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 (in years)	Value
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,					Nine Months Ended September 30,				
	2016		2015		Change	2016		2015		Change
Provision for income taxes	$ 11.7		$ 8.9		$ 2.8	$ 39.2		$ 31.3		$ 7.9
Effective tax rates	18.4	%	24.3	%		21.6	%	24.8	%	

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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.

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

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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.

Liquidity and Capital Resources

We fund our operations primarily from product sales and available cash and cash equivalents and marketable securities. As of September 30, 2016 and December 31, 2015, we had the following cash, cash equivalents, and short-term and long-term marketable securities (in thousands):

	September 30, 2016	December 31, 2015
Cash and cash equivalents	$419,948	$ 167,714
Short-term investments	193,018	359,581
Long-term investments	62,820	151,370
Total	$675,786	$ 678,665

Cash flows (in thousands):

	Nine Months Ended September 30, 2016	2015
Net cash flow provided by (used in):		
Operating activities	$166,674	$158,642
Investing activities	142,859	(92,625)
Financing activities	(57,619)	(88,955)
Effect of exchange rate changes on cash and cash equivalents	320	(2,893)
Net increase (decrease) in cash and cash equivalents	$252,234	$(25,831)

As of September 30, 2016, we had $675.8 million of cash, cash equivalents and short-term and long-term marketable securities. Cash equivalents and marketable securities are comprised primarily of money market funds and debt instruments which include corporate bonds, U.S. dollar denominated foreign corporate bonds, commercial paper, municipal securities, U.S. government agency bonds, U.S. government treasury bonds and asset-backed securities. We do not enter into investments for trading or speculative purposes.

As of September 30, 2016, approximately $387.5 million of cash, cash equivalents and short-term and long-term marketable securities was held by our foreign subsidiaries. Amounts held by foreign subsidiaries are generally subject to U.S. income taxation on repatriation to the U.S. The costs to repatriate our foreign earnings to the U.S. would likely be material; however, our intent is to permanently reinvest our earnings from foreign operations, and our current plans do not require us to repatriate them to fund our U.S. operations as we generate sufficient domestic operating cash flow and have access to external funding under our current revolving line of credit. Additionally, we implemented a new international corporate structure on July 1, 2016. This corporate structure may reduce our overall effective tax rate over time through changes in the structure of our international procurement and sales operations, as well as realignment of the ownership and use of intellectual property among our wholly-owned subsidiaries.

The structure includes legal entities located in jurisdictions with income tax rates lower than the U.S. federal statutory tax rate. Such intercompany arrangements would be designed to result in income earned by such entities in accordance with arm's-length principles and commensurate with functions performed, risks assumed and ownership of valuable corporate assets. 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 the medium to long term.

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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.

During 2016, we have repurchased on the open market 88,000 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. (Refer to Note 10 "Common Stock Repurchase", of the Notes to condensed consolidated financial statements for details of common stock repurchase).

We believe that our current cash and cash equivalents and marketable securities combined with our positive cash flows from operations will be sufficient to fund our operations and stock repurchases for at least the next 12 months. If we are unable to generate adequate operating cash flows, we may need to suspend our stock repurchase program or seek additional sources of capital through equity or debt financing, collaborative or other arrangements with other companies, bank financing and other sources in order to realize our objectives and to continue our operations. There can be no assurance that we will be able to obtain additional debt or equity financing on terms acceptable to us, or at all. If adequate funds are not available, we may need to make business decisions that could adversely affect our operating results such as modifications to our pricing policy, business structure or operations. Accordingly, the failure to obtain sufficient funds on acceptable terms when needed could have a material adverse effect on our business, results of operations and financial condition.

Operating Activities

For the nine months ended September 30, 2016, cash flows from operations of $166.7 million resulted primarily from our net income of approximately $142.1 million as well as the following:

Significant non-cash activities:

• a net change in deferred tax assets of $17.5 million,

- depreciation and amortization of $16.8 million related to our fixed assets and acquired intangible assets,
- stock-based compensation of $39.9 million related to equity incentive compensation awards granted to our employees,
- net tax benefits from stock based compensation of $13.1 million and
- excess tax benefits from our share-based payment arrangements of $13.9 million.

Significant changes in working capital:

- an increase of $93.1 million in accounts receivable which is a result of the increase in net revenues,
- an increase of $46.5 million in deferred revenues corresponding to the increases in case shipments, and
- an increase of $39.0 million in accrued and other long-term liabilities due to timing of payments and activities.

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Investing Activities

Net cash provided by investing activities was $142.9 million for the nine months ended September 30, 2016 primarily consisting of purchases of marketable securities of $283.8 million, and property, plant and equipment purchases of $56.4 million and $46.7 million related to our acquisition of 17% equity interest of SmileDirectClub, LLC ("SDC"). These outflows were partially offset by $537.8 million of maturities and sales of our marketable securities.

For the remainder of 2016, we expect to spend an additional $20 million to $25 million on capital expenditures for estimated total capital expenditures of $76 million to $81 million for 2016 primarily for additional manufacturing capacity, new facilities and a new enterprise resource planning system. Although we believe our current investment portfolio has little risk of impairment, we cannot predict future market conditions or market liquidity and can provide no assurance that our investment portfolio will remain unimpaired.

Financing Activities

Net cash used in financing activities was $57.6 million for the nine months ended September 30, 2016 primarily resulting from a common stock repurchase of $58.2 million and payroll taxes paid for vesting of restricted stock units through share withholdings of $26.3 million. These outflows were offset in part by $13.9 million from excess tax benefits from our share-based compensation arrangements and $12.9 million in proceeds from issuance of common stock.

Contractual Obligations

Our contractual obligations have not significantly changed since December 31, 2015 as disclosed in our Annual Report on Form 10-K. We believe that our current cash, cash equivalents and short-term marketable securities combined with our existing borrowing capacity will be sufficient to fund our operations for at least the next 12 months. If we are unable to generate adequate operating cash flows and need more funds beyond our available liquid investments and those available under our credit facility, we may need to suspend our stock repurchase program or seek additional sources of capital through equity or debt financing, collaborative or other arrangements with other companies, bank financing and other sources in order to realize our objectives and to continue our operations. There can be no assurance that we will be able to obtain additional debt or equity financing on terms acceptable to us, or at all. If adequate funds are not available, we may need to make business decisions that could adversely affect our operating results such as modifications to our pricing policy, business structure or operations. Accordingly, the failure to obtain sufficient funds on acceptable terms when needed could have a material adverse effect on our business, results of operations and financial condition. (Refer to Note 8 "Commitments and Contingencies", of the Notes to our condensed consolidated financial statements for details on our commitments and contingencies).

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 certain of our officers that will require us, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers.

Several of these agreements limit the time within which an indemnification claim can be made and the amount of the claim.
It is not possible to make a reasonable estimate of the maximum potential amount under these indemnification agreements due to the unique facts and circumstances involved in each particular agreement. Additionally, we have a limited history of prior indemnification claims and the payments we have made under such agreements have not had a material adverse effect on our results of operations, cash flows, or financial position. However, to the extent that valid indemnification claims arise in the future, future payments by us could be significant and could have a material adverse effect on our results of operations or cash flows in a particular period. As of September 30, 2016, we did not have any material indemnification claims that were probable or reasonably possible.

Critical Accounting Policies and Estimates

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Management's discussion and analysis of our financial condition and results of operations is based upon our Condensed Consolidated Financial Statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of condensed consolidated financial statements requires our management to make estimates and judgments that affect the reported amounts of assets and liabilities, net revenues and expenses and disclosures at the date of the financial statements. We evaluate our estimates on an on-going basis, including those related to revenue recognition, accounts receivable, intangible assets, legal contingencies, impairment of goodwill and income taxes. We use authoritative pronouncements, historical experience and other assumptions as the basis for making estimates. Actual results could differ from those estimates.

We believe the following critical accounting policies reflect our most significant estimates, judgments and assumptions used in the preparation of our consolidated financial statements. These critical accounting policies and related disclosures appear in our Annual Report on Form 10-K for the year ended December 31, 2015:

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

Recent Accounting Pronouncements

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

ITEM 3.QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

Interest Rate Risk

Changes in interest rates could impact our anticipated interest income on our cash equivalents and investments in marketable securities. Our cash equivalents and investments are fixed-rate short-term and long-term securities. Fixed-rate securities may have their fair market value adversely impacted due to a rise in interest rates, and, as a result, our future investment income may fall short of expectations due to changes in interest rates or we may suffer losses in principal if forced to sell securities which have declined in market value due to changes in interest rates. As of September 30, 2016, we had approximately $255.8 million invested in available-for-sale marketable securities. An immediate 10% change in interest rates would not have a material adverse impact on our future operating results and cash flows.

We do not enter into investments for trading or speculative purposes and have not used any derivative financial instruments to manage our interest rate risk exposure. We do not have interest bearing liabilities outstanding as of September 30, 2016, and, therefore, we were not subject to risks from immediate interest rate increases.

Currency Rate Risk

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

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 cash and certain trade and intercompany receivables and payables. These forward contracts are not designated as hedging instruments and do not subject us to material balance sheet risk due to fluctuations in foreign currency exchange rates. The gains and losses on these forward contracts are intended to offset the gains and losses in the underlying foreign currency denominated monetary assets and liabilities being economically hedged. These instruments are marked to market through earnings every period and generally are one month in original maturity. We do not enter into foreign currency forward contracts for trading or speculative purposes. As our international operations grow, we will continue to reassess our approach to managing the risks relating to fluctuations in currency rates. It is difficult to predict the impact hedging activities could have on our results of operations. As of September 30, 2016 we had no foreign currency forward contracts outstanding.

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

ITEM 4.CONTROLS AND PROCEDURES

Evaluation of disclosure controls and procedures.

Under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, we have evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of the end of the period covered by this Quarterly Report on Form 10-Q. Based upon that evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that our disclosure controls and procedures are effective as of September 30, 2016, to provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our Chief Executive Officer and our Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure, and that such information is recorded, processed, summarized and reported within the time periods specified in the SEC rules and forms.

Changes in internal control over financial reporting.

During the third quarter of 2016, we implemented the first phase of a multi- year, company-wide program to transform certain business processes or extend established processes including the transition to a new enterprise resource planning ("ERP") software system to perform various functions. The first phase included our North America and EMEA operations. In connection with this implementation, we have updated our internal controls over financial reporting, as necessary, to accommodate modifications to our business processes and accounting procedures. We do not believe that the ERP implementation will have an adverse effect on our internal control over financial reporting. Except as described above, there were no changes in our internal control over financial reporting that occurred during the third quarter of 2016 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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PART II—OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

Securities Class Action Lawsuit

On November 28, 2012, plaintiff City of Dearborn Heights Act 345 Police & Fire Retirement System filed a lawsuit against Align, Thomas M. Prescott ("Mr. Prescott"), Align's 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 appeals 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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ITEM 1A.RISK FACTORS

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

We expect that net revenues from the sale of the Invisalign System, primarily Invisalign Full and Invisalign Teen, will continue to account for the vast majority of our total net revenues for the foreseeable future. Continued and widespread market acceptance of Invisalign by orthodontists, GPs and consumers is critical to our future success. If orthodontists and GPs experience a reduction in consumer demand for orthodontic services, if consumers prove unwilling to adopt Invisalign as rapidly as we anticipate or in the volume that we anticipate, if orthodontists or GPs choose to use a competitive product rather than Invisalign or if the average selling price of our product declines, our operating results would be harmed.

Demand for our products may not increase as rapidly as we anticipate due to a variety of factors including a weakness in general economic conditions.

Consumer spending habits are affected by, among other things, prevailing economic conditions, levels of employment, salaries and wage rates, gas prices, consumer confidence and consumer perception of economic conditions. A general slowdown in the U.S. economy and certain international economies or an uncertain economic outlook would adversely affect consumer spending habits which may, among other things, result in a decrease in the number of overall orthodontic case starts, reduced patient traffic in dentists' offices, reduction in consumer spending on higher value procedures or a reduction in the demand for dental services generally, each of which would have a material adverse effect on our sales and operating results. Weakness in the global economy results in a challenging environment for selling dental technologies and dentists may postpone investments in capital equipment, such as intra-oral scanners. In addition, Invisalign treatment, which currently accounts for the vast majority of our net revenues, represents a significant change from traditional orthodontic treatment, and customers and consumers may be reluctant to accept it or may not find it preferable to traditional treatment. We have generally received positive feedback from orthodontists, GPs and consumers regarding Invisalign treatment as both an alternative to braces and as a clinical method for the treatment of malocclusion, but a number of dental professionals believe that the Invisalign treatment is appropriate for only a limited percentage of their patients. Increased market acceptance of all of our products will depend in part upon the recommendations of dental professionals, as well as other factors including effectiveness, safety, ease of use, reliability, aesthetics, and price compared to competing products.

The frequency of use of the Invisalign system by orthodontists or GPs may not increase at the rate that we anticipate or at all.

One of our key objectives is to continue to increase utilization, or the adoption and frequency of use, of the Invisalign System by new and existing customers. If utilization of the Invisalign System by our existing and newly trained orthodontists or GPs does not occur or does not occur as quickly as we anticipate, our operating results could be harmed.

We may experience declines in average selling prices of our products which may decrease our net revenues.

We provide volume based discount programs to our doctors. In addition, we sell a number of products at different list prices. If we introduce any price reductions or consumer rebate programs; if we expand our discount programs in the future or participation in these programs increases; if our product mix shifts to lower priced products or products that have a higher percentage of deferred revenue, our average selling prices would be adversely affected and our net revenues, gross profit, gross margin and net income may be reduced. In July 2015, we launched a new product policy called "Additional Aligners at No Charge" that addresses one of our customer's top complaints. With this product policy change, we no longer distinguish between mid-course correction and case refinements and allow doctors to order additional aligners to address either treatment need at no charge, subject to certain requirements. Based on this new product policy, beginning in the third quarter of 2015, we deferred more revenue as a result of providing free additional aligners for eligible treatments. Additionally, as we grandfathered over 1 million open cases, we will recognize lower revenues as additional aligners are shipped for at least the next two years until these cases complete.

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

Although the U.S. dollar is our reporting currency, a portion of our net revenues and net income are generated in foreign currencies. Net revenues and net income generated by subsidiaries operating outside of the U.S. are translated into U.S. dollars using exchange rates effective during the respective period and are affected by changes in exchange rates. As a result, negative movements in currency exchange rates against the U.S. dollar will adversely affect our net revenues and net income in our consolidated financial statements. The exchange rate between the U.S. dollar and foreign currencies has fluctuated substantially

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in recent years and may continue to fluctuate substantially in the future. We have in the past and may in the future enter into currency hedging transactions in an effort to cover some of our exposure to foreign currency exchange fluctuations. These transactions may not operate to fully or effectively hedge our exposure to currency fluctuations, and, under certain circumstances, these transactions could have an adverse effect on our financial condition.

As we continue to grow, we are subject to growth related risks, including risks related to excess or constrained capacity at our existing facilities.

We are subject to growth related risks, including excess or constrained capacity and pressure on our internal systems and personnel. In order to manage current operations and future growth effectively, we will need to continue to implement and improve our operational, financial and management information systems and to hire, train, motivate, manage and retain employees. We may be unable to manage such growth effectively. Any such failure could have a material adverse impact on our business, operations and prospects. 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. Our ability to plan, construct and equip additional manufacturing facilities is subject to significant risk and uncertainty, including risks inherent in the establishment of a new manufacturing facility, such as hiring and retaining employees and delays and cost overruns as a result of a number of factors, any of which may be out of our control. If the transition into this additional facility is significantly delayed or demand for our product exceeds our current expectations, we may not be able to fulfill orders timely, which may negatively impact our financial results and overall business. In addition, because we cannot immediately adapt our production capacity and related cost structures to changing market conditions, our manufacturing capacity may at times exceed or fall short of our production requirements. In addition, if product demand decreases or we fail to forecast demand accurately, we could be required to write off inventory or record excess capacity charges, which would lower our gross margin. Production of our intra oral scanners may also be limited by capacity constraints due to a variety of factors, including our dependency on third party vendors for key components in addition to limited production yields. Any or all of these problems could result in the loss of customers, provide an opportunity for competing products to gain market acceptance and otherwise harm our business and financial results.

If we fail to sustain or increase profitability or revenue growth in future periods, the market price for our common stock may decline.

If we are to sustain or increase profitability in future periods, we will need to continue to increase our net revenues, while controlling our expenses. Because our business is evolving, it is difficult to predict our future operating results or levels of growth, and we have in the past not been and may in the future not be able to sustain our historical growth rates. If we do not increase profitability or revenue growth or otherwise meet the expectations of securities analysts or investors, the market price of our common stock will likely decline.

Our financial results have fluctuated in the past and may fluctuate in the future which may cause volatility in our stock price.

Our operating results have fluctuated in the past and we expect our future quarterly and annual operating results to fluctuate as we focus on increasing doctor and consumer demand for our products. These fluctuations could cause our stock price to decline or significantly fluctuate. Some of the factors that could cause our operating results to fluctuate include:

- limited visibility into and difficulty predicting the level of activity in our customers' practices from quarter to quarter;
- weakness in consumer spending as a result of the slowdown in the U.S. economy and global economies;
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- changes in relationships with our distributors;
- changes in the timing of receipt of Invisalign case product orders during a given quarter which, given our cycle time and the delay between case receipts and case shipments, could have an impact on which quarter revenue can be recognized;
- fluctuations in currency exchange rates against the U.S. dollar;
- changes in product mix;
- our inability to scale production of our iTero Element scanner to meet customer demand;
- if participation in our customer rebate or discount programs increases our average selling price will be adversely affected;
- seasonal fluctuations in the number of doctors in their offices and their availability to take appointments;

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- success of or changes to our marketing programs from quarter to quarter;
- our reliance on our contract manufacturers for the production of sub-assemblies for our intra-oral scanners;
- timing of industry tradeshows;
- changes in the timing of when revenue is recognized, including as a result of the introduction of new products or promotions, modifications to our terms and conditions or as a result of changes to critical accounting estimates or new accounting pronouncements;
- changes to our effective tax rate;
- unanticipated delays in production caused by insufficient capacity or availability of raw materials;
- any disruptions in the manufacturing process, including unexpected turnover in the labor force or the introduction of new production processes, power outages or natural or other disasters beyond our control;
- the development and marketing of directly competitive products by existing and new competitors;
- disruptions to our business as a result our agreement to manufacture clear aligners for SmileDirectClub, including, market acceptance of the SmileDirectClub business model and product, possible adverse customer reaction, and negative publicity about us and our products,
- major changes in available technology or the preferences of customers may cause our current product offerings to become less competitive or obsolete;
- aggressive price competition from competitors;
- costs and expenditures in connection with litigation;
- the timing of new product introductions by us and our competitors, as well as customer order deferrals in anticipation of enhancements or new products;
- unanticipated delays in our receipt of patient records made through an intraoral scanner for any reason;
- disruptions to our business due to political, economic or other social instability, including the impact of an epidemic any of which results in changes in consumer spending habits, consumers unable or unwilling to visit the orthodontist or general practitioners office, as well as any impact on workforce absenteeism;
- inaccurate forecasting of net revenues, production and other operating costs,
- investments in research and development to develop new products and enhancements; and
- our ability to successfully hedge against a portion of our foreign currency-denominated assets and liabilities.

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

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

Our future success may depend on our ability to develop, manufacture, market, and obtain regulatory approval or clearance of new products. There can be no assurance that we will be able to successfully develop, sell and achieve market acceptance of these and other new products and applications and enhanced versions of our existing product or software. The extent of, and rate at which, market acceptance and penetration are achieved by future products is a function of many variables, which include, among other things, our ability to:

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- correctly identify customer needs and preferences and predict future needs and preferences;
- include functionality and features that address customer requirements;
- ensure compatibility of our computer operating systems and hardware configurations with those of our customers;
- allocate our research and development funding to products with higher growth prospects;
- anticipate and respond to our competitors' development of new products and technological innovations;
- differentiate our offerings from our competitors' offerings;
- innovate and develop new technologies and applications;
- the availability of third-party reimbursement of procedures using our products;
- obtain adequate intellectual property rights; and
- encourage customers to adopt new technologies.

If we fail to accurately predict customer needs and preferences or fail to produce viable technologies, we may invest heavily in research and development of products that do not lead to significant revenue. Even if we successfully innovate and develop new products and produce enhancements, we may incur substantial costs in doing so, and our profitability may suffer. In addition, even if our new products are successfully introduced, it is unlikely that they will rapidly gain market share and acceptance primarily due to the relatively long period of time it takes to successfully treat a patient with Invisalign. Since it takes approximately 12 to 24 months to treat a patient, our customers may be unwilling to rapidly adopt our new products until they successfully complete at least one case or until more historical clinical results are available.

Our ability to market and sell new products may also be subject to government regulation, including approval or clearance by the FDA, and foreign government agencies. Any failure in our ability to successfully develop and introduce or achieve market acceptance of our new products or enhanced versions of existing products could have a material adverse effect on our operating results and could cause our net revenues to decline.

A disruption in the operations of our primary freight carrier or higher shipping costs could cause a decline in our net revenues or a reduction in our earnings.

We are dependent on commercial freight carriers, primarily UPS, to deliver our products to our customers. If the operations of these carriers are disrupted for any reason, we may be unable to deliver our products to our customers on a timely basis. If we cannot deliver our products in an efficient and timely manner, our customers may reduce their orders from us and our net revenues and operating profits could materially decline. In a rising fuel cost environment, our freight costs will increase. If freight costs materially increase and we are unable to pass that increase along to our customers for any reason or otherwise offset such increases in our cost of net revenues, our gross margin and financial results could be adversely affected.

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

Our key production steps are performed in operations located outside of the U.S. At our facility in San Jose, Costa Rica, technicians use a sophisticated, internally developed computer-modeling program to prepare digital treatment plans, which are then transmitted electronically to Juarez, Mexico. These digital files form the basis of the ClinCheck treatment plan and are used to manufacture aligner molds. Our order acquisition, aligner fabrication and shipping operations are conducted in Juarez, Mexico. In addition to the research and development efforts conducted in our North America facilities, we also carry out research and development at locations in Moscow, Russia. In addition, our customer-care, accounts receivable, credit and collections and customer event registration organizations are located at our facility in San Jose, Costa Rica. We also have operations in Israel where the design and wand assembly and our intra-oral scanner are manufactured. Our reliance on international operations exposes us to risks and uncertainties that may affect our business or results of operation, including:

- difficulties in hiring and retaining employees generally, as well as difficulties in hiring and retaining employees with the necessary skills to perform the more technical aspects of our operations;
- difficulties in managing international operations, including any travel restrictions to or from our facilities located in Russia and Israel;

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- fluctuations in currency exchange rates;
- increased income taxes, and other restrictions and limitations, if we were to decide to repatriate any of our foreign cash balances back to the U.S.;
- import and export license requirements and restrictions;
- controlling production volume and quality of the manufacturing process;
- political, social and economic instability, including as a result of increased levels of violence in Juarez, Mexico or the Middle East. We cannot predict the effect on us of any future armed conflict, political instability or violence in these regions. In addition, some of our employees in Israel are obligated to perform annual reserve duty in the Israeli military and are subject to being called for additional active duty under emergency circumstances. We cannot predict the full impact of these conditions on us in the future, particularly if emergency circumstances or an escalation in the political situation occurs. If many of our employees are called for active duty, our operations in Israel and our business may not be able to function at full capacity;
- acts of terrorism and acts of war;
- general geopolitical instability and the responses to it, such as the possibility of additional sanctions against Russia which continue to bring uncertainty to this region;
- interruptions and limitations in telecommunication services;
- product or material transportation delays or disruption, including as a result of increased levels of violence, acts of terrorism, acts of war or health epidemics restricting travel to and from our international locations or as a result of natural disasters, such as earthquakes or volcanic eruptions;
- burdens of complying with a wide variety of local country and regional laws, including the risks associated with the Foreign Corrupt Practices Act and local anti-bribery compliance;
- trade restrictions and changes in tariffs; and
- potential adverse tax consequences.

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

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

We earn an increasingly larger portion of our total revenues from international sales generated through our foreign direct and indirect operations. Since our growth strategy depends in part on our ability to further penetrate markets outside the U.S. and increase the localization of our products and services, we expect to continue to increase our sales and presence outside the U.S., particularly in the high-growth markets. Our international operations are subject to risks that are customarily encountered in non-U.S. operations, including:

- local political and economic instability;

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

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

- fluctuations in currency exchange rates; and

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

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

If we are unable to accurately predict our volume growth, and fail to hire a sufficient number of technicians in advance of such demand, the delivery time of our products could be delayed which could adversely affect our results of operations.

Treatment planning is a key step leading to our manufacturing process which relies on sophisticated computer technology requiring new technicians to undergo a relatively long training process. Training production technicians takes approximately 90 to 120 days. As a result, if we are unable to accurately predict our volume growth, we may not have a sufficient number of trained technicians to deliver our products within the timeframe our customers expect. Such a delay could cause us to lose existing customers or fail to attract new customers. This could cause a decline in our net revenues and net income and could adversely affect our results of operations.

Our headquarters, digital dental modeling processes, and other manufacturing processes are principally located in regions that are subject to earthquakes and other natural disasters.

Our digital dental modeling is processed in our facility located in San Jose, Costa Rica. The operations team in Costa Rica creates ClinCheck treatment plans using sophisticated computer software. In addition, our customer facing operations are located in Costa Rica. Our aligner molds and finished aligners are fabricated in Juarez, Mexico. Both locations in Costa Rica and Mexico are in earthquake zones and may be subject to other natural disasters. If there is a major earthquake or any other natural disaster in a region where one of these facilities is located, our ability to create ClinCheck treatment plans, respond to customer inquiries or manufacture and ship our aligners could be compromised which could result in our customers experiencing a significant delay in receiving their completed aligners and a decrease in service levels for a period of time. In addition, our headquarters facility in California is located in the San Francisco Bay Area. An earthquake or other natural disaster in this region could result in a disruption in our operations. Any such business interruption could materially and adversely affect our business, financial condition and results of operations.

Our information technology systems are critical to our business. System integration and implementation issues and system security risks could disrupt our operations, which could have a material adverse impact on our business and operating results.

We rely on the efficient and uninterrupted operation of complex information technology systems. All information technology systems are vulnerable to damage or interruption from a variety of sources. As our business has grown in size and complexity, the growth has placed, and will continue to place, significant demands on our information technology systems. To effectively manage this growth, our information systems and applications require an ongoing commitment of significant resources to maintain, protect and enhance existing systems and develop new systems to keep pace with continuing changes in information processing technology, evolving industry and regulatory standards and changing customer preferences. We are in the process of implementing a multi-year, company-wide program to transform certain business processes or extend established processes, including the transition to a new enterprise resource planning ("ERP") software system to perform various functions. We implemented the first phase of our ERP on July 1, 2016, and while we believe we are past any potential significant business disruption, we are still monitoring and troubleshooting potential issues. The implementation of additional functionality in the ERP system entails certain risks, including difficulties with changes in business processes that could disrupt our operations, such as our ability to track orders and timely ship products, manage our supply chain and aggregate financial and operational data. Additionally, this implementation may not achieve the anticipated benefits and may divert management's attention from other operational activities, negatively affect employee morale, or have other unintended consequences. Additionally, if we are not able to accurately forecast expenses and capitalized costs related to the project, this may have an adverse impact on our financial condition and operating results.

If the information we rely upon to run our businesses were to be found to be inaccurate or unreliable, if we fail to properly maintain our information systems and data integrity, or if we fail to develop new capabilities to meet our business needs in a timely manner, we could have operational disruptions, have customer disputes, lose our ability to produce timely and accurate reports, have regulatory or other legal problems, have increases in operating and administrative expenses, lose existing customers, have difficulty in attracting new customers or in implementing our growth strategies, or suffer other adverse consequences. In addition, experienced computer programmers and hackers may be able to penetrate our network security and misappropriate our confidential information or that of third parties, create system disruptions or cause shutdowns. Furthermore, sophisticated hardware and operating system software and applications that we either internally develop or procure from third parties which we depend upon may contain defects in design and manufacture, including “bugs” and other problems that can unexpectedly interfere with the operation of the system. The costs to eliminate or alleviate security problems, viruses and bugs could be significant, and the efforts to address these problems could result in interruptions that may have a material adverse impact on our operations, net revenues and operating results.

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System upgrades and enhancements require significant expenditures and allocation of valuable employee resources. Delays in integration or disruptions to our business from implementation of these new or upgraded systems could have a material adverse impact on our financial condition and operating results.

Additionally, we continuously upgrade our customer facing software applications, specifically the ClinCheck and MyAligntech software. Software applications frequently contain errors or defects, especially when they are first introduced or when new versions are released. The discovery of a defect or error or the incompatibility with the computer operating system and hardware configurations of customers in a new upgraded version or the failure of our primary information systems may result in the following consequences, among others: loss of revenue or delay in market acceptance, damage to our reputation or increased service costs, any of which could have a material adverse effect on our business, financial condition or results of operations.

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

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

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

Currently, our products compete directly against products manufactured and distributed by various companies, both within and outside the U.S. Many of these manufacturers, including Danaher Corporation, 3M, and Dentsply Sirona Inc., have substantially greater financial resources and manufacturing and marketing experience than we do and may, in the future, attempt to develop an orthodontic system similar to ours or combine technologies that make our product economically unattractive. The expiration of certain key patents commencing in 2017 owned by us may result in additional competition. Existing competitors may begin offering products more similar to ours. We may face more intense competition if new entrants to the clear aligner market are significantly larger than we are with greater resources and the ability to leverage their existing channels in the dental market to compete directly with us. In addition, corresponding foreign patents will start to expire in 2018, which may lead to increased competition in some of the markets outside the U.S. Large consumer product companies may also enter the orthodontic supply market. Furthermore, we may face competition in the future from new companies that may introduce new technologies. We may be unable to compete with these competitors and one or more of these competitors may render our technology obsolete or economically unattractive. If we are unable to compete effectively with existing products or respond effectively to any products developed by new or existing competitors, our business could be harmed. Increased competition has resulted in the past and may in the future result in volume discounting and price reductions, reduced gross margins, reduced profitability and loss of market share, and reduce dental professionals' efforts and commitment to expand their use of our products, any of which could have a material adverse effect on our net revenues, volume growth, net income and stock price. We cannot assure you that we will be able to compete successfully against our current or future competitors or that competitive pressures will not have a material adverse effect on our business, results of operations and financial condition.

If the security of our customer and patient information is compromised, patient care could suffer, and we could be liable for related damages, and our reputation could be impaired.

We retain confidential customer and patient information in our processing centers. Therefore, it is critical that our facilities and infrastructure remain secure and that our facilities and infrastructure are perceived by the marketplace and our customers to be secure. Despite the implementation of security measures, our infrastructure may be vulnerable to physical break-ins, computer viruses, programming errors, attacks by third parties or similar disruptive problems. If we fail to meet our clients' expectations regarding the security of healthcare information, we could be liable for damages and our reputation could be impaired. In addition, patient care could suffer, and we could be liable if our systems fail to deliver correct information in a timely manner. Our insurance may not protect us from this risk.

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

Our success will depend in part on our ability to maintain existing intellectual property and to obtain and maintain further intellectual property protection for our products, both in the U.S. and in other countries. Our inability to do so could harm our competitive position. As of September 30, 2016, we had issued 417 U.S. patents, 331 foreign issued patents, and 374 pending global patent applications.

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

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

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

Pursuant to the Sarbanes-Oxley Act of 2002 and the rules and regulations promulgated by the SEC, we are required to furnish in our Form 10-K a report by our management regarding the effectiveness of our internal control over financial reporting. The report includes, among other things, an assessment of the effectiveness of our internal control over financial reporting as of the end of our fiscal year, including a statement as to whether or not our internal control over financial reporting is effective. This assessment must include disclosure of any material weaknesses in our internal control over financial reporting identified by management. While we believe our internal control over financial reporting is currently effective, the effectiveness of our internal controls in future periods is subject to the risk that our controls may become inadequate because of changes in conditions, and, as a result, the degree of compliance of our internal control over financial reporting with the existing policies or procedures may become ineffective. Establishing, testing and maintaining an effective system of internal control over financial reporting requires significant resources and time commitments on the part of our management and our finance staff, may require additional staffing and infrastructure investments, and would increase our costs of doing business. If we are unable to assert that our internal control over financial reporting is effective in any future period (or if our auditors are unable to express an opinion on the effectiveness of our internal controls or conclude that our internal controls are ineffective), we could lose investor confidence in the accuracy and completeness of our financial reports, which could have an adverse effect on our stock price.

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

We are highly dependent on the key employees in our clinical engineering, technology development, sales, training and marketing personnel and management teams. The loss of the services provided by those individuals may significantly delay or prevent the achievement of our product development and other business objectives and could harm our business. Our future success will also depend on our ability to identify, recruit, train and retain additional qualified personnel, including orthodontists. Few orthodontists are accustomed to working in a manufacturing environment since they are generally trained to work in private practices, universities and other research institutions. Thus, we may be unable to attract and retain personnel with the advanced

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qualifications necessary for the further development of our business. Furthermore, we may not be successful in retaining our key personnel or their services. If we are unable to attract and retain key personnel, our business could be materially harmed. In addition, David L. White, our CFO announced his retirement effective November 10, 2016. While we also announced the appointment of John F. Morici as CFO effective that same date and we expect to engage in an orderly transition, our ability to execute our business strategy and retain key personnel may be adversely affected by the uncertainty associated with this transaction.

If we infringe the patents or proprietary rights of other parties or are subject to a patent infringement claim, our ability to grow our business may be severely limited.

Extensive litigation over patents and other intellectual property rights is common in the medical device industry. We have been sued for infringement of third party's patents in the past and we may be the subject of patent or other litigation in the future. From time to time, we have received and may in the future receive letters from third parties drawing our attention to their patent rights. While we do not believe that we infringe upon any valid and enforceable rights that have been brought to our attention, there may be other more pertinent rights of which we are presently unaware. The defense and prosecution of intellectual property suits, interference proceedings and related legal and administrative proceedings could result in substantial expense to us and significant diversion of effort by our technical and management personnel. An adverse determination of any litigation or interference proceeding to which we may become a party could subject us to significant liabilities. An adverse determination of this nature could also put our patents at risk of being invalidated or interpreted narrowly or require us to seek licenses from third parties. Licenses may not be available on commercially reasonable terms or at all, in which event, our business would be materially adversely affected.

We maintain single supply relationships for certain of our key machines and materials technologies, and our business and operating results could be harmed if supply is restricted or ends or the price of raw materials used in our manufacturing process increases.

We are highly dependent on manufacturers of specialized scanning equipment, rapid prototyping machines, resin and other advanced materials, as well as the optics, electronic and other mechanical components of our intra-oral scanners. We maintain single supply relationships for many of these machines and materials technologies. In particular, our CT scanning and stereolithography equipment used in our aligner manufacturing and many of the critical components for the optics of our scanners are provided by single suppliers. We are also committed to purchasing the vast majority of our resin and polymer, the primary raw materials used in our manufacturing process for clear aligners, from a single source. If these or other suppliers encounter financial, operating or other difficulties or if our relationship with them changes, we might not be able to quickly establish or qualify replacement sources of supply and could face production interruptions, delays and inefficiencies. In addition, technology changes by our vendors could disrupt access to required manufacturing capacity or require expensive, time consuming development efforts to adapt and integrate new equipment or processes. Our growth may exceed the capacity of one or more of these manufacturers to produce the needed equipment and materials in sufficient quantities to support our growth. Conversely, in order to secure supplies for production of products, we sometimes enter into non-cancelable purchase commitments with vendors, which could impact our ability to adjust our inventory to reflect declining market demands. If demand for our products is less than we expect, we may experience additional excess and obsolete inventories and be forced to incur additional charges and our profitability may suffer. In the event of technology changes, delivery delays, or shortages of or increases in price for these items, our business and growth prospects may be harmed.

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

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

We primarily rely on our direct sales force to sell our products, and any failure to maintain our direct sales force could harm our business.

Our ability to sell our products and generate revenues primarily depends upon our direct sales force within our North American and international markets. We do not have any long-term employment contracts with the members of our direct sales force. The loss of the services provided by these key personnel may harm our business. If we are unable to retain our direct sales force

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personnel or replace them with individuals of equivalent technical expertise and qualifications, or if we are unable to successfully instill such technical expertise or if we fail to establish and maintain strong relationships with our customers within a relatively short period of time, our net revenues and our ability to maintain market share could be materially harmed. In addition, due to our large and fragmented customer base, we may not be able to provide all of our customers with product support immediately upon the launch of a new product. As a result, adoption of new products by our customers may be slower than anticipated and our ability to grow market share and increase our net revenues may be harmed.

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

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

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

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

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

- product design, development, manufacturing and testing;
- product labeling;
- product storage;
- pre-market clearance or approval;
- complaint handling and corrective actions;
- advertising and promotion; and
- product sales and distribution.

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

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

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If any of these events were to occur, they could harm our business. We must comply with facility registration and product listing requirements of the FDA and adhere to applicable Quality System regulations. The FDA enforces its Quality System regulations through periodic unannounced inspections. Our failure to take satisfactory corrective action in response to an adverse inspection or the failure to comply with applicable manufacturing regulations could result in enforcement action, and we may be required to find alternative manufacturers, which could be a long and costly process. Any FDA enforcement action could have a material adverse effect on us.

Before we can sell a new medical device in the U.S., or market a new use of or claim for an existing product we must obtain FDA clearance or approval, unless an exemption applies. Obtaining regulatory clearances or approvals can be a lengthy and time-consuming process. Even though the devices we market have obtained the necessary clearances from the FDA, we may be unable to maintain such clearances in the future. Furthermore, we may be unable to obtain the necessary clearances for new devices that we intend to market in the future. Our inability to maintain or obtain regulatory clearances or approvals could materially harm our business.

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

If compliance with healthcare regulations becomes costly and difficult for our customers or for us, we may not be able to grow our business.

Participants in the healthcare industry are subject to extensive and frequently changing regulations under numerous laws administered by governmental entities at the federal, state and local levels, some of which are, and others of which may be, applicable to our business. In response to perceived increases in health care costs in recent years, Congress passed health care reform legislation that President Obama signed into law in March 2010. This legislation contains many provisions designed to generate the revenues necessary to fund the coverage expansions. The most relevant of these provisions are those that impose fees or taxes on certain health-related industries, including medical device manufacturers.

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

Extensive and changing government regulation of the healthcare industry may be expensive to comply with and exposes us to the risk of substantial government penalties.

In addition to medical device laws and regulations, numerous state and federal healthcare-related laws regulate our business, covering areas such as:

- storage, transmission and disclosure of medical information and healthcare records;
- prohibitions against the offer, payment or receipt of remuneration to induce referrals to entities providing healthcare services or goods or to induce the order, purchase or recommendation of our products; and
- the marketing and advertising of our products.

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

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

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

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

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

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

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

- quarterly variations in our results of operations and liquidity;
- changes in recommendations by the investment community or in their estimates of our net revenues or operating results;
- speculation in the press or investment community concerning our business and results of operations;
- strategic actions by our competitors, such as product announcements or acquisitions;
- announcements of technological innovations or new products by us, our customers or competitors; and
- general economic market conditions.

In addition, the stock market in general, and the market for technology and medical device companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated to or disproportionate to the operating performance of those companies. These broad market and industry factors may seriously harm the market price of our common stock, regardless of our operating performance. Historically, class action litigation is often brought against an issuing company following periods of volatility in the market price of a company's securities.

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

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

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If our goodwill or long-lived assets become impaired, we may be required to record a significant charge to earnings.

Under Generally Accepted Accounting Principles in the United States ("U.S. GAAP"), we review our goodwill and long-lived asset group for impairment when events or changes in circumstances indicate the carrying value may not be recoverable. Additionally, goodwill is required to be tested for impairment at least annually. The qualitative and quantitative analysis used to test goodwill are dependent upon various assumptions and reflect management's best estimates. Changes in certain assumptions including revenue growth rates, discount rates, earnings multiples and future cash flows may cause a change in circumstances indicating that the carrying value of goodwill or the asset group may be impaired. We may be required to record a significant charge to earnings in the financial statements during the period in which any impairment of goodwill or asset group are determined.

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

We prepare our consolidated financial statements in conformity with U.S. GAAP. These principles are subject to interpretation by the SEC and various bodies formed to interpret and create appropriate accounting policies. A change in these policies can have a significant effect on our reported results and may even retroactively affect previously reported transactions. Our accounting policies that recently have been, or may be affected by changes in the accounting rules relate to revenue recognition and leases.

If we fail to manage our exposure to global financial and securities market risk successfully, our operating results and financial statements could be materially impacted.

The primary objective of our investment activities is to preserve principal. To achieve this objective, a majority of our marketable investments are investment grade, liquid, fixed-income securities and money market instruments denominated in U.S. dollars. If the carrying value of our investments exceeds the fair value, and the decline in fair value is deemed to be other-than-temporary, we will be required to write down the value of our investments, which could materially harm our results of operations and financial condition. Moreover, the performance of certain securities in our investment portfolio correlates with the credit condition of the U.S. financial sector. In a current unstable credit environment, we might incur significant realized, unrealized or impairment losses associated with these investments.

On July 1, 2016, we changed our corporate structure; however, if we are unable to maintain this structure or if it is challenged by U.S. or foreign tax authorities, we may be unable to realize tax savings which could materially and adversely affect our operating results.

We implemented a new international corporate structure on July 1, 2016. This corporate structure may reduce our overall effective tax rate over time through changes in the structure of our international procurement and sales operations, as well as realignment of the ownership and use of intellectual property among our wholly-owned subsidiaries.

The structure includes legal entities located in jurisdictions with income tax rates lower than the U.S. federal statutory tax rate. Such intercompany arrangements would be designed to result in income earned by such entities in accordance with arm's-length principles and commensurate with functions performed, risks assumed and ownership of valuable corporate assets. 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 the medium to long term.

If the structure is challenged by U.S. or foreign tax authorities, if changes in domestic and international tax laws negatively impact the structure, including proposed legislation to reform U.S. taxation of international business activities, or if we do not operate our business in a manner consistent with the structure and applicable regulatory provisions, we may fail to achieve the financial and operational efficiencies that we anticipate as a result of the structure, and our business, financial condition and operating results may be materially and adversely affected.

Our effective tax rate may vary significantly from period to period.

Various internal and external factors may have favorable or unfavorable effects on our future effective tax rate. These factors include, but are not limited to, changes in tax laws, regulations and/or rates, non-deductible goodwill impairments, changing interpretations of existing tax laws or regulations, changes in the relative proportions of revenues and income before taxes in the various jurisdictions in which we operate that have differing statutory tax rates, the future levels of tax benefits of stock option deductions relating to incentive stock options and employee stock purchase plans, settlement of income tax audits, and changes in overall levels of pretax earnings. For example, the FASB issued ASU No. 2016-19 “Improvements to Employee Share-Based Payment Accounting,” which will, among other things, change how we account for our tax shortfalls or benefits from stock based awards, and this guidance may have a favorable or unfavorable effect on our future effective tax rate. We are still evaluating the impact of this guidance on our consolidated financial statements.

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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.

Changes in tax laws or tax rulings could negatively impact our income tax provision and net income.

As a U.S. multinational corporation, we are subject to changing tax laws both within and outside of the U.S. Changes in tax laws or tax rulings, or changes in interpretations of existing tax laws, could affect our income tax provision and net income or require us to change the manner in which we operate our business. Many countries in Europe, as well as a number of other countries and organizations, have recently proposed or recommended changes to existing tax laws or have enacted new laws. For example, the Organization for Economic Cooperation and Development ("OECD") has been working on a "Base Erosion and Profit Shifting Project," which is focused on a number of issues, including the shifting of profits between affiliated entities in different tax jurisdictions. The OECD has issued in 2015, and is expected to continue to issue, guidelines and proposals that may change various aspects of the existing framework under which our tax obligations are determined in many of the countries in which we do business. In addition, the current U.S. administration and key members of Congress have made public statements indicating that tax reform is a priority. Certain changes to U.S. tax laws, including limitations on the ability to defer U.S. taxation on earnings outside of the United States until those earnings are repatriated to the United States, could affect the tax treatment of our foreign earnings.

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

Following is a summary of stock repurchases for the three months ended September 30, 2016:

Period	Total Number of Shares Repurchased	Average Price Paid per Share	Total Number of Shares Repurchased as Part of Publicly Announced Program	Approximate Dollar Value of Shares that May Yet Be Repurchased Under the Programs (1)
July 1, 2016 through July 31, 2016	—	$—	—	$364,978,175
August 1, 2016 through August 31, 2016	—	$—	—	$364,978,175
September 1, 2016 through September 30, 2016	231,009	$100.32	231,009	$341,803,668

(1)Stock repurchase Programs
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.

During 2016, we have repurchased on the open market 88,000 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. (Refer to Note 10 "Common Stock Repurchase", of the Notes to condensed consolidated financial statements for details of common stock repurchase).

We expect to finance future stock repurchases with current cash on hand.
ITEM 3.DEFAULTS UPON SENIOR SECURITIES

Not applicable.

ITEM 4.MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None

ITEM 6. EXHIBITS

(a) Exhibits:

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Exhibit Number	Description	Filing	Date	Exhibit Number	Filed here with
10.1	Class C Non-Incentive Unit Purchase Agreement, July 25, 2016	Form 8-K	07/28/16	10.1	
10.2	Employment Agreement between the Align Technology, Inc. and John Morici				*
31.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				*
31.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				*
32.1	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				*
101.INS	XBRL Instance Document				*
101.SCH	XBRL Taxonomy Extension Schema Document				*
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document				*
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document				*
101.LAB	XBRL Taxonomy Extension Label Linkbase Document				*
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document				*

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SIGNATURES

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

	ALIGN TECHNOLOGY, INC.
November 8, 2016	By: /S/ JOSEPH M. HOGAN Joseph M. Hogan President and Chief Executive Officer
	By: /S/ DAVID L. WHITE David L. White Chief Financial Officer

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