manufacture Aligners at our existing facility in Juarez. Our ability to plan, construct and equip manufacturing facilities is subject to significant risk and uncertainty, including delays and cost overruns. If demand for our product in 2015 exceeds our current expectations, or if the timing of receipt of case product orders during a given quarter is different from our expectations,

we may not be able to fulfill orders in a timely manner, which may negatively impact our financial results and overall business. Conversely, if demand decreases or if we fail to forecast demand accurately, we could be required to record excess capacity charges, which would lower our gross margin.

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. During the first two quarters of 2015, we continued to experience a negative impact from the weakening of the Euro and other foreign currencies relative to the U.S. dollar. The foreign exchange impact on net revenues for the three and nine month ended September 30, 2015 compared to the same periods in 2014 is discussed under "Clear Aligner - International" in the Results of Operations. If the U.S. dollar continues to strengthen compared to other foreign currencies, including the Euro, our reported amount of net revenues and income will be negatively impacted compared to the same period last year. Although we have historically accepted the exposure to exchange rate movements without using derivative financial instruments to manage this risk, in the third quarter of 2015, we initiated a foreign currency economic hedging program to mitigate the foreign currency risk in countries where we have significant monetary assets and liabilities denominated in currencies other than the functional currency. The impact from these forward contracts was not material to our financial statements for the three months ended September 30, 2015.

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 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.

In January 2015, we completed the first \$100.0 million under the program, and our Board of Directors authorized the repurchase of the next \$100.0 million under the repurchase program, which we anticipate completing within twelve months. On April 28, 2015, we entered into an accelerated share repurchase agreement ("2015 ASR") to repurchase \$70.0 million of our common stock. Under the terms of the 2015 ASR, we paid \$70.0 million on April 29, 2015 and received an initial delivery of approximately 0.8 million shares based on the then current market price, which were retired. The 2015 ASR was completed on July 23, 2015 with a final delivery of approximately 0.3 million shares. Under the 2015 ASR, we received a total of approximately 1.2 million shares of our common stock for an average share price of \$60.52. 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 third quarter of 2015, we also repurchased approximately 0.3 million shares on the open market for a total purchase price of \$18.8 million. As of September 30, 2015, there remains approximately \$111.2 million available under our existing stock repurchase program, \$11.2 million of which we expect to purchase within the next six months.

Results of Operations

Net revenues by Reportable Segment

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

Table of Contents

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, 2015 and 2014 is as follows (in millions):

| Net Revenues | For the Three Months Ended, September 30, | | | | For the Nine Months Ended, September 30, | | | | | |
|----------------------------------|--|---------|---------------|-------------|---|---------|---------------|-------------|---------|---|
| | 2015 | 2014 | Net Change | % Change | 2015 | 2014 | Net Change | % Change | | |
| Clear Aligner Revenues: | | | | | | | | | | |
| North America | \$124.1 | \$113.3 | \$10.8 | 9.5 | % | \$369.1 | \$332.9 | \$36.2 | 10.9 | % |
| International | 61.3 | 53.4 | 7.9 | 14.8 | % | 179.1 | 159.3 | 19.8 | 12.4 | % |
| Invisalign non-case | 12.9 | 11.4 | 1.5 | 13.2 | % | 38.0 | 33.9 | 4.1 | 12.1 | % |
| Total Clear Aligner net revenues | \$198.3 | \$178.1 | \$20.2 | 11.3 | % | \$586.1 | \$526.1 | \$60.0 | 11.4 | % |
| Scanner net revenues | 9.3 | 11.7 | (2.4) | (20.5) | % | \$29.1 | 36.9 | (7.8) | (21.1) | % |
| Total net revenues | \$207.6 | \$189.9 | \$17.6 | 9.3 | % | \$615.2 | \$563.1 | \$52.1 | 9.3 | % |

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

Clear Aligner Case Volume by Region

Case volume data which represents Invisalign case shipments by region for the three and nine months ended September 30, 2015 and 2014 is as follows (in thousands):

| Region | For the Three Months Ended, September 30, | | | | For the Nine Months Ended, September 30, | | | | | |
|------------------------------|--|-------|---------------|-------------|---|-------|---------------|-------------|------|---|
| | 2015 | 2014 | Net Change | % Change | 2015 | 2014 | Net Change | % Change | | |
| North American Invisalign | 101.3 | 85.4 | 15.9 | 18.6 | % | 292.0 | 251.7 | 40.3 | 16.0 | % |
| International Invisalign | 46.2 | 34.2 | 12.0 | 35.1 | % | 130.8 | 99.4 | 31.4 | 31.6 | % |
| Total Invisalign case volume | 147.5 | 119.6 | 27.9 | 23.3 | % | 422.8 | 351.1 | 71.7 | 20.4 | % |

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

Total net revenues increased by \$17.6 million and \$52.1 million for the three and nine months ended September 30, 2015, respectively, as compared to the same period in 2014, primarily as a result of Invisalign case volume growth across all regions and most products.

Clear Aligner - North America

In the three months ended September 30, 2015, Clear Aligner North America net revenues increased by \$10.8 million or 9.5% compared to the same period in 2014 primarily due to Invisalign case volume growth of approximately \$21.1 million across all channels and most products. These increases were offset in part by lower average selling prices ("ASP") which decreased net revenues by approximately \$10.3 million. The decrease in ASP was primarily due to the impact of our new additional aligner product policy launched in July 2015, and, to a lesser extent, due to higher promotional discounts in the current period compared to the same period in the prior year. The decrease in ASP was offset in part by the price increase on our Full products effective April 1, 2015.

Based on our new "Additional Aligners at No Charge" product policy, beginning in July 2015, we no longer charge customers for additional aligners ordered beyond those covered by the initial treatment. As a result, we deferred more revenue in the three months ended September 30, 2015 due to providing free additional aligners for eligible

treatments. This deferred revenue will be recognized in the future as the additional aligners are shipped. Additionally, since we grandfathered over one million open cases, we recognized lower revenues when additional aligners were shipped. This new product policy decreased Clear Aligner net revenues by approximately \$6.7 million in the third quarter of 2015 as compared to the same period in the prior year. We expect this policy to continue to impact Clear Aligner net revenues for at least the next two years until the grandfathered cases are closed. We believe that the new product policy will result in a significant improvement in customer satisfaction and loyalty, which we expect will help increase Invisalign utilization and volume over time.

Table of Contents

In the nine months ended September 30, 2015, Clear Aligner North America net revenues increased by \$36.2 million or 10.9% compared to the same period in 2014 primarily due to Invisalign case volume growth of approximately \$53.4 million across all channels and products. These increases were offset in part by lower ASP, which contributed approximately \$17.2 million to the decrease in net revenues. The decrease in ASP was as a result of higher promotional discounts in the current period compared to the same period in the prior year as well as the impact of our new additional aligner product policy launched in July 2015. The decrease in ASP was offset in part by the price increase on our Full products effective April 1, 2015.

Clear Aligner - International

In the three months ended September 30, 2015, Clear Aligner international net revenues increased by \$7.9 million or 14.8% compared to the same period in 2014 primarily driven by Invisalign case volume growth of \$18.8 million across all products. This was offset in part by lower ASP which decreased net revenues by approximately \$10.9 million. The decrease in ASP was primarily a result of the unfavorable impact from foreign exchange rates of \$8.7 million due to the weakening of the Euro compared to the U.S. dollar in the current period compared to the same period in the prior year, and, to a lesser extent, due to the impact of our new additional aligner product policy launched in July 2015 of \$4.0 million. These decreases were partially offset by an increase in ASP as we acquired certain distributors in the APAC region, as well as the price increase on our Full products effective July 1, 2015.

In the nine months ended September 30, 2015, Clear Aligner International net revenues increased by \$19.8 million or 12.4% compared to the same period in 2014 primarily driven by Invisalign case volume growth of \$50.3 million across all products. This was offset by lower ASP which decreased net revenues by approximately \$30.5 million. The decrease in ASP was primarily a result of the unfavorable impact from foreign exchange rates of \$26.7 million due to the weakening of the Euro compared to the U.S. dollar in the current period compared to the same period in the prior year, and, to a lesser extent, due to the impact of our new additional aligner product policy launched in July 2015 of \$4.6 million. These decreases were partially offset by an increase in ASP as we acquired certain distributors in the APAC region, as well as the price increase on our Full products effective July 1, 2015.

Clear Aligner - Invisalign Non-Case

Invisalign non-case net revenues consists of training fees and ancillary product revenues. Invisalign non-case net revenues increased by \$1.5 million or 13.2% and \$4.1 million or 12.1%, for the three and nine months ended September 30, 2015, respectively compared to the same periods in 2014 primarily due to increased Vivera volume both in North America and International.

Scanner and Services

Scanner and Services net revenues decreased \$2.4 million or 20.5% and \$7.8 million or 21.1% for the three and nine months ended September 30, 2015, respectively, compared to the same periods in 2014. In March 2015, we announced our next generation scanner which did not begin shipping until September 2015; therefore, our net revenues declined for both the three and nine months ended September 30, 2015 primarily due to fewer scanners recognized and permanent price reductions on our previous generation scanner.

Table of Contents

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

| | Three Months Ended September 30, | | | Nine Months Ended September 30, | | |
|-----------------------------|----------------------------------|---------|----------|---------------------------------|---------|----------|
| | 2015 | 2014 | Change | 2015 | 2014 | Change |
| Clear Aligner | | | | | | |
| Cost of net revenues | \$42.1 | \$37.0 | \$5.1 | \$124.6 | \$110.2 | \$14.4 |
| % of net segment revenues | 21.2 | % 20.8 | % | 21.3 | % 20.9 | % |
| Gross profit | \$156.2 | \$141.1 | \$15.1 | \$461.5 | \$415.9 | \$45.6 |
| Gross margin % | 78.8 | % 79.2 | % | 78.7 | % 79.1 | % |
| Scanner and Services | | | | | | |
| Cost of net revenues | \$8.0 | \$7.8 | \$0.2 | \$23.3 | \$25.1 | \$(1.8) |
| % of net segment revenues | 85.3 | % 66.5 | % | 80.1 | % 67.8 | % |
| Gross profit | \$1.4 | \$3.9 | \$(2.5) | \$5.8 | \$11.9 | \$(6.1) |
| Gross margin % | 14.7 | % 33.5 | % | 19.9 | % 32.2 | % |
| Total cost of net revenues | \$50.1 | \$44.8 | \$5.3 | \$147.9 | \$135.3 | \$12.6 |
| % of net revenues | 24.1 | % 23.6 | % | 24.0 | % 24.0 | % |
| Gross profit | \$157.6 | \$145.1 | \$12.5 | \$467.3 | \$427.8 | \$39.5 |
| Gross margin % | 75.9 | % 76.4 | % | 76.0 | % 76.0 | % |

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 declined slightly for the three and nine months ended September 30, 2015 compared to the same periods in 2014 due to lower ASP which was partially offset by lower manufacturing costs.

Scanner

Gross margin decreased for the three and nine months ended September 30, 2015 compared to the same periods in 2014 due to lower ASP from permanent price reductions on our previous generation scanner and lower absorption of manufacturing spend on lower production volumes.

Selling, General and administrative (in millions):

Effective for the first quarter of 2015, we combined Sales and Marketing and General and Administrative together to report as Selling, General and Administrative.

| | Three Months Ended September 30, | | | Nine Months Ended September 30, | | |
|-------------------------------------|----------------------------------|--------|--------|---------------------------------|---------|--------|
| | 2015 | 2014 | Change | 2015 | 2014 | Change |
| Selling, general and administrative | \$101.8 | \$80.7 | \$21.1 | \$290.7 | \$246.2 | \$44.5 |
| % of net revenues | 49.0 | % 42.5 | % | 47.2 | % 43.7 | % |

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

Selling, general and administrative expense includes personnel-related costs including payroll, commissions and stock-based compensation for our sales force, marketing and administration in addition to media and advertising expenses, clinical education, trade shows and industry events, product marketing, 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.

Selling, general and administrative expense for the three months ended September 30, 2015 increased compared to the same period in 2014 primarily due to higher compensation related costs of \$15.9 million as a result of increased headcount, which led to higher salaries, stock based compensation and commissions. In addition, we incurred increased consulting expense of \$2.6

Table of Contents

million primarily as a result of our enterprise resource planning “ERP” project and higher clinical education of \$1.7 million due to customer events. These increased expenses were partially offset by lower advertising and media costs of \$1.7 million.

Selling, general and administrative expense for the nine months ended September 30, 2015 increased compared to the same period in 2014 primarily due to higher compensation related costs of \$33.4 million as a result of increased headcount, which led to higher salaries, stock based compensation and commissions. In addition, consulting costs increased by \$9.1 million primarily due to our ERP project. We also incurred higher expenses from clinical education costs, travel, outside legal fees and public relations costs. These increased expenses were partially offset by lower advertising and media costs of \$3.1 million. In addition, in the first quarter of 2015, the IRS approved our MDET refund claim of \$6.8 million related to our aligners, reducing expense for the nine months ended September 30, 2015.

Research and development (in millions):

| | Three Months Ended September 30, | | | Nine Months Ended September 30, | | |
|--------------------------|----------------------------------|--------|--------|---------------------------------|--------|--------|
| | 2015 | 2014 | Change | 2015 | 2014 | Change |
| Research and development | \$17.8 | \$12.9 | \$4.9 | \$47.3 | \$39.5 | \$7.8 |
| % of net revenues | 8.6 | % 6.8 | % | 7.7 | % 7.0 | % |

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 including stock-based compensation and outside consulting expenses associated with the research and development of new products and enhancements to existing products and allocations of corporate overhead expenses including facilities and IT.

Research and development expense for the three and nine months ended September 30, 2015 increased compared to the same period in 2014 due to our investment in new products; however, in the third quarter of 2015, we discontinued our research and development for the treatment of obstructive sleep apnea and incurred a \$2.0 million charge related to the termination of an agreement with a third party. While we continue to believe that the opportunities in the obstructive sleep apnea market are potentially interesting, we have decided to remain focused on our core business and organic growth opportunities .

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

| | Three Months Ended September 30, | | | Nine Months Ended September 30, | | |
|--|----------------------------------|----------|--------|---------------------------------|--------|--------|
| | 2015 | 2014 | Change | 2015 | 2014 | Change |
| Interest and other income (expense), net | \$(1.6) | \$(2.0) | \$0.4 | (2.8) | (1.5) | (1.4) |

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

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

Interest and other income (expense), net for the three months ended September 30, 2015 increased slightly compared to the same period in 2014 due to increased interest income on higher balances of cash, cash equivalents and investments.

Interest and other income (expense), net for the nine months ended September 30, 2015 decreased compared to the same period in 2014 primarily due to higher foreign exchange losses in the current year period mainly as a result of

the strengthening of the U.S. dollar to the Euro and Australian dollar offset in part by increased interest income on higher balances of cash, cash equivalents and investments.

Income tax (in millions):

| | Three Months Ended September 30, | | | Nine Months Ended September 30, | | |
|----------------------------|----------------------------------|--------|----------|---------------------------------|--------|----------|
| | 2015 | 2014 | Change | 2015 | 2014 | Change |
| Provision for income taxes | \$8.9 | \$11.3 | \$(2.4) | \$31.3 | \$34.3 | \$(3.0) |
| Effective tax rates | 24.3 | % 22.8 | % | 24.8 | % 24.4 | % |

Our provision for income taxes was \$8.9 million and \$11.3 million for the three months ended September 30, 2015 and 2014, respectively. This represents effective tax rates of 24.3% and 22.8%, respectively. Our effective tax rates differ from the statutory

Table of Contents

federal income tax rate of 35% due to certain foreign earnings, primarily from Costa Rica, which are subject to a lower tax rate, state income tax expense, the tax impact of certain stock-based compensation charges and unrecognized tax benefits. The increase in the effective rate for the three months ended September 30, 2015 compared to the three month ended September 30, 2014 reflects a jurisdictional shift in forecasted earnings from lower tax non-U.S. jurisdictions to the U.S.

Our provision for income taxes was \$31.3 million and \$34.3 million for the nine months ended September 30, 2015 and 2014, respectively. This represents effective tax rates of 24.8% and 24.4%, respectively. The increase in the effective rate for the nine months ended September 30, 2015 compared to the nine months ended September 30, 2014 reflects a jurisdictional shift in forecasted earnings from lower tax non-U.S. jurisdictions to the U.S., offset by a negative impact in prior year from a \$1.8 million adjustment which related to prior periods.

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, 2015, we maintained a valuation allowance of \$32.8 million against deferred tax assets primarily related to Israel and California operating loss carryforwards and Australia 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.

Our total gross unrecognized tax benefits was \$37.8 million and \$33.1 million as of September 30, 2015 and December 31, 2014, respectively, 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 and nine months ended September 30, 2015 was not material. We do not expect any significant changes to the amount of unrecognized tax benefit within the next twelve months.

We file U.S. federal, U.S. state, and non-U.S. income tax returns. Our major tax jurisdictions are U.S. federal and the State of California. For U.S. federal and state tax returns, we are no longer subject to tax examinations for years before 2000. With few exceptions, we are no longer subject to examination by foreign tax authorities for years before 2007. We are currently under audit by the California Franchise Tax Board for fiscal year 2011, 2012 and 2013.

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 2015 and 2014. Income taxes were reduced by \$8.2 million and \$7.7 million for the three months ended September 30, 2015 and 2014, respectively, representing a benefit to diluted net income per share of \$0.10 and \$0.09 in 2015 and 2014, respectively. As a result of these incentives, our income taxes were reduced by \$24.6 million and \$22.8 million for the nine months ended September 30, 2015 and 2014, respectively, representing a benefit to diluted net income per share of \$0.30 and \$0.28 in 2015 and 2014, respectively.

Liquidity and Capital Resources

Edgar Filing: ALIGN TECHNOLOGY INC - Form 10-Q

We fund our operations from product sales and the proceeds from the sale of our common stock. As of September 30, 2015 and December 31, 2014, we had the following cash, cash equivalents, and short-term and long-term marketable securities (in thousands):

| | September 30, 2015 | December 31, 2014 |
|---|--------------------------|----------------------|
| Cash and cash equivalents | \$174,040 | \$199,871 |
| Marketable securities, short-term | 310,715 | 254,787 |
| Marketable securities, long-term | 145,246 | 147,892 |
| Total cash, cash equivalents and short-term and long-term marketable securities | \$630,001 | \$602,550 |

Table of Contents

Cash flows (in thousands):

| | Nine Months Ended September 30, | |
|--|------------------------------------|-------------|
| | 2015 | 2014 |
| Net cash flow provided by (used in): | | |
| Operating activities | \$158,642 | \$155,294 |
| Investing activities | (92,625 |) (171,373 |
| Financing activities | (88,955 |) (46,918 |
| Effect of exchange rate changes on cash and cash equivalents | (2,893 |) 720 |
| Net decrease in cash and cash equivalents | \$(25,831 |) \$(62,277 |

As of September 30, 2015, we had \$630.0 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 corporate bonds, U.S. dollar dominated foreign corporate bonds, commercial paper, municipal securities, U.S. government agency bonds, U.S. government treasury bonds and asset-backed securities. We do not enter into investments for trading or speculative purposes.

As of September 30, 2015, approximately \$417.4 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 authorized 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, on April 28, 2014, we entered into an accelerated share repurchase agreement ("2014 ASR") to repurchase \$70.0 million of our common stock which was completed on July 2014. We received a total of approximately 1.4 million shares under the 2014 ASR for an 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 2014, we repurchased on the open market approximately 0.6 million shares of our common stock at an average price of \$50.93 per share, including commissions, for an aggregate purchase price of approximately \$28.2 million. In the first quarter of 2015, we repurchased on the open market approximately 0.03 million shares of our common stock at an average price of \$57.49 per share, including commission for an aggregate purchase price of approximately \$1.8 million. All repurchased shares were retired.

In January 2015, our Board of Directors authorized the repurchase of the next \$100.0 million under the repurchase program which we anticipate completing within twelve months. On April 28, 2015, we entered into an accelerated stock repurchase agreement ("2015 ASR") to repurchase \$70.0 million of our common stock. The 2015 ASR was completed on July 23, 2015. We received a total of approximately 1.2 million shares for an average share price of \$60.52 under the 2015 ASR, which were all 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. In addition, during the three months ended September 30, 2015, we repurchased on the open market approximately 0.3 million shares of our common stock at an average price of \$57.04 per share, including commissions, for an aggregate

purchase price of \$18.8 million. All repurchased shares were retired. We have \$111.2 million remaining under the April 2014 stock repurchase program, \$11.2 million of which we expect to purchase within 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 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

Table of Contents

adjusted LIBOR rate (based on one, three, nine or twelve-month interest periods) plus a spread of 1.75%. As of September 30, 2015, we had no outstanding borrowings under this credit facility; however, we were not in compliance with certain negative covenants. As a result, on October 15, 2015, we received a waiver for our non-compliance and also amended the credit facility in regards to these negative covenants.

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 suspend our stock repurchase program or 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.

Operating Activities

For the nine months ended September 30, 2015, cash flows from operations of \$158.6 million resulted primarily from our net income of approximately \$95.1 million as well as the following:

Significant non-cash activities:

- stock-based compensation of \$39.1 million related to equity incentive compensation awards granted to our employees, and
- depreciation and amortization of \$13.1 million related to our fixed assets and acquired intangible assets, offset in part by
- excess tax benefits from our share-based compensation arrangements of \$8.7 million.

Significant changes in working capital:

- an increase of \$28.2 million in deferred revenues corresponding to the increases in case shipments, and
- an increase of \$27.1 million in accounts receivable which is a result of the increase in net revenues.

Investing Activities

Net cash used in investing activities was \$92.6 million for the nine months ended September 30, 2015 primarily consisting of purchases of marketable securities of \$306.9 million, and property, plant and equipment purchases of \$36.7 million. These outflows were partially offset in part by \$250.9 million of maturities and sales of our marketable securities.

For the remainder of 2015, we expect to spend an additional \$18.0 million to \$23.0 million on capital expenditures for estimated total capital expenditures of \$55.0 million to \$60.0 million for 2015 primarily for additional manufacturing capacity and infrastructure including a project to implement a new enterprise resource planning system. 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 \$89.0 million for the nine months ended September 30, 2015 primarily resulting from \$90.6 million for the repurchase of our common stock and \$17.6 million related to payroll taxes paid for vesting of restricted stock units through share withholdings. These outflows were offset in part by \$10.6 million in proceeds from issuance of common stock and \$8.7 million from excess tax benefits from our share-based compensation arrangements.

Table of Contents

Contractual Obligations

Our contractual obligations have not significantly changed since December 31, 2014 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 suspend our stock repurchase program or 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, 2015, 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 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, 2015, 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, 2014:

• Revenue recognition;

• Stock-based compensation expense;

• Goodwill and finite-lived acquired intangible assets,

• Impairment of goodwill, finite-lived acquired intangible assets and long-lived assets, and

• Accounting for income taxes.

Table of Contents

Revenue Recognition

In July 2015, we launched a new product policy called "Additional Aligners at No Charge" that addressed one of our customers' top complaints. Previously, we charged customers for additional aligners ordered beyond those covered by the initial treatment plan. With this product policy change, we no longer distinguish between mid-course corrections and case refinements and allow doctors to order additional aligners to address either treatment need at no charge. As part of this change, we also grandfathered over one million open cases under this product policy change. These changes were effective for all new Invisalign Full, Teen, and Assist treatments shipped worldwide after July 18, 2015 as well as any open Invisalign Full, Teen and Assist cases as of that date.

We concluded that additional aligners is a separate unit of accounting in our treatment plans, similar to case refinement and mid-course correction. We determined the best estimated selling price ("BESP") of additional aligners based on a cost and margin analysis, as well as other inputs based on our historical pricing practices. Further, we will continue to allocate revenue to each unit in our treatment plan based on the unit's relative selling price based on BESP, and recognize the revenue upon the delivery of each unit in the treatment plan. We regularly review our estimates of selling price and maintain internal controls over the establishment and update of these estimates.

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

In the normal course of business, we are exposed to foreign currency exchange rate and interest rate risks that could impact our financial position and results of operations.

Interest Rate Risk

Changes in interest rates could impact our anticipated interest income on our cash equivalents and investments in marketable securities. Our cash equivalents and investments are fixed-rate short-term and long-term securities. Fixed-rate securities may have their fair market value adversely impacted due to a rise in interest rates, and, as a result, our future investment income may fall short of expectations due to changes in interest rates or we may suffer losses in principal if forced to sell securities which have declined in market value due to changes in interest rates. As of September 30, 2015, we had approximately \$456.0 million invested in available-for-sale marketable securities. An immediate 10% change in interest rates would not have a material adverse impact on our future operating results and cash flows.

We do not enter into investments for trading or speculative purposes and have not used any derivative financial instruments to manage our interest rate risk exposure. We do not have interest bearing liabilities as of September 30, 2015, and, therefore, we are not subject to risks from immediate interest rate increases.

Currency Rate Risk

We operate in North America, Europe, Asia Pacific, Costa Rica and Israel. As a result of our international business activities, our financial results could be affected by factors such as changes in foreign currency exchange rates or economic conditions in foreign markets, and there is no assurance that exchange rate fluctuations will not harm our business in the future. We generally sell our products in the local currency of the respective countries. This provides some natural hedging because most of the subsidiaries' operating expenses are generally denominated in their local

currencies as discussed further below. Regardless of this natural hedging, our results of operations may be adversely impacted by exchange rate fluctuations.

In September 2015, we entered into foreign currency forward contracts to minimize the short-term impact of foreign currency exchange rate fluctuations on cash and certain trade and intercompany receivables and payables. These forward contracts are not designated as hedging instruments and do not subject us to material balance sheet risk due to fluctuations in foreign currency exchange rates. The gains and losses on these forward contracts are intended to offset the gains and losses in the underlying foreign currency denominated monetary assets and liabilities being economically hedged. These instruments are marked to market through earnings every period and generally are one month in original maturity. We do not enter into foreign currency forward contracts for trading or speculative purposes. As our international operations grow, we will continue to reassess our approach to managing the risks relating to fluctuations in currency rates. It is difficult to predict the impact hedging activities could have on our results of operations. The fair value of foreign exchange forward contracts outstanding as of September 30, 2015 was not material.

Table of Contents

Although we will continue to monitor our exposure to currency fluctuations, and, where appropriate, may use financial hedging techniques in the future to minimize the effect of these fluctuations, the impact of an aggregate change of 10% in foreign currency exchange rates relative to the U.S. dollar on our results of operations and financial position could be material.

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, 2015, 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.

Table of Contents

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 former 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.

Table of Contents

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 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. 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 the treatment of malocclusion, but a number of dental professionals believe that the 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.

We 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. In July 2015, we launched a new product policy called "Additional Aligners at No Charge" that addresses one of our customer's top complaints. With this product policy change, we no longer distinguish between mid-course correction and case refinements and allow doctors to order additional aligners to address either treatment need at no charge, subject to certain requirements. Based on this new product policy, beginning in the third quarter of 2015, we deferred more revenue as a result of providing free additional aligners for eligible treatments. Additionally, as we grandfathered over 1 million open cases, we will recognize lower revenues as additional aligners are shipped for at least the next two years until these cases complete.

We are exposed to fluctuations in currency exchange rates, which could negatively affect our financial condition and results of operations.

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 net revenues and net income in our consolidated financial statements. The exchange rate between the U.S. dollar and foreign currencies has fluctuated substantially

Table of Contents

in recent years and may continue to fluctuate substantially in the future. As a result, beginning in September 2015, we began entering into currency hedging transactions in an effort to cover some of our exposure to foreign currency exchange fluctuations. These transactions may not operate to fully or effectively hedge our exposure to currency fluctuations, and, under certain circumstances, these transactions could have an adverse effect on our financial condition.

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 excess or constrained capacity and pressure on our internal systems and personnel. In order to manage current operations and future growth effectively, we will need to continue to implement and improve our operational, financial and management information systems and to hire, train, motivate, manage and retain employees. We may be unable to manage such growth effectively. Any such failure could have a material adverse impact on our business, operations and prospects. In addition, in order to meet the demands from expected volumes, we purchased a second manufacturing facility in Juarez, Mexico. We began manufacturing aligners in this second facility in September 2015 while continuing to manufacture Aligners at our existing facility in Juarez. Our ability to plan, construct and equip additional manufacturing facilities is subject to significant risk and uncertainty, including risks inherent in the establishment of a new manufacturing facility, such as hiring and retaining employees and delays and cost overruns as a result of a number of factors, any of which may be out of our control. If the transition into this additional facility is significantly delayed or demand for our product exceeds our current expectations, we may not be able to fulfill orders timely, which may negatively impact our financial results and overall business. In addition, 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.

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.

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;

our inability to scale production of our iTero Element scanner to meet customer demand;

if participation in our customer rebate or discount programs 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;

Table of Contents

- 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, modifications to our terms and conditions 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;
 - unanticipated delays in our receipt of patient records made through an intraoral scanner for any reason;
 - 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,
 - investments in research and development to develop new products and enhancements; and
- our ability to successfully hedge against a portion of our foreign currency-denominated assets and liabilities.

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;

Table of Contents

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.

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 North America facilities, 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 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.;

Table of Contents

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:

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 indefinitely 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.

Table of Contents

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.

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 in 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 which we depend upon 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.

Table of Contents

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.

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 certain key 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 and stock price. We cannot assure you that we will be able to compete successfully against our current or future competitors or that competitive pressures will not have a material adverse effect on our business, results of operations and financial condition.

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, 2015, we had issued 373 U.S. patents, 271 foreign issued patents, and 235 pending global 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

Table of Contents

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 in 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 existing policies or procedures may become ineffective. Establishing, testing and maintaining an effective system of internal control over financial reporting requires significant resources and time commitments on the part of our management and our finance staff, may require additional staffing and infrastructure investments, and would increase our costs of doing business. If we are unable to assert that our internal control over financial reporting is effective in any future period (or if our auditors are unable to express an opinion on the effectiveness of our internal controls or conclude that our internal controls are ineffective), we could lose investor confidence in the accuracy and completeness of our financial reports, which could have an adverse effect on our stock price.

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

We are highly dependent on the key employees in our clinical engineering, technology development, sales, training and marketing personnel and management teams. The loss of the services provided by those individuals may significantly delay or prevent the achievement of our product development and other business objectives and could harm our business. Our future success will also depend on our ability to identify, recruit, train and retain additional qualified personnel, including orthodontists. Few orthodontists are accustomed to working in a manufacturing

environment since they are generally trained to work in private practices, universities and other research institutions. Thus, we may be unable to attract and retain personnel with the advanced qualifications necessary for the further development of our business. Furthermore, we may not be successful in retaining our key personnel or their services. If we are unable to attract and retain key personnel, our business could be materially harmed. In addition, our ability to recognize revenue on the direct sales of our intra-oral scanners depends in part upon our ability to schedule and staff trainings. The loss of the services provided by these individuals or our ability to timely hire such personnel in sufficient numbers based on our volume growth, may harm our business. If we are unable to retain our trainers or replace such individuals with persons having equivalent technical expertise and qualifications, or if we are unable to 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. While Thomas M. Prescott, the Company's former Chief Executive Officer ("CEO") retired effective June 1, 2015, we also announced the appointment of Joseph M. Hogan as President and CEO effective that same date. Leadership changes can be inherently difficult to manage and our ability to execute our business strategy and retain key personnel may be adversely affected by the uncertainty associated with this transaction.

Table of Contents

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.

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 the Czech Republic to supply key sub-assemblies for our iTero Element scanner. As a result, if this third party manufacturer fails to deliver its components, if we lose its services or if we fail to negotiate acceptable terms, 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, 2015, our North American sales organization consisted of approximately 330 people. Internationally, we had approximately 230 people engaged in direct sales and sales support as of September 30, 2015. 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

Table of Contents

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;
- 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

Table of Contents

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 proposed by the European Union. The 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. 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 which is not material. The MDET is included in selling, 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

Table of Contents

the marketing and advertising of our products.

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

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

Outside of North America, we currently sell our products in Europe, Asia Pacific, Latin America and the Middle East and may expand into other countries from time to time. For sales of our products outside the U.S., we are subject to foreign regulatory requirements that vary widely from country to country. The time required to obtain clearances or approvals required by other countries may be longer than that required for FDA clearance or approval, and requirements for such approvals may differ from FDA requirements. We may be unable to obtain regulatory approvals in one or more of the other countries in which we do business or in which we may do business in the future. We may also incur significant costs in attempting to obtain and maintain foreign regulatory approvals. If we experience delays in receipt of approvals to market our products outside of the U.S., or if we fail to receive these approvals, we may be unable to market our products or enhancements in international markets in a timely manner, if at all.

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

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

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

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

- quarterly variations in our results of operations and liquidity;
- changes in recommendations by the investment community or in their estimates of our 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.

Table of Contents

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 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 negotiation, 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.

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

Table of Contents

have a negative impact on our operating results. The Costa Rica corporate income tax rate that would apply, absent the incentives, is 30% for 2015 and 2014. Income taxes were reduced by \$8.2 million and \$7.7 million for the three months ended September 30, 2015 and 2014, respectively, representing a benefit to diluted net income per share of \$0.10 and \$0.09 in 2015 and 2014, respectively. As a result of these incentives, our income taxes were reduced by \$24.6 million and \$22.8 million for the nine months ended September 30, 2015 and 2014, respectively, representing a benefit to diluted net income per share of \$0.30 and \$0.28 in 2015 and 2014, respectively. Our subsidiary in Israel is under audit by the local tax authorities for calendar years 2006 through 2012. We were currently under audit by the California Franchise Tax Board for fiscal year 2011, 2012 and 2013.

Table of Contents

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, 2015:

| Period | Total Number of Shares Repurchased ⁽³⁾ | Average Price Paid per Share | Total Number of Shares Repurchased as Part of Publicly Announced Program ⁽¹⁾ | Approximate Dollar Value of Shares that May Yet Be Repurchased Under the Program ⁽¹⁾ |
|--|---|------------------------------|---|---|
| July 1, 2015 through July 31, 2015 | 332,462 | \$63.17 | 332,462 | \$ 129,988,318 |
| August 1, 2015 through August 31, 2015 | 177,702 | \$58.19 | 177,702 | \$ 119,648,031 |
| September 1, 2015 through September 30, 2015 | 152,265 | \$55.71 | 152,265 | \$ 111,165,553 |

(1) As part of our \$300.0 million April 2014 stock repurchase program, our Board of Directors authorized the next \$100 million to be purchased over the 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 of September 30, 2015, we have approximately \$111.2 million remaining under the April 2014 stock repurchase program.

(2) We entered into an accelerated share repurchase agreement ("2015 ASR") on April 28, 2015 to repurchase \$70.0 million of our common stock. Under the terms of the 2015 ASR, we agreed to repurchase in total \$70.0 million of our common stock, with an initial delivery of approximately 0.8 million shares based on the then current market price. The 2015 ASR was completed on July 23, 2015 with a final delivery of approximately 0.3 million shares. Under the 2015 ASR, we received a total of approximately 1.2 million shares for an average purchase share price of \$60.52. 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.

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

ITEM 3.DEFAULTS UPON SENIOR SECURITIES

Not applicable.

ITEM 4.MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None

ITEM 6. EXHIBITS

(a) Exhibits:

Table of Contents

| Exhibit Number | Description | Filing | Date | Exhibit Number | Filed here with |
|----------------|--|--------|------|----------------|-----------------|
| 31.1 | Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. | | | | * |
| 31.2 | Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. | | | | * |
| 32.1 | Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. | | | | * |
| 101.INS | XBRL Instance Document | | | | * |
| 101.SCH | XBRL Taxonomy Extension Schema Document | | | | * |
| 101.CAL | XBRL Taxonomy Extension Calculation Linkbase Document | | | | * |
| 101.DEF | XBRL Taxonomy Extension Definition Linkbase Document | | | | * |
| 101.LAB | XBRL Taxonomy Extension Label Linkbase Document | | | | * |
| 101.PRE | XBRL Taxonomy Extension Presentation Linkbase Document | | | | * |

Table of Contents

SIGNATURES

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

ALIGN TECHNOLOGY, INC.

October 29, 2015

By: /S/ JOSEPH M. HOGAN
Joseph M. Hogan
President and Chief Executive Officer

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

Table of Contents

EXHIBIT INDEX

| Exhibit Number | Description | Filing | Date | Exhibit Number | Filed here with |
|----------------|--|--------|------|----------------|-----------------|
| 31.1 | Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. | | | | * |
| 31.2 | Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. | | | | * |
| 32.1 | Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. | | | | * |
| 101.INS | XBRL Instance Document | | | | * |
| 101.SCH | XBRL Taxonomy Extension Schema Document | | | | * |
| 101.CAL | XBRL Taxonomy Extension Calculation Linkbase Document | | | | * |
| 101.DEF | XBRL Taxonomy Extension Definition Linkbase Document | | | | * |
| 101.LAB | XBRL Taxonomy Extension Label Linkbase Document | | | | * |
| 101.PRE | XBRL Taxonomy Extension Presentation Linkbase Document | | | | * |