ALIGN TECHNOLOGY INC
Form 10-Q
November 08, 2016
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)
x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended September 30, 2016
OR

¨ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from to
Commission file number: 0-32259

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

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

2560 Orchard Parkway
San Jose, California 95131
(Address of principal executive offices)
(408) 470-1000
(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No ¨
Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No ¨
Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definitions of "large accelerated filer," "accelerated filer," and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ¨ No x
The number of shares outstanding of the registrant's Common Stock, $0.0001 par value, as of October 31, 2016 was 79,689,402.

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Invisalign, Align, the Invisalign logo, ClinCheck, Invisalign Assist, Invisalign Teen, Vivera, 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.

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PART I—FINANCIAL INFORMATION
ITEM 1 FINANCIAL STATEMENTS
ALIGN TECHNOLOGY, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except per share data)
(unaudited)

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2016 | 2015 | 2016 | 2015 |
| Net revenues | $278,589 | $207,636 | $786,671 | $615,210 |
| Cost of net revenues | 69,387 | 50,060 | 191,626 | 147,910 |
| Gross profit | 209,202 | 157,576 | 595,045 | 467,300 |
| Operating expenses: | | | | |
| Selling, general and administrative | 126,708 | 101,751 | 360,385 | 290,657 |
| Research and development | 20,415 | 17,779 | 54,111 | 47,348 |
| Total operating expenses | 147,123 | 119,530 | 414,496 | 338,005 |
| Income from operations | 62,079 | 38,046 | 180,549 | 129,295 |
| Interest and other income (expenses), net | 1,463 | (1,568) | 1,161 | (2,846) |
| Net income before provision for income taxes and equity in losses of investee | 63,542 | 36,478 | 181,710 | 126,449 |
| Provision for income taxes | 11,698 | 8,862 | 39,172 | 31,306 |
| Equity in losses of investee, net of tax | 477 | — | 477 | — |
| Net income | $51,367 | $27,616 | $142,061 | $95,143 |
| | | | | |
| Net income per share: | | | | |
| Basic | $0.64 | $0.35 | $1.78 | $1.19 |
| Diluted | $0.63 | $0.34 | $1.74 | $1.17 |
| Shares used in computing net income per share: | | | | |
| Basic | 79,977 | 79,808 | 79,920 | 80,173 |
| Diluted | 81,466 | 81,092 | 81,523 | 81,576 |

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

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ALIGN TECHNOLOGY, INC.
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME
(in thousands)
(unaudited)

| | Three Months Ended | | Nine Months Ended | |
|---|---|---|---|---|
| | September 30, | | September 30, | |
| | 2016 | 2015 | 2016 | 2015 |
| Net income | $51,367 | $27,616 | $142,061 | $95,143 |
| Net change in currency translation adjustment | (76) | 114 | (143) | (95) |
| Change in unrealized gains (losses) on available-for-sale securities, net of tax | (437) | 98 | 1,038 | 260 |
| Other comprehensive income (loss) | (513) | 212 | 895 | 165 |
| Comprehensive income | $50,854 | $27,828 | $142,956 | $95,308 |

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

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

| | September 30, 2016 (unaudited) | December 31, 2015 |
|---|---|---|
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents | $ 419,948 | $ 167,714 |
| Marketable securities, short-term | 193,018 | 359,581 |
| Accounts receivable, net of allowances for doubtful accounts and returns of $3,925 and $2,472, respectively | 244,992 | 158,550 |
| Inventories | 26,341 | 19,465 |
| Prepaid expenses and other current assets | 27,469 | 26,700 |
| Total current assets | 911,768 | 732,010 |
| Marketable securities, long-term | 62,820 | 151,370 |
| Property, plant and equipment, net | 172,658 | 136,473 |
| Equity method investments | 46,268 | — |
| Goodwill and intangible assets, net | 82,987 | 79,162 |
| Deferred tax assets | 68,918 | 51,416 |
| Other assets | 13,474 | 8,202 |
| Total assets | $ 1,358,893 | $ 1,158,633 |
| LIABILITIES AND STOCKHOLDERS’ EQUITY | | |
| Current liabilities: | | |
| Accounts payable | $ 33,104 | $ 34,354 |
| Accrued liabilities | 132,538 | 107,765 |
| Deferred revenues | 177,409 | 129,553 |
| Total current liabilities | 343,051 | 271,672 |
| Income tax payable | 42,539 | 37,512 |
| Other long-term liabilities | 993 | 1,523 |
| Total liabilities | 386,583 | 310,707 |
| Commitments and contingencies (Note 7 and 8) | | |
| Stockholders’ equity: | | |
| Preferred stock, $0.0001 par value (5,000 shares authorized; none issued) | — | — |
| Common stock, $0.0001 par value (200,000 shares authorized; 79,867 and 79,500 issued and outstanding, respectively) | 8 | 8 |
| Additional paid-in capital | 854,422 | 821,507 |
| Accumulated other comprehensive income (loss), net | (85 ) | (980 ) |
| Retained earnings | 117,965 | 27,391 |
| Total stockholders’ equity | 972,310 | 847,926 |
| Total liabilities and stockholders’ equity | $ 1,358,893 | $ 1,158,633 |

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

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

| | Nine Months Ended September 30, | |
|---|---|---|
| | 2016 | 2015 |
| CASH FLOWS FROM OPERATING ACTIVITIES: | | |
| Net income | $142,061 | $95,143 |
| Adjustments to reconcile net income to net cash provided by operating activities: | | |
| Deferred taxes | (17,476) | (4,646) |
| Depreciation and amortization | 16,786 | 13,141 |
| Stock-based compensation | 39,934 | 39,135 |
| Net tax benefits from stock-based awards | 13,057 | 8,663 |
| Excess tax benefit from share-based payment arrangements | (13,943) | (8,663) |
| Equity in losses of investee, net of tax | 477 | — |
| Other non-cash operating activities | 9,525 | 9,252 |
| Changes in assets and liabilities: | | |
| Accounts receivable | (93,122) | (27,123) |
| Inventories | (6,873) | (3,033) |
| Prepaid expenses and other assets | (5,069) | (2,529) |
| Accounts payable | (4,134) | 4,408 |
| Accrued and other long-term liabilities | 38,969 | 6,712 |
| Deferred revenues | 46,482 | 28,182 |
| Net cash provided by operating activities | 166,674 | 158,642 |
| CASH FLOWS FROM INVESTING ACTIVITIES: | | |
| Purchase of property, plant and equipment | (56,368) | (36,663) |
| Purchase of marketable securities | (283,797) | (306,938) |
| Proceeds from maturities of marketable securities | 328,498 | 238,412 |
| Purchase of equity method investments | (46,745) | — |
| Proceeds from sales of marketable securities | 209,302 | 12,518 |
| Other investing activities | (8,031) | 46 |
| Net cash provided by (used in) investing activities | 142,859 | (92,625) |
| CASH FLOWS FROM FINANCING ACTIVITIES: | | |
| Proceeds from issuance of common stock | 12,877 | 10,559 |
| Common stock repurchases | (58,174) | (90,603) |
| Excess tax benefit from share-based payment arrangements | 13,943 | 8,663 |
| Employees' taxes paid upon the vesting of restricted stock units | (26,265) | (17,574) |
| Net cash used in financing activities | (57,619) | (88,955) |
| Effect of foreign exchange rate changes on cash and cash equivalents | 320 | (2,893) |
| Net increase (decrease) in cash and cash equivalents | 252,234 | (25,831) |
| Cash and cash equivalents, beginning of the period | 167,714 | 199,871 |
| Cash and cash equivalents, end of the period | $419,948 | $174,040 |

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

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ALIGN TECHNOLOGY, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(unaudited)
Note 1. Summary of Significant Accounting Policies

Basis of presentation

The accompanying unaudited Condensed Consolidated Financial Statements have been prepared by Align Technology, Inc. (“we”, “our”, or “Align”) in accordance with the rules and regulations of the Securities and Exchange Commission ("SEC") and contain all adjustments, including normal recurring adjustments, necessary to state fairly our results of operations for the three and nine months ended September 30, 2016 and 2015, our comprehensive income for the three and nine months ended September 30, 2016 and 2015, our financial position as of September 30, 2016 and our cash flows for the nine months ended September 30, 2016 and 2015. The Condensed Consolidated Balance Sheet as of December 31, 2015 was derived from the December 31, 2015 audited financial statements but does not include all disclosures required by accounting principles generally accepted in the United States of America.

The results of operations for the three and nine months ended September 30, 2016 are not necessarily indicative of the results that may be expected for the year ending December 31, 2016 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, 2015.

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.

Variable Interest Entities
We have interests in entities determined to be Variable Interest Entities (“VIEs”). If we determine we are the primary beneficiary of these VIEs, we would consolidate the VIE into our financial statements. In determining if we are the primary beneficiary, we evaluate whether we have the power to direct the activities that most significantly impact the VIEs economic performance and the obligation to absorb losses or the right to receive benefits of the VIE that could potentially be significant to the VIE. Our evaluation includes identification of significant activities and an assessment of our ability to direct those activities based on governance provisions and arrangements to provide or receive product and process technology, product supply, operations services, equity funding, financing, and other applicable agreements and circumstances. Our assessments of whether we are the primary beneficiary of our VIEs require significant assumptions and judgments. We have concluded that we are not the primary beneficiary of our VIE investments; therefore, we do not consolidate their results into our consolidated financials.

Investments in Privately-Held Companies

Investments in privately held companies in which we can exercise significant influence but do not own a majority equity interest or otherwise control, are accounted for under the equity method of accounting. Equity method investments are reported on our balance sheet as a single amount, and we record our share of their operating results within equity in losses of investee in our results of operation.

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (" FASB") released Accounting Standards Update ("ASU") 2014-9 "Revenue from Contracts with Customers" (Topic 606) to supersede nearly all existing revenue recognition guidance under GAAP. The core principle of the standard is to recognize revenues when promised goods or services are transferred to customers in an amount that reflects the consideration that is expected to be received for the goods or services. The new standard defines a five step process to achieve this core principle and, in doing so, it is possible more judgment and estimates may be required within the

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revenue recognition process than required under existing GAAP including identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligation. In addition, the new standard requires that reporting companies disclose the nature, amount, timing, and uncertainty of revenue and cash flows arising from contracts with customers. We are required to adopt this standard starting in the first quarter of fiscal year 2018 using either of two methods: (i) retrospective to each prior reporting period presented with the option to elect certain practical expedients as defined within the standard; or (ii) retrospective with the cumulative effect of initially applying the standard recognized at the date of initial application and providing certain additional disclosures as defined per the standard. We have not yet selected a transition method, and are in the process of determining the impact that the new standard will have on our consolidated financial statements.

In April 2016, the Financial Accounting Standards Board (" FASB") released ASU No. 2016-10 "Revenue from Contracts with Customers" to clarify the following two aspects of Topic 606: identifying performance obligations and the licensing implementation guidance, while retaining the principles for those areas of the ASU 2014-9 issued in May 2014. The effective date and the transition requirement of the amendments in this update are the same as the effective date and transition requirements of Topic 606.

In May 2016, the Financial Accounting Standards Board (" FASB") released ASU No. 2016-12 "Revenue from Contracts with Customers" to address certain issues in the Topic 606 guidance on assessing the collectibility, presentation of sales taxes, non-cash consideration, and completed contracts and contract modifications at transition. The ASU provides narrow-scope improvements and practical expedients to the ASU 2014-9 issued in May 2014. The effective date and the transition requirement of the amendments in this update are the same as the effective date and transition requirements of Topic 606.

In February 2016, the FASB issued ASU No. 2016-02, “Leases” (Topic 842). The FASB issued this update to increase transparency and comparability among organizations by recognizing lease assets and lease liabilities on the balance sheet and disclosing key information about leasing arrangements. The updated guidance is effective for annual periods beginning after December 15, 2018, including interim periods within those fiscal years. Early adoption of the standard is permitted. The Company is evaluating the impact of the adoption of this update on our consolidated financial statements and related disclosures.

In March 2016, the FASB issued ASU No. 2016-09, "Improvements to Employee Share-Based Payment Accounting" This ASU affects entities that issue share-based payment awards to their employees. The ASU is designed to simplify several aspects of accounting for share-based payment award transactions, which include the income tax consequences, classification of awards as either equity or liabilities, classification on the statement of cash flows and forfeiture rate calculations. This ASU will become effective for Align on January 1, 2017. Early adoption is permitted in any interim or annual period. We are currently evaluating the impact of this guidance on our consolidated financial statements.

In June 2016, the FASB issued ASU No. 2016-13, “Financial Instruments - Credit Losses” (Topic 326). The FASB issued this update to provide financial statement users with more decision-useful information about the expected credit losses on financial instruments and other commitments to extend credit held by a reporting entity at each reporting date. The amendments in this update replace the existing guidance of incurred loss impairment methodology with an approach that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information to inform credit loss estimates. The updated guidance is effective for annual periods beginning after December 15, 2019, including interim periods within those fiscal years. Early adoption of the update is permitted as of the fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. We are evaluating the impact of the adoption of this update on our consolidated financial statements and related disclosures.

In August 2016, the FASB issued ASU 2016-15, Classification of Certain Cash Receipts and Cash Payments ("ASU 2016-15"). ASU 2016-15 clarifies the presentation and classification of certain cash receipts and cash payments in the statement of cash flows. This ASU is effective for fiscal years, and interim periods within those years, beginning after December 15, 2017. Early adoption is permitted. We are currently assessing the potential impact of ASU 2016-15 on our financial statements and related disclosures.

Note 2. Marketable Securities and Fair Value Measurements

As of September 30, 2016 and December 31, 2015, the estimated fair value of our short-term and long-term marketable securities, classified as available for sale, are as follows (in thousands):

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Short-term

| September 30, 2016 | Amortized Cost | Gross Unrealized Gains | Gross Unrealized Losses | Fair Value |
|---|---|---|---|---|
| Commercial paper | $ 19,029 | $ — | $ — | $ 19,029 |
| Corporate bonds | 81,955 | 18 | (29 ) | 81,944 |
| Municipal securities | 9,205 | — | (4 ) | 9,201 |
| U.S. government agency bonds | 30,587 | 24 | — | 30,611 |
| U.S. government treasury bonds | 47,702 | 31 | — | 47,733 |
| Certificates of deposits | 4,500 | — | — | 4,500 |
| Total Marketable Securities, Short-Term | $ 192,978 | $ 73 | $ (33 ) | $ 193,018 |

Long-term

| September 30, 2016 | Amortized Cost | Gross Unrealized Gains | Gross Unrealized Losses | Fair Value |
|---|---|---|---|---|
| U.S. government agency bonds | $ 9,249 | $ 11 | $ — | $ 9,260 |
| Corporate bonds | 43,101 | 118 | (7 ) | 43,212 |
| U.S. government treasury bonds | 10,027 | 21 | — | 10,048 |
| Asset-backed securities | 300 | — | — | 300 |
| Total Marketable Securities, Long-Term | $ 62,677 | $ 150 | $ (7 ) | $ 62,820 |

Short-term

| December 31, 2015 | Amortized Cost | Gross Unrealized Gains | Gross Unrealized Losses | Fair Value |
|---|---|---|---|---|
| Commercial paper | $ 38,537 | $ — | $ — | $ 38,537 |
| Corporate bonds | 179,765 | 6 | (251 ) | 179,520 |
| U.S. dollar denominated foreign corporate bonds | 510 | — | (2 ) | 508 |
| Municipal securities | 14,209 | 7 | (2 ) | 14,214 |
| U.S. government agency bonds | 75,172 | — | (53 ) | 75,119 |
| U.S. government treasury bonds | 51,763 | 1 | (81 ) | 51,683 |
| Total Marketable Securities, Short-Term | $ 359,956 | $ 14 | $ (389 ) | $ 359,581 |

Long-term

| December 31, 2015 | Amortized Cost | Gross Unrealized Gains | Gross Unrealized Losses | Fair Value |
|---|---|---|---|---|
| U.S. government agency bonds | $ 43,853 | $ — | $ (178 ) | $ 43,675 |
| Corporate bonds | 64,012 | 9 | (218 ) | 63,803 |
| U.S. government treasury bonds | 37,673 | — | (107 ) | 37,566 |
| Municipal securities | 3,993 | — | (2 ) | 3,991 |
| Asset-backed securities | 2,338 | — | (3 ) | 2,335 |
| Total Marketable Securities, Long-Term | $ 151,869 | $ 9 | $ (508 ) | $ 151,370 |

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, 2016 and December 31, 2015. Amounts reclassified to earnings from accumulated other comprehensive income related to unrealized gains or losses were immaterial for the three and nine months ended September 30, 2016 and 2015. For the three and nine months ended September 30, 2016 and 2015, realized gains or losses were immaterial.

Our fixed-income securities investment portfolio consists of commercial paper, corporate bonds, municipal securities, U.S. government agency bonds, U.S. government treasury bonds, U.S. dollar denominated foreign corporate bonds, certificates of deposits, and asset-backed securities that have a maximum effective maturity of 27 months. The securities that we invest in are

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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 these investments upon maturity or sale. The weighted average remaining duration of these securities was approximately 8 months and 9 months as of September 30, 2016 and December 31, 2015, 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, 2016 and December 31, 2015 (in thousands):

| | September 30, 2016 | December 31, 2015 |
|---|---|---|
| Due in one year or less | $ 193,018 | $ 359,581 |
| Due in greater than one year | 62,820 | 151,370 |
| Total available for sale short-term and long-term marketable securities | $ 255,838 | $ 510,951 |

Fair Value Measurements

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

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

Our Level 1 assets consist of money market funds and U.S. government treasury bonds. We did not hold any Level 1 liabilities as of September 30, 2016 and December 31, 2015.

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 denominated foreign corporate bonds and our Israeli funds that are mainly invested in insurance policies and foreign currency forward contracts. We obtain fair values for our Level 2 investments. 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. We did not hold any Level 2 liabilities as of September 30, 2016 or December 31, 2015.

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.

Our Level 3 assets consist of long-term notes receivable and are included in other assets on our consolidated balance sheet. In the third quarter of 2016, we entered into long-term notes receivable and, as of September 30, 2016, the fair value approximated its carrying value of $2.0 million.

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The following tables summarize our financial assets measured at fair value on a recurring basis as of September 30, 2016 and December 31, 2015 (in thousands):

| Description | Balance as of September 30, 2016 | Quoted Prices in Active Markets for Identical Assets (Level 1) | Significant Other Observable Inputs (Level 2) | Significant Other Observable Inputs (Level 3) |
|---|---|---|---|---|
| Cash equivalents: | | | | |
| Money market funds | $ 92,931 | $ 92,931 | $ — | $ — |
| Short-term investments: | | | | |
| Commercial paper | 19,029 | — | 19,029 | — |
| Corporate bonds | 81,944 | — | 81,944 | — |
| Municipal securities | 9,201 | — | 9,201 | — |
| U.S. government agency bonds | 30,611 | — | 30,611 | — |
| U.S. government treasury bonds | 47,733 | 47,733 | — | — |
| Certificates of deposits | 4,500 | — | 4,500 | — |
| Long-term investments: | | | | |
| U.S. government agency bonds | 9,260 | — | 9,260 | — |
| Corporate bonds | 43,212 | — | 43,212 | — |
| U.S. government treasury bonds | 10,048 | 10,048 | — | — |
| Asset-backed securities | 300 | — | 300 | — |
| Prepaid expenses and other current assets: | | | | |
| Israeli funds | 2,527 | — | 2,527 | — |
| Other assets: | | | | |
| Long-term notes receivable | 2,000 | — | — | 2,000 |
| | $ 353,296 | $ 150,712 | $ 200,584 | $ 2,000 |

| Description | Balance as of December 31, 2015 | Quoted Prices in Active Markets for Identical Assets (Level 1) | Significant Other Observable Inputs (Level 2) |
|---|---|---|---|
| Cash equivalents: | | | |
| Money market funds | $ 70,148 | $ 70,148 | $ — |
| Commercial paper | 36,887 | — | 36,887 |
| U.S. government agency bonds | 3,599 | — | 3,599 |
| Corporate bonds | 625 | — | 625 |
| Short-term investments: | | | |
| Commercial paper | 38,537 | — | 38,537 |
| Corporate bonds | 179,520 | — | 179,520 |
| U.S. dollar denominated foreign corporate bonds | 508 | — | 508 |
| Municipal securities | 14,214 | — | 14,214 |
| U.S. government agency bonds | 75,119 | — | 75,119 |
| U.S. government treasury bonds | 51,683 | 51,683 | — |
| Long-term investments: | | | |
| U.S. government agency bonds | 43,675 | — | 43,675 |
| Corporate bonds | 63,803 | — | 63,803 |

| | | | |
|---|---|---|---|
| U.S. government treasury bonds | 37,566 | 37,566 | — |
| Municipal securities | 3,991 | — | 3,991 |
| Asset-backed securities | 2,335 | — | 2,335 |
| Prepaid expenses and other current assets: | | | |
| Israeli funds | 2,436 | — | 2,436 |
| | $ 624,646 | $ 159,397 | $ 465,249 |

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Derivative Financial Instruments

We have in the past and may in the future enter into foreign currency forward contracts to minimize the short-term impact of foreign currency exchange rate fluctuations on certain trade and intercompany receivables and payables, which are classified within level 2 of the fair value hierarchy. The net loss on these forward contracts was immaterial for the nine months ended September 30, 2016. The net gain or loss from the settlement of these foreign currency forward contracts is recorded in Interest and other income (expenses), net in the Consolidated Statement of Operations. We had no foreign exchange forward contracts outstanding as of September 30, 2016. Certain of our investment in private companies contain embedded derivatives, which do not require bifurcation as we have elected to measure these investments at fair value.

Note 3. Balance Sheet Components

Inventories

Inventories consist of the following (in thousands):

| | September 30, 2016 | December 31, 2015 |
|---|---|---|
| Raw materials | $ 12,018 | $ 9,950 |
| Work in process | 1,488 | 7,067 |
| Finished goods | 12,835 | 2,448 |
| Total Inventories | $ 26,341 | $ 19,465 |

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

Accrued liabilities

Accrued liabilities consist of the following (in thousands):

| | September 30, 2016 | December 31, 2015 |
|---|---|---|
| Accrued payroll and benefits | $ 65,848 | $ 55,430 |
| Accrued sales and marketing expenses | 14,303 | 7,071 |
| Accrued sales rebates | 9,258 | 8,486 |
| Accrued sales tax and value added tax | 6,087 | 4,801 |
| Accrued income taxes | 5,043 | 2,646 |
| Accrued professional fees | 4,947 | 2,775 |
| Accrued warranty | 3,397 | 2,638 |
| Other accrued liabilities | 23,655 | 23,918 |
| Total Accrued Liabilities | $ 132,538 | $ 107,765 |

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 and 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.

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Warranty accrual as of September 30, 2016 and 2015 consists of the following activity (in thousands):

| | Nine Months Ended September 30, | |
|---|---|---|
| | 2016 | 2015 |
| Balance at beginning of period | $ 2,638 | $ 3,148 |
| Charged to cost of net revenues | 3,440 | 1,308 |
| Actual warranty expenditures | (2,681 ) | (1,745 ) |
| Balance at end of period | $ 3,397 | $ 2,711 |

Note 4. Equity Method Investments

On July 25, 2016, we acquired a 17% equity interest, on a fully diluted basis, in SmileDirectClub, LLC (“SDC”) for $46.7 million, and account for this as an equity method investment. Thus, we include our proportional share of SDC's earnings or losses in our consolidated statement of operations. The investment is reported on our consolidated balance sheet as a single amount under Equity Method Investments, and we record our share of their operating results within Equity in losses of investee in our consolidated statement of operations. As of September 30, 2016, the balance of our equity method investments was $46.3 million.

Concurrently with the investment, on July 25, 2016, we also entered into a supply agreement with SDC to manufacture clear aligners for SDC's doctor-led, at-home program for simple teeth straightening. The term of the supply agreement expires on December 31, 2019. We commenced supplying aligners to SDC in October 2016. The sale of aligners to SDC and the income from under the supply agreement will be reported in our Clear Aligner business segment after eliminating outstanding intercompany transactions.

Note 5. Goodwill and Intangible Long-lived Assets

Goodwill

The change in the carrying value of goodwill for the nine months ended September 30, 2016, all attributable to our Clear Aligner reporting unit, is as follows (in thousands):

| | Clear Aligner |
|---|---|
| Balance as of December 31, 2015 | $61,074 |
| Adjustments [1] | 121 |
| Balance as of September 30, 2016 | $61,195 |

[1] The adjustments to goodwill during the nine months ended September 30, 2016 were due to foreign currency translation.

During the fourth quarter of fiscal 2015, 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.

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Intangible Long-Lived Assets

Acquired intangible assets are being amortized as follows (in thousands):

| | Weighted Average Amortization Period (in years) | Gross Carrying Amount as of September 30, 2016 | Accumulated Amortization | Accumulated Impairment Loss | Net Carrying Value as of September 30, 2016 |
|---|---|---|---|---|---|
| Trademarks | 14 | $ 7,100 | $ (1,597 ) | $ (4,179 ) | $ 1,324 |
| Existing technology | 13 | 12,600 | (4,000 ) | (4,328 ) | 4,272 |
| Customer relationships | 11 | 33,500 | (12,353 ) | (10,751 ) | 10,396 |
| Patents | 8 | 6,316 | (516 ) | — | 5,800 |
| Total Intangible Assets | | $ 59,516 | $ (18,466 ) | $ (19,258 ) | $ 21,792 |

| | Weighted Average Amortization Period (in years) | Gross Carrying Amount as of December 31, 2015 | Accumulated Amortization | Accumulated Impairment Loss | Net Carrying Value as of December 31, 2015 |
|---|---|---|---|---|---|
| Trademarks | 15 | $ 7,100 | $ (1,492 ) | $ (4,179 ) | $ 1,429 |
| Existing technology | 13 | 12,600 | (3,577 ) | (4,328 ) | 4,695 |
| Customer relationships | 11 | 33,500 | (10,957 ) | (10,751 ) | 11,792 |
| Patents | 8 | 285 | (113 ) | — | 172 |
| Total Intangible Assets | | $ 53,485 | $ (16,139 ) | $ (19,258 ) | $ 18,088 |

During the second quarter of 2016, we acquired a patent for $6.0 million, which will be amortized over its remaining useful life of approximately eight years.

The total estimated annual future amortization expense for these acquired intangible assets as of September 30, 2016 is as follows (in thousands):

| | |
|---|---|
| Remainder of 2016 | $840 |
| 2017 | 3,353 |
| 2018 | 3,353 |
| 2019 | 3,346 |
| 2020 | 3,336 |
| Thereafter | 7,564 |
| Total | $21,792 |

Amortization for the nine months ended September 30, 2016 was $2.2 million.

Note 6. Credit Facilities

On March 17, 2016, we amended the credit facility and extended the maturity date to March 22, 2017. The credit facility provides for a $50.0 million revolving line of credit, with a $10.0 million letter of credit sublimit. 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, 2016, we had no outstanding borrowings under this credit facility and were in compliance with the conditions and performance requirements.

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Note 7. Legal Proceedings

Securities Class Action Lawsuit

On November 28, 2012, plaintiff City of Dearborn Heights Act 345 Police & Fire Retirement System filed a lawsuit against Align, Thomas M. Prescott (“Mr. Prescott”), Align’s 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. Briefing for the appeal was completed in May 2015 and the Ninth Circuit held oral arguments in October 2016. 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, if any.

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

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Note 8. Commitments and Contingencies

Operating Leases

As of September 30, 2016, minimum future lease payments for non-cancelable operating leases are as follows (in thousands):

| Fiscal Year Ending December 31, | Operating leases |
|---|---|
| Remainder of 2016 | $ 3,354 |
| 2017 | 10,258 |
| 2018 | 6,441 |
| 2019 | 4,161 |
| 2020 | 3,671 |
| Thereafter | 4,732 |
| Total minimum future lease payments | $ 32,617 |

Other Commitments

On July 25, 2016, we entered into a Loan and Security Agreement (the "Loan Agreement") with SDC where we agreed to provide a loan of up to $15.0 million in one or more advances to SDC (the "Loan Facility"). Available advances under the Loan Facility are subject to a borrowing base of 80% of SDC's eligible accounts receivable, determined in accordance with the terms of the Loan Agreement, and the satisfaction of other customary conditions. The advances bear interest, paid quarterly, at the rate of 7% per annum. Advances that are repaid or prepaid may be reborrowed. All outstanding principal and accrued and unpaid interest on the advances are due and payable on July 25, 2021. SDC's obligations in respect of the Loan Agreement are secured by a security interest in substantially all of SDC's assets. As of September 30, 2016, no advances on the Loan Facility were issued or outstanding. (Refer to Note 4 "Equity Method Investments" of the Notes of these Condensed Consolidated Financial Statements for more information on our investments in SDC.)

We have entered into certain investments with a privately held company where we have committed to purchase up to $5.0 million in convertible promissory notes. The first convertible promissory note for $2.0 million was issued in July 2016 and is outstanding as of September 30, 2016. The remaining $3.0 million is conditioned upon achievement of various business milestones. The notes all mature on December 30, 2018 and accrue interest annually at 2.5%.

Off-balance Sheet Arrangements

As of September 30, 2016, 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, 2016, we did not have any material indemnification claims that were probable or reasonably possible.

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Note 9. Stock-based Compensation

Summary of stock-based compensation expense

As of September 30, 2016, the 2005 Incentive Plan (as amended) has a total reserve of 30,169,000 shares of which 8,036,000 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, 2016 and 2015 is as follows (in thousands):

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2016 | 2015 | 2016 | 2015 |
| Cost of net revenues | $ 995 | $ 984 | $ 2,888 | $ 2,929 |
| Selling, general and administrative | 10,797 | 11,564 | 31,474 | 30,106 |
| Research and development | 1,919 | 2,113 | 5,572 | 6,100 |
| Total stock-based compensation | $ 13,711 | $ 14,661 | $ 39,934 | $ 39,135 |

Options

Activity for the nine months ended September 30, 2016 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, 2015 | 496 | $ 15.14 | | |
| Granted | — | — | | |
| Exercised | (224) | 14.69 | | |
| Cancelled or expired | — | — | | |
| Outstanding as of September 30, 2016 | 272 | $ 15.52 | 1.25 | $ 21,248 |
| Vested and expected to vest at September 30, 2016 | 272 | $ 15.52 | 1.25 | $ 21,248 |
| Exercisable at September 30, 2016 | 272 | $ 15.52 | 1.25 | $ 21,248 |

There were no stock options granted during the nine months ended September 30, 2016 and 2015. All compensation costs relating to stock options have been recognized as of September 30, 2016.

Restricted Stock Units (“RSU”)

A summary of the RSU activity for the nine months ended September 30, 2016 is as follows (in thousands, except years):

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

| | | | Grant Date Fair Value | Contractual Period | Value |
|---|---|---|---|---|---|
| | | | | (in years) | |
| Nonvested as of December 31, 2015 | 2,079 | | $ 49.45 | | |
| Granted | 683 | | 66.64 | | |
| Vested and released | (774 | ) | 44.89 | | |
| Forfeited | (120 | ) | 52.86 | | |
| Nonvested as of September 30, 2016 | 1,868 | | $ 57.42 | 1.29 | $ 175,091 |

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As of September 30, 2016, the total unamortized compensation cost related to RSU, net of estimated forfeitures, was $71.2 million, which we expect to recognize over a weighted average period of 2.2 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, 2016 (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, 2015 | 611 | $ 51.41 | | |
| Granted | 219 | 55.77 | | |
| Vested and released | (271) | 36.73 | | |
| Forfeited | (39) | 56.41 | | |
| Nonvested as of September 30, 2016 | 520 | $ 60.49 | 1.35 | $ 48,783 |

As of September 30, 2016, the total unamortized compensation costs related to the MSU, net of estimated forfeitures, was $13.4 million, which we expect to recognize over a weighted average period of 1.4 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, 2016, 937,000 shares remain 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, | |
|---|---|---|---|---|
| | 2016 | 2015 | 2016 | 2015 |
| Expected term (in years) | 1.2 | 1.2 | 1.2 | 1.2 |
| Expected volatility | 27.4 % | 27.9 % | 30.5 % | 31.1 % |
| Risk-free interest rate | 0.53 % | 0.41 % | 0.65 % | 0.29 % |
| Expected dividends | — | — | — | — |
| Weighted average fair value at grant date | $24.44 | $17.10 | $22.23 | $16.19 |

As of September 30, 2016, the total unamortized compensation cost related to employee purchases was $1.2 million, which we expect to recognize over a weighted average period of 0.5 year.

Note 10. Common Stock Repurchase

April 2014 Repurchase Program

In April 2014, we announced that our Board of Directors had authorized a stock repurchase program ("April 2014 Repurchase Program") pursuant to which we may purchase up to $300.0 million of our common stock over the next three years.

On May 3, 2016, as part of our $300.0 million April 2014 Repurchase Program, we entered into an accelerated share repurchase agreement ("ASR") to repurchase $50.0 million of our common stock (the "2016 ASR".) Under the terms of the 2016 ASR, we paid $50.0 million and received an initial delivery of approximately 0.5 million shares. The 2016 ASR was completed on September 6, 2016 with a final delivery of approximately 0.1 million shares. We received a total of approximately 0.6 million shares under the 2016 ASR at a weighted average share price of $81.89. 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.

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During 2016, we have repurchased on the open market approximately 0.1 million shares of our common stock at a weighted average of $93.21 per share, including commissions, for an aggregate purchase price of approximately $8.2 million. All repurchased shares were retired. As of September 30, 2016, we have $41.8 million remaining under the April 2014 Repurchase Program.

April 2016 Repurchase Program

On April 28, 2016, we announced that our Board of Directors had authorized an additional plan to repurchase up to $300.0 million of the Company's stock ("the April 2016 Repurchase Plan"). 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, 2016, there have not been any repurchases under this plan.

Note 11. Accounting for Income Taxes

Our provision for income taxes was $11.7 million and $8.9 million for the three months ended September 30, 2016 and 2015, respectively, representing effective tax rates of 18.4% and 24.3%, respectively. Our effective tax rate differs from the statutory federal income tax rate of 35% due to certain foreign earnings, most significantly in Costa Rica and the Netherlands, which is subject to lower tax rates, and the impacts from our international corporate restructuring, explained below, partially offset by the tax impact of certain stock-based compensation charges, and unrecognized tax benefits. The decrease in the effective tax rate for the three months ended September 30, 2016 compared to the three months ended September 30, 2015 was primarily related to our international corporate restructuring described below.

Our provision for income taxes was $39.2 million and $31.3 million for the nine months ended September 30, 2016 and 2015, respectively, representing effective tax rates of 21.6% and 24.8%, respectively. Our effective tax rate differs from the statutory federal income tax rate of 35% due to certain foreign earnings, most significantly in Costa Rica and the Netherlands, which is subject to lower tax rates, and the impacts from our international corporate restructuring, explained below, partially offset by the tax impact of certain stock-based compensation charges, and unrecognized tax benefits. The decrease in the effective tax rate for the nine months ended September 30, 2016 compared to the nine months ended September 30, 2015 was primarily related to our international corporate restructuring described below.

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.

Our total gross unrecognized tax benefits, excluding interest and penalties was $43.9 million and $39.4 million as of September 30, 2016 and December 31, 2015, respectively, all of which would impact our effective tax rate if recognized. Our total interest and penalties accrued as of September 30, 2016 was $1.7 million. We have elected to recognize interest and penalties related to unrecognized tax benefits as a component of income taxes. 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. Our subsidiary in Israel is under audit by the local tax authorities for calendar years 2006 through 2013. The audit by the California Franchise Tax Board for fiscal years 2011, 2012 and 2013 was concluded without material adjustment during the quarter ended September 30, 2016.

On July 1, 2016, we implemented a new international corporate structure. This changes the structure of our international procurement and sales operations, as well as realigns the ownership and use of intellectual property among our wholly-owned subsidiaries. We continue to anticipate that an increasing percentage of our consolidated pre-tax income will be derived from, and reinvested in our foreign operations. We believe that income taxed in certain foreign jurisdictions at a lower rate relative to the U.S. federal statutory rate will have a beneficial impact on our worldwide effective tax rate over time. Although the license of intellectual property rights between consolidated entities did not result in any gain in the consolidated financial statements, the Company generated taxable gains in certain jurisdictions resulting in a tax expense in the quarter of $26.6 million. Additionally, as a result of the restructuring, we reassessed the need for a valuation allowance against our deferred tax assets considering all available evidence. Given the current earnings and anticipated future earnings of our subsidiary in Israel, we concluded that we have sufficient positive evidence to release the valuation allowance against our Israel operating loss carryforwards of $31.4 million, which resulted in an income tax benefit in this period of the same amount.

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As of September 30, 2016, we maintained a valuation allowance of $0.3 million against Australia capital loss carryforwards. These net capital loss carryforwards would result in the recording of an income tax benefit if we were to conclude it is more likely than not that the related deferred tax assets will be realized.

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. We intend to seek a renewal of these income tax incentives before they expire. Under these incentives, all of the income in Costa Rica during these twelve year incentive periods is subject to a reduced tax rate. 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 2016 and 2015. Income taxes were reduced by $0.3 million and $8.2 million for the three months ended September 30, 2016 and 2015, respectively, representing a minimal impact to diluted net income per share to the three months ended September 30, 2016 and a benefit to diluted net income per share of $0.10 in 2015. As a result of these incentives, our income taxes were reduced by $17.5 million and $24.6 million for the nine months ended September 30, 2016 and 2015, respectively, representing a benefit to diluted net income per share of $0.21 and $0.30 in 2016 and 2015, respectively.

We maintain sufficient cash reserves in the U.S. and do not intend to repatriate our foreign earnings. As a result, income taxes have not been provided on these foreign earnings.  If these earnings were distributed in the form of dividends or otherwise, or if the shares of the relevant foreign subsidiaries were sold or otherwise transferred, we would be subject to additional U.S. income taxes subject to an adjustment for foreign tax credits and foreign withholding taxes. We intend to use the undistributed earnings for local operating expansions and to meet local operating working capital needs. In addition, a significant amount of the cash earned by foreign subsidiaries is deployed to effect this international restructure.

Note 12. Net Income Per Share

Basic net income per share is computed using the weighted average number of shares of common stock outstanding during the period. Diluted net income per share is computed using the weighted average number of shares of common stock, adjusted for any dilutive effect of potential common stock. Potential common stock, computed using the treasury stock method, includes 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, | |
|---|---|---|---|---|
| | 2016 | 2015 | 2016 | 2015 |
| Numerator: | | | | |
| Net income | $51,367 | $27,616 | $142,061 | $95,143 |
| Denominator: | | | | |
| Weighted-average common shares outstanding, basic | 79,977 | 79,808 | 79,920 | 80,173 |
| Dilutive effect of potential common stock | 1,489 | 1,284 | 1,603 | 1,403 |
| Total shares, diluted | 81,466 | 81,092 | 81,523 | 81,576 |
| | | | | |
| Net income per share, basic | $0.64 | $0.35 | $1.78 | $1.19 |

| | | | | |
|---|---|---|---|---|
| Net income per share, diluted | $0.63 | $0.34 | $1.74 | $1.17 |

For the nine months ended September 30, 2016 and 2015, the anti-dilutive effect from RSU, MSU, stock options and ESPP was not material.

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Note 13. Segments and Geographical Information

Segment Information

Operating segments are defined as components of an enterprise for which separate financial information is available and 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 the CODM for decision making and performance assessment as the basis for determining our reportable segments. The performance measures of our reportable segments include net revenues and gross profit.

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

- Our Clear Aligner segment consists of our Invisalign system which includes Invisalign Full, Express/Lite, Teen, Assist, Vivera retainers, along with our training and ancillary products for treating malocclusion.
- Our Scanner segment consists of intra-oral scanning systems and additional services available with the intra-oral scanners that provide digital alternatives to the traditional cast models. This segment includes our iTero scanner and OrthoCAD services.

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, | |
|---|---|---|---|---|
| Net Revenues | 2016 | 2015 | 2016 | 2015 |
| Clear Aligner | $243,668 | $198,292 | $706,802 | $586,138 |
| Scanner | 34,921 | 9,344 | 79,869 | 29,072 |
| Total net revenues | $278,589 | $207,636 | $786,671 | $615,210 |
| | | | | |
| Gross profit | | | | |
| Clear Aligner | $189,270 | $156,205 | $552,663 | $461,502 |
| Scanner | 19,932 | 1,371 | 42,382 | 5,798 |
| Total gross profit | $209,202 | $157,576 | $595,045 | $467,300 |

Geographical Information

On July 1, 2016, we implemented a new international corporate structure. This changed the structure of our international procurement and sales operations.

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

| | For the Three Months Ended September 30, | | For the Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2016 | 2015 | 2016 | 2015 |
| Net revenues: [1] | | | | |
| U.S. | $168,501 | $143,933 | $516,924 | $429,005 |
| the Netherlands | 87,051 | 37,427 | 191,049 | 118,295 |
| Other international | 23,037 | 26,276 | 78,698 | 67,910 |
| Total net revenues | $278,589 | $207,636 | $786,671 | $615,210 |

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

As a result of the new international corporate structure changes approximately $92.0 million in long-lived assets were transfered into our Netherlands entity as of July 1, 2016. Tangible long-lived assets are presented below by geographic area (in thousands):

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| | September 30, 2016 | December 31, 2015 |
|---|---|---|
| Long-lived assets:[2] | | |
| United States | $ 43,652 | $ 112,632 |
| Netherlands | 109,156 | 486 |
| Mexico | 17,055 | 15,422 |
| Other International | 2,795 | 7,933 |
| Total long-lived assets | $ 172,658 | $ 136,473 |

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

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

In addition to historical information, this quarterly report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. These statements include, among other things, our expectations regarding the anticipated impact that our new products and product enhancements will have on doctor utilization and our market share, our expectation that the policy simplification “Additional Aligners at No Charge" will help increase Invisalign utilization and volume, 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, our expectations regarding our stock repurchase program, the level of our operating expenses and gross margins, that the SmileDirectClub transaction will be incremental to our revenue and earnings in 2017, 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 and with our audited consolidated financial statements included in our Annual Report on form 10-K for the year ended December 31, 2015, as filed with the Securities and Exchange Commission.

### Overview

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 2016 and beyond may be affected by a number of other factors including:

- Departure of our CFO and appointment of new CFO. On November 7, 2016, David L. White, our Chief Financial Officer ("CFO"), announced his retirement as our Chief Financial Officer effective November 10, 2016. Mr. White will remain employed in a non-executive role until March 1, 2017 in order to, among other things, oversee planning and ERP implementation projects and assist in the transition of his duties.  Also effective  November 10, 2016, John F. Morici joined us as our new CFO. While we expect to engage in an orderly transition with Mr. Morici as our new CFO, our ability to execute our business strategies and retain key personnel may be adversely affected by the uncertainty associated with this transition.

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Additional Aligners at No Charge. In July 2015, we launched a new product policy called "Additional Aligners at No Charge" which allows doctors to order additional aligners to address either mid-course corrections and case refinements at no charge, subject to certain requirements. While this policy change was largely immaterial to our cash flows, it does impact the timing at which we recognize revenue. 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. While this product policy change will impact the timing of our revenue recognition, we believe this policy change will result in a significant improvement in customer satisfaction and loyalty, and ultimately increase Invisalign utilization and volume over time.

- 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 our Invisalign "G-Series" of product innovations, including our most recent October 2016 release, Invisalign G7. Invisalign G7 delivers better upper lateral control, improved root control, and features to address prevention of posterior open bites. We also announced ClinCheck Pro 5.0, which has new features designed to deliver an improved and user friendly experience and increased control to Invisalign providers. Since the iTero Element began shipping in September 2015, the use of iTero scanners for Invisalign case submissions in place of Polyvinyl-siloxane ("PVS") impressions has gradually increased to a record 48.4% of cases from North America and 39.6% of cases from doctors worldwide. We believe that over the long-term, clinical solutions and treatment tools will increase adoption of Invisalign and increase sales of our Intra-oral scanners; however, it is difficult to predict the rate of adoption which may vary by region and channel.
- Invisalign Adoption. 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 2016 increased to 5.0 cases per doctor compared to 4.7 in the third quarter of 2015. Utilization among our North American orthodontist customers reached an all time high of 11.1 cases per doctor in the third quarter of 2016 compared to 9.9 in the third quarter of 2015. The increase in North America orthodontist

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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. North American GP doctor utilization in third quarter of 2016 was consistent when compared to the third quarter of 2015. International doctor utilization increased to 4.9 cases in the third quarter of 2016 from 4.6 in the third quarter of 2015. Increased International utilization reflects growth in both the Europe, Middle East and Africa ("EMEA") and Asia Pacific regions due to increasing adoption of the product and its ability to treat more complex cases, particularly in the Asia Pacific region. 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; 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.

- Number of new Invisalign doctors trained. We continue to expand our Invisalign customer base through the training of new doctors. During fiscal year 2015, Invisalign growth was driven primarily by increased utilization across all regions as well as by the continued expansion of our customer base as we trained a total of 9,795 new Invisalign doctors, of which 56% were trained internationally. During the third quarter of 2016, we trained 2,615 new Invisalign doctors, up from 2,260 trained in third quarter of 2015.

- International Clear Aligner Growth. 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 33.8 % driven primarily by strong performance in our Asia Pacific and in Europe regions. In 2016, 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 Clear Aligner 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. As our international Clear Aligner revenues have increased from $61.3 million in the third quarter of 2015 to $84.3 million in the third quarter of 2016, we are increasingly subject to fluctuations in foreign currency exchange rates relative to the U.S. dollar. Although we have historically accepted the exposure to exchange rate movements without using derivative financial instruments to manage risk, we have in the past and may in the future initiate 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 forward contracts was not material to our financial statements for the nine months ended September 30, 2016.

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.

- Establish Regional Order Acquisition and Treatment Planning facilities: We intend to establish additional Order Acquisition and Treatment Planning facilities closer to our International customers in order to improve our operational efficiency and provide doctors with a great experience to further improve their confidence in using Invisalign to treat more patients, more often. If demand for our product 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.

- Operating Expenses. We expect operating expenses to increase in 2016 due in part to:
  - investments in international expansion in new country markets such as India and Korea;
  - the increase in sales and customer support resources; and
  - product and technology innovation to address such things as treatment times, indications unique to teens, and predictability.

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

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• Stock Repurchases:

Stock Repurchase Authorization. On April 28, 2016, we announced that our Board of Directors had authorized a plan to repurchase up to $300.0 million of the Company's stock. 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.

Accelerated Stock Repurchase. On May 3, 2016, as part of our $300.0 million April 2014 stock repurchase program, we entered into an Accelerated Stock Repurchase agreement to repurchase $50.0 million of our common stock (the "2016 ASR"). Under the terms of the 2016 ASR, we paid $50.0 million on May 4, 2016 and received an initial delivery of approximately 0.5 million  shares based on current market prices. The 2016 ASR was completed on September 6, 2016 with a final delivery of approximately 0.1 million shares. All repurchased shares were retired. (Refer to Note 9 "Common Stock Repurchase", of the Notes to condensed consolidated financial statements for details on common stock repurchase).

10b5-1 Stock Repurchase Plan. On May 3, 2016, we also entered into a stock repurchase plan under which we will repurchase up to $50 million of our common stock. During 2016, we repurchased on the open market approximately 0.1 million shares of our common stock at an average of $93.21 per share, including commissions, for an aggregate purchase price of approximately $8.2 million. This stock repurchase plan will operate in accordance with guidelines specified under Rule 10b5-1 of the Securities Exchange Act of 1934. Accordingly, transactions, if any, will be carried out in accordance with the terms of the share repurchase plan, including specified price, volume, and timing conditions.

Remaining Available Repurchases. As of September 30, 2016, we have $41.8 million remaining under the April 2014 Repurchase Program and $300.0 million under the April 2016 Repurchase Plan. (Refer to Note 9 "Common Stock Repurchase", of the Notes to condensed consolidated financial statements for details on common stock repurchase).

• SmileDirectClub. On July 25, 2016, we entered into a supply agreement with SmileDirectClub, LLC to manufacture clear aligners for SmileDirectClub's doctor-led, at-home program for simple teeth straightening. SmileDirectClub aligners will use our single-layer EX30 material for cases without attachments or interproximal reduction and will be manufactured by Align according to SmileDirectClub's specifications for minor tooth movement. The Invisalign brand and system of clear aligners will continue to be available exclusively through Invisalign-trained orthodontists and general dentists for in-office treatment. In October 2016, we became SmileDirectClub's exclusive third-party supplier and commercial supplying aligners for its minor tooth movement aligner program. We also provided a revolving line of credit to SmileDirectClub of up to $15 million to fund their working capital and general corporate needs. As part of the transaction, we acquired a 17% equity interest in SmileDirectClub for $46.7 million. As a result of our equity holdings in SmileDirectClub, we are required to account for SmileDirectClub's operations in our financial statements based on the equity method of accounting. Our financial results, therefore will reflect two components as follows:

The investment is reported on our balance sheet as a single amount under Equity Method Investments and we record our share of their operating results after eliminating outstanding intercompany transactions within Equity in losses of investee in our consolidated statement of operation. As of September 30, 2016 the balance of our equity method investments was $46.3 million. Align is performing a fair value assessment in order to determine if we need to value components of the SDC agreements including any identifiable intangible assets. We expect to complete our valuation in the fourth quarter of 2016.

Commencing in October 2016, when we began supplying aligners, the sale of aligners to SDC and the income from under the supply agreement will be reported in our Clear Aligner business segment.

We expect the transaction to be incremental to both our revenue growth and earnings in 2017.

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Results of Operations

Net revenues by Reportable Segment

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

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

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

Net revenues for our Clear Aligner segment by region and our Scanner segment by region for the three and nine months ended September 30, 2016 and 2015 is as follows (in millions):

| Net Revenues | For the Three Months Ended, September 30, 2016 | 2015 | Net Change | % Change | For the Nine Months Ended, September 30, 2016 | 2015 | Net Change | % Change |
|---|---|---|---|---|---|---|---|---|
| Clear Aligner Revenues: | | | | | | | | |
| North America | $143.8 | $124.1 | $ 19.7 | 15.9 % | $423.4 | $369.1 | $54.3 | 14.7 % |
| International | 84.3 | 61.3 | 23.0 | 37.5 % | 237.9 | 179.1 | 58.8 | 32.8 % |
| Invisalign non-case | 15.6 | 12.9 | 2.7 | 20.9 % | 45.5 | 38.0 | 7.5 | 19.7 % |
| Total Clear Aligner net revenues | $243.7 | $198.3 | $ 45.4 | 22.9 % | $706.8 | $586.1 | $120.7 | 20.6 % |
| Scanner net revenues | 34.9 | 9.3 | 25.6 | 273.7% | 79.9 | 29.1 | 50.8 | 174.6% |
| Total net revenues | $278.6 | $207.6 | $ 71.0 | 34.2 % | $786.7 | $615.2 | $171.5 | 27.9 % |

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, 2016 and 2015 is as follows (in thousands):

| Region | For the Three Months Ended, September 30, 2016 | 2015 | Net Change | % Change | For the Nine Months Ended, September 30, 2016 | 2015 | Net Change | % Change |
|---|---|---|---|---|---|---|---|---|
| North America Invisalign | 115.9 | 101.3 | 14.6 | 14.4 % | 341.3 | 292.0 | 49.3 | 16.9 % |
| International Invisalign | 61.9 | 46.2 | 15.7 | 34.0 % | 177.2 | 130.8 | 46.4 | 35.5 % |
| Total Invisalign case volume | 177.8 | 147.5 | 30.3 | 20.5 % | 518.5 | 422.8 | 95.7 | 22.6 % |

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

Total net revenues increased by $71.0 million and $171.5 million for the three and nine months ended September 30, 2016, respectively, as compared to the same period in 2015, primarily as a result of Invisalign case volume growth across all regions and products.

Clear Aligner - North America

In the three months ended September 30, 2016, Clear Aligner North America net revenues increased by $19.7 million compared to the same period in 2015 primarily due to Invisalign case volume growth of approximately $18.0 million across all channels and products, and, to a lesser extent, due to higher average selling prices (“ASP”) which increased net revenues by $1.7 million. ASP increased in the current period compared to the same period in the prior year as a result of the price increase on our Full products effective April 1, 2016 which contributed approximately $5.6 million to net revenues, offset in part by higher promotional discounts of approximately $4.0 million.

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In the nine months ended September 30, 2016, Clear Aligner North America net revenues increased by $54.3 million compared to the same period in 2015 primarily due to Invisalign case volume growth of approximately $62.3 million across all channels and products. This increase was offset in part by lower ASP which decreased net revenues by $8.0 million. ASP declined in the current period compared to the same period in the prior year as a result of higher promotional discounts of $11.5 million as well as an increase in net deferrals of $7.9 million primarily related to our additional aligners product policy change in July 2015. These declines were partially offset by the price increases on our Full products effective April 1, 2015 and April 1, 2016 which contributed $11.6 million to net revenues.

Clear Aligner - International

In the three months ended September 30, 2016, Clear Aligner international net revenues increased by $23.0 million compared to the same period in 2015 primarily driven by Invisalign case volume growth of $21.2 million across all geographies and products, and, to a lesser extent, due to higher ASP which increased net revenues by $1.8 million. ASP increased in the current period compared to the same period in the prior year as a result of increased additional aligner revenue which contributed $2.6 million to net revenues, as well as the price increase on our Full products effective July 1, 2016 which contributed $0.8 million to net revenues. These increases in ASP were offset in part by unfavorable impact of foreign exchange rates as well as higher promotional discounts of $1.6 million.

In the nine months ended September 30, 2016, Clear Aligner international net revenues increased by $58.8 million compared to the same period in 2015 primarily driven by Invisalign case volume growth of $64.5 million across all products. This was offset in part by lower ASP which decreased net revenues by approximately $5.7 million. ASP declined in the current period compared to the same period in the prior year primarily a result of a region and product mix shift towards lower priced Invisalign products of $4.2 million, higher promotional discounts of $2.5 million, and higher net deferrals of $1.8 million primarily related to additional aligners as a result of our product policy change in July 2015, and the unfavorable impact of foreign exchange rates of $1.5 million. These decreases were partially offset by the price increase on our Full products effective July 1, 2015 and July 1, 2016 which contributed $4.6 million to net revenues in the current period compared to the same period in the prior year.

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 $2.7 million and $7.5 million, respectively for the three and nine months ended September 30, 2016, respectively compared to the same periods in 2015 primarily due to increased Vivera volume both in North America and International.

Scanner

Scanner net revenues increased $25.6 million and $50.8 million for the three and nine months ended September 30, 2016, respectively, compared to the same periods in 2015 primarily as a result of an increase in the number of scanners recognized as we began shipping our next generation iTero Element scanner in September 2015, and, to a lesser extent, due to an increase in ASP.

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

| | Three Months Ended September 30, | | | Nine Months Ended September 30, | | |
|---|---|---|---|---|---|---|
| | 2016 | 2015 | Change | 2016 | 2015 | Change |
| Clear Aligner | | | | | | |
| Cost of net revenues | $54.4 | $42.1 | $ 12.3 | $154.1 | $124.6 | $29.5 |
| % of net segment revenues | 22.3 % | 21.2 % | | 21.8 % | 21.3 % | |
| Gross profit | $189.3 | $156.2 | $ 33.1 | $552.6 | $461.5 | $91.1 |
| Gross margin % | 77.7 % | 78.8 % | | 78.2 % | 78.7 % | |
| Scanner and Services | | | | | | |
| Cost of net revenues | $15.0 | $8.0 | $ 7.0 | $37.5 | $23.3 | $14.2 |
| % of net segment revenues | 42.9 % | 85.3 % | | 46.9 % | 80.1 % | |
| Gross profit | $20.0 | $1.4 | $ 18.6 | $42.4 | $5.8 | $36.6 |
| Gross margin % | 57.1 % | 14.7 % | | 53.1 % | 19.9 % | |
| Total cost of net revenues | $69.4 | $50.1 | $ 19.3 | $191.6 | $147.9 | $43.7 |
| % of net revenues | 24.9 % | 24.1 % | | 24.4 % | 24.0 % | |
| Gross profit | $209.2 | $157.6 | $ 51.6 | $595.0 | $467.3 | $127.7 |
| Gross margin % | 75.1 % | 75.9 % | | 75.6 % | 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 decreased for the three months ended September 30, 2016 compared to the same period in 2015 primarily driven by a higher number of aligners per case, partially offset by a higher worldwide ASP.

Gross margin declined for the nine months ended September 30, 2016 compared to the same period in 2015 from lower worldwide ASP and higher number of aligners per case.

Scanner

Gross margin increased for the three and nine months ended September 30, 2016 compared to the same period in 2015 due to a product mix shift to our iTero Element scanner resulting in a higher ASP and lower costs per unit.

Selling, General and administrative (in millions):

| | Three Months Ended September 30, | | | Nine Months Ended September 30, | | |
|---|---|---|---|---|---|---|
| | 2016 | 2015 | Change | 2016 | 2015 | Change |
| Selling, general and administrative | $ 126.7 | $ 101.8 | $ 24.9 | $360.4 | $290.7 | $ 69.7 |
| % of net revenues | 45.5 % | 49.0 % | | 45.8 % | 47.2 % | |

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, 2016 increased compared to the same period in 2015 primarily due to higher compensation related costs of $9.7 million primarily due to increased headcount in sales and customer support, which includes higher salaries expense, incentive bonuses and fringe benefits. In addition, we also incurred

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higher expenses from advertising and marketing of $5.1 million, equipment and material costs of $3.5 million, and outside services costs of $6.1 million.

Selling, general and administrative expense for the nine months ended September 30, 2016 increased compared to the same period in 2015 primarily due to higher compensation related costs of $33.3 million primarily due to increased headcount in sales and customer support, which includes higher salaries expense, incentive bonuses and fringe benefits. We also incurred higher expenses from advertising and marketing of $12.1 million, equipment and material costs of $6.6 million, and outside services costs of $5.7 million; additionally, during the first quarter of 2015 there was a refund of MDET taxes paid in 2014 of $6.8 million as our aligners are now no longer subject to the excise tax.

Research and development (in millions):

| | Three Months Ended September 30, | | | Nine Months Ended September 30, | | |
|---|---|---|---|---|---|---|
| | 2016 | 2015 | Change | 2016 | 2015 | Change |
| Research and development | $ 20.4 | $ 17.8 | $ 2.6 | $ 54.1 | $ 47.3 | $ 6.8 |
| % of net revenues | 7.3 % | 8.6 % | | 6.9 % | 7.7 % | |

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, 2016 increased compared to the same period in 2015 due to higher compensation costs from additional headcount and salary increases, offset by lower outside services.

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

| | Three Months Ended September 30, | | | Nine Months Ended September 30, | | |
|---|---|---|---|---|---|---|
| | 2016 | 2015 | Change | 2016 | 2015 | Change |
| Interest and other income (expenses), net | $ 1.5 | $ (1.6 ) | $ 3.1 | $ 1.2 | $ (2.8 ) | $ 4.0 |

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

Interest and other income (expenses), 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 (expenses), net increased for the three and nine months ended September 30, 2016 compared to the same period in 2015 due to foreign currency fluctuations against the U.S. dollar, and increased interest income on higher average balances of marketable securities.

Equity in losses of investee, net of tax:

We invested $46.7 million in SDC on July 25, 2016 and we account for this investment based on the equity method of accounting. For both the three and nine months ended September 30, 2016, we recognized a $0.5 million charge representing our share of losses attributable to equity method investments. (Refer to Note 4 "Equity Method Investments", of the Notes to our condensed consolidated financial statements for details on equity method investments.)

Income tax (in millions):

Three Months Ended September 30,