

ALIGN TECHNOLOGY INC

FORM 10-Q (Quarterly Report)

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2017

OR

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

For the transition period from _____ to _____

Commission file number: 0-32259

ALIGN TECHNOLOGY, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

94-3267295
(I.R.S. Employer
Identification Number)

2820 Orchard Parkway
San Jose, California 95134
(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 No

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

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

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 7(a)(2)(B) of the Securities Act.

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

The number of shares outstanding of the registrant's Common Stock, \$0.0001 par value, as of October 27, 2017 was 80,177,704.

ALIGN TECHNOLOGY, INC.

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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,	
	2017	2016	2017	2016
Net revenues	\$ 385,267	\$ 278,589	\$ 1,052,090	\$ 786,671
Cost of net revenues	92,779	69,387	253,060	191,626
Gross profit	292,488	209,202	799,030	595,045
Operating expenses:				
Selling, general and administrative	169,524	126,708	483,636	360,385
Research and development	24,201	20,415	71,389	54,111
Total operating expenses	193,725	147,123	555,025	414,496
Income from operations	98,763	62,079	244,005	180,549
Interest and other income (expense), net	3,750	1,463	8,607	1,161
Net income before provision for income taxes and equity in losses of investee	102,513	63,542	252,612	181,710
Provision for income taxes	18,344	11,698	26,508	39,172
Equity in losses of investee, net of tax	1,614	477	4,950	477
Net income	\$ 82,555	\$ 51,367	\$ 221,154	\$ 142,061
Net income per share:				
Basic	\$ 1.03	\$ 0.64	\$ 2.76	\$ 1.78
Diluted	\$ 1.01	\$ 0.63	\$ 2.71	\$ 1.74
Shares used in computing net income per share:				
Basic	80,163	79,977	80,086	79,920
Diluted	81,789	81,466	81,757	81,523

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Net income	\$ 82,555	\$ 51,367	\$ 221,154	\$ 142,061
Net change in foreign currency translation adjustment	884	(76)	1,624	(143)
Change in unrealized gains (losses) on investments, net of tax	60	(437)	102	1,038
Other comprehensive income (loss)	944	(513)	1,726	895
Comprehensive income	<u>\$ 83,499</u>	<u>\$ 50,854</u>	<u>\$ 222,880</u>	<u>\$ 142,956</u>

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

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

	September 30, 2017	December 31, 2016
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 362,613	\$ 389,275
Marketable securities, short-term	316,454	250,981
Accounts receivable, net of allowance for doubtful accounts and returns of \$5,843 and \$4,310, respectively	321,328	247,415
Inventories	36,941	27,131
Prepaid expenses and other current assets	63,667	38,176
Total current assets	1,101,003	952,978
Marketable securities, long-term	58,842	59,783
Property, plant and equipment, net	295,901	175,167
Equity method investments	52,875	45,061
Goodwill and intangible assets, net	90,070	81,998
Deferred tax assets	73,532	67,844
Other assets	25,400	13,320
Total assets	<u>\$ 1,697,623</u>	<u>\$ 1,396,151</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 45,942	\$ 28,596
Accrued liabilities	173,851	134,332
Deferred revenues	241,576	191,407
Total current liabilities	461,369	354,335
Income tax payable	45,375	45,133
Other long-term liabilities	8,921	1,294
Total liabilities	515,665	400,762
Commitments and contingencies (Note 8 and 9)		
Stockholders' equity:		
Preferred stock, \$0.0001 par value (5,000 shares authorized; none issued)	—	—
Common stock, \$0.0001 par value (200,000 shares authorized; 80,176 and 79,553 issued and outstanding, respectively)	8	8
Additional paid-in capital	880,045	864,871
Accumulated other comprehensive income (loss), net	788	(938)
Retained earnings	301,117	131,448
Total stockholders' equity	1,181,958	995,389
Total liabilities and stockholders' equity	<u>\$ 1,697,623</u>	<u>\$ 1,396,151</u>

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

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

	Nine Months Ended September 30,	
	2017	2016
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net income	\$ 221,154	\$ 142,061
Adjustments to reconcile net income to net cash provided by operating activities:		
Deferred taxes	(5,481)	(17,476)
Depreciation and amortization	26,715	16,786
Stock-based compensation	44,024	39,934
Net tax benefits from stock-based awards	—	13,057
Excess tax benefit from share-based payment arrangements	—	(13,943)
Equity in losses of investee	4,950	477
Other non-cash operating activities	9,432	9,525
Changes in assets and liabilities, net of effects of acquisitions:		
Accounts receivable	(84,437)	(93,122)
Inventories	(10,709)	(6,873)
Prepaid expenses and other assets	(5,848)	(5,069)
Accounts payable	4,220	(4,134)
Accrued and other long-term liabilities	18,995	38,969
Deferred revenues	53,198	46,482
Net cash provided by operating activities	<u>276,213</u>	<u>166,674</u>
CASH FLOWS FROM INVESTING ACTIVITIES:		
Acquisitions, net of cash acquired	(8,953)	—
Purchase of property, plant and equipment	(126,150)	(56,368)
Purchase of marketable securities	(356,928)	(283,797)
Proceeds from maturities of marketable securities	260,487	328,498
Purchase of equity method investments	(12,764)	(46,745)
Proceeds from sales of marketable securities	32,291	209,302
Loan advances to equity investee	(23,000)	—
Loan repayment from equity investee	6,000	—
Other investing activities	397	(8,031)
Net cash provided by (used in) investing activities	<u>(228,620)</u>	<u>142,859</u>
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock	13,850	12,877
Common stock repurchases	(53,793)	(58,174)
Excess tax benefit from share-based payment arrangements	—	13,943
Employees' taxes paid upon the vesting of restricted stock units	(39,093)	(26,265)
Net cash used in financing activities	<u>(79,036)</u>	<u>(57,619)</u>
Effect of foreign exchange rate changes on cash and cash equivalents	4,781	320
Net increase (decrease) in cash and cash equivalents	(26,662)	252,234
Cash and cash equivalents, beginning of the period	389,275	167,714
Cash and cash equivalents, end of the period	<u>\$ 362,613</u>	<u>\$ 419,948</u>
SUPPLEMENTAL CASH FLOW INFORMATION:		
Accounts payable or accrued liabilities related to property, plant and equipment	21,992	9,709

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

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, 2017 and 2016, our comprehensive income for the three and nine months ended September 30, 2017 and 2016, our financial position as of September 30, 2017 and our cash flows for the nine months ended September 30, 2017 and 2016. The Condensed Consolidated Balance Sheet as of December 31, 2016 was derived from the December 31, 2016 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, 2017 are not necessarily indicative of the results that may be expected for the year ending December 31, 2017 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, 2016.

Out of Period Adjustment

During the second quarter of 2017, we recorded an out of period adjustment of \$1.9 million that resulted in a decrease in interest and other income (expense), net and an increase in accrued liabilities. We do not believe the out of period adjustment is material to the Consolidated Financial Statements for the three and nine months ended September 30, 2017 or to prior period’s Consolidated Financial Statements.

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, equity method investments, useful lives of intangible assets and property and equipment, revenue recognition, stock-based compensation, equity losses of investee, income taxes and contingent liabilities, among others. We base our estimates on historical experience and on various other assumptions that are believed to be reasonable, the results of which form the basis for making judgments about the carrying values of assets and liabilities.

Recent Accounting Pronouncements

(i) New Accounting Updates Recently Adopted

In March 2016, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) 2016-09, “*Improvements to Employee Share-Based Payment Accounting*” (Topic 718). We adopted the standard in the first quarter of fiscal year 2017. With this adoption, excess tax benefits related to stock-based compensation expense are reflected in our condensed consolidated statement of operations as a component of the provision for income taxes instead of additional paid-in capital in our condensed consolidated balance sheet. We elected to apply the standard on a prospective basis. In addition, we elected to continue to estimate expected forfeitures rather than as they occur to determine the amount of compensation cost to be recognized in each period. During the nine months ended September 30, 2017, we recognized excess tax benefits of \$24.1 million in our provision for income taxes. Excess tax benefits from share-based payment arrangements are classified as an operating activity in our condensed consolidated statement of cash flows in the same manner as other cash flows related to income taxes.

In October 2016, the FASB issued ASU 2016-16, “*Intra-Entity Transfers of Assets Other Than Inventory*,” (Topic 740) which requires entities to recognize the income tax consequences of an intra-entity transfer of an asset other than inventory when the

transfer occurs. We early adopted the standard in the first quarter of fiscal year 2017 by applying the modified retrospective approach. During the first quarter of fiscal year 2017, we recognized a \$1.3 million decrease to retained earnings as a cumulative-effect adjustment.

(ii) Recent Accounting Updates Not Yet Effective

In May 2014, the FASB released 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 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 disclosure of the nature, amount, timing, and uncertainty of revenue and cash flows arising from contracts with customers. We plan to adopt the standard in the first quarter of fiscal year 2018 by applying the full retrospective method. Our ability to adopt using the full retrospective method is dependent on the completion of our analysis of information necessary to recast prior period financial statements. We are continuing to evaluate the accounting, transition and disclosure requirements of the standard and are in process of assessing the financial statement impact of adoption including, but not limited to, volume-based discount programs, sales commissions and the identification of performance obligations. The adoption of the standard may have a material impact on our consolidated financial statements and related disclosures.

In April 2016, the FASB released ASU 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 FASB released ASU 2016-12, " *Revenue from Contracts with Customers*, " to address certain issues in the Topic 606 guidance on assessing the collectability, 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 December 2016, the FASB released ASU 2016-20, " *Technical Corrections and Improvements to Topic 606, Revenue from Contracts with Customers*, " to clarify certain aspects of guidance in the Topic 606 including its scope, disclosure requirements and contract cost accounting, 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 February 2016, the FASB issued ASU 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. We plan to adopt the standard in the first quarter of fiscal year 2019 by electing practical expedients available in the standard. While we are currently evaluating the impact of the adoption of this guidance on our consolidated financial statements, we expect the adoption will have a material increase to the assets and liabilities of our consolidated balance sheet.

In June 2016, the FASB issued ASU 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 currently evaluating the impact of this guidance 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* " (Topic 230). This FASB clarifies the presentation and classification of certain cash receipts and cash payments in the statements of cash flows.

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The amendments are effective for fiscal years and interim periods within those years beginning after December 15, 2017. Early adoption is permitted. We do not expect the guidance will have a material impact on our consolidated statements of cash flows.

In November 2016, the FASB issued ASU 2016-18, "Statement of Cash Flows - Restricted Cash," which provides guidance to address the classification and presentation of changes in restricted cash in the statements of cash flows. The amendments are effective for fiscal years and interim periods within those years beginning after December 15, 2017 on a retrospective basis, and early adoption is permitted. We are currently evaluating the impact of this guidance on our consolidated financial statements and related disclosures.

In January 2017, the FASB issued ASU 2017-01, "Business Combinations (Topic 805): Clarifying the Definition of a Business," to clarify the definition of a business when evaluating whether transactions should be accounted for as acquisitions of assets or businesses. The amendments are effective for fiscal years and interim periods within those years beginning after December 15, 2017 on a prospective basis, and early adoption is permitted. We are currently evaluating the impact of this guidance on our consolidated financial statements and related disclosures.

In January 2017, the FASB issued ASU 2017-04, "Intangibles—Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment," to simplify the subsequent measurement of goodwill by eliminating step two from the goodwill impairment test. Under the amendments, an entity will recognize an impairment charge for the amount by which the carrying value exceeds the fair value. The amendments are effective for fiscal years and interim periods within those years beginning after December 15, 2019 on a prospective basis, and early adoption is permitted. We are currently evaluating the impact of this guidance on our consolidated financial statements and related disclosures.

In May 2017, the FASB issued ASU 2017-09, "Compensation — Stock Compensation (Topic 718): Scope of Modification Accounting," to clarify when to account for a change to the terms or conditions of a share-based payment award as a modification. The amendments are effective for fiscal years and interim periods within those years beginning after December 15, 2017 on a prospective basis, and early adoption is permitted. While we are currently evaluating the impact of this guidance, we do not expect the guidance will have a material impact on our consolidated financial statements and related disclosures.

Note 2. Marketable Securities and Fair Value Measurements

As of September 30, 2017 and December 31, 2016, the estimated fair value of our short-term and long-term marketable securities, classified as available for sale, are as follows (in thousands):

Short-term

September 30, 2017	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Commercial paper	\$ 62,348	\$ —	\$ —	\$ 62,348
Corporate bonds	164,661	31	(61)	164,631
U.S. government agency bonds	7,769	—	(8)	7,761
U.S. government treasury bonds	78,370	2	(33)	78,339
Certificates of deposit	3,375	—	—	3,375
Total marketable securities, short-term	\$ 316,523	\$ 33	\$ (102)	\$ 316,454

Long-term

September 30, 2017	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. government agency bonds	\$ 7,990	\$ 3	\$ —	\$ 7,993
Corporate bonds	45,815	40	(18)	45,837
U.S. government treasury bonds	5,025	—	(13)	5,012
Total marketable securities, long-term	\$ 58,830	\$ 43	\$ (31)	\$ 58,842

Short-term

December 31, 2016	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Commercial paper	\$ 42,397	\$ —	\$ (6)	\$ 42,391
Corporate bonds	122,788	22	(121)	122,689
Municipal securities	5,852	—	(5)	5,847
U.S. government agency bonds	28,903	9	(4)	28,908
U.S. government treasury bonds	45,146	7	(7)	45,146
Certificates of deposit	6,000	—	—	6,000
Total marketable securities, short-term	\$ 251,086	\$ 38	\$ (143)	\$ 250,981

Long-term

December 31, 2016	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. government agency bonds	\$ 6,805	\$ —	\$ (16)	\$ 6,789
Corporate bonds	40,889	8	(85)	40,812
U.S. government treasury bonds	12,016	5	(16)	12,005
Asset-backed securities	177	—	—	177
Total marketable securities, long-term	\$ 59,887	\$ 13	\$ (117)	\$ 59,783

Cash equivalents are not included in the table above as the gross unrealized gains and losses are not material. We have no short-term or long-term investments that have been in a continuous material unrealized loss position for greater than twelve months as of September 30, 2017 and December 31, 2016. Amounts reclassified to earnings from accumulated other comprehensive income (loss), net related to unrealized gains or losses were not material for the three and nine months ended September 30, 2017 and 2016. For the three and nine months ended September 30, 2017 and 2016, realized gains or losses were not material.

Our fixed-income securities investment portfolio consists of investments that have a maximum effective maturity of 27 months. The securities that we invest in are generally deemed to be low risk based on their credit ratings from the major rating agencies. The longer the duration of these securities, the more susceptible they are to changes in market interest rates and bond yields. As interest rates increase, those securities purchased at a lower yield show a mark-to-market unrealized loss. The unrealized losses are due primarily to changes in credit spreads and interest rates. We expect to realize the full value of all these investments upon maturity or sale. The weighted average remaining duration of these securities was approximately 7 months for both September 30, 2017 and December 31, 2016.

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, 2017 and December 31, 2016 (in thousands):

	September 30, 2017	December 31, 2016
One year or less	\$ 316,454	\$ 250,981
Due in greater than one year	58,842	59,783
Total available for sale short-term and long-term marketable securities	\$ 375,296	\$ 310,764

Fair Value Measurements

We measure the fair value of financial assets 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.

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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, 2017 and December 31, 2016.

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 deposit, U.S. government agency bonds and our Israeli funds that are mainly invested in insurance policies. 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. We did not hold any Level 2 liabilities as of September 30, 2017 and December 31, 2016.

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. Certain investments in private companies contain embedded derivatives, which do not require bifurcation as we elected to measure these investments at fair value. Our Level 3 assets consist of long-term notes receivable. We did not hold any Level 3 liabilities as of September 30, 2017 and December 31, 2016.

The following table summarizes the reconciliation of assets measured and recorded at fair value on a recurring basis using significant unobservable inputs Level 3 (in thousands):

	Long-term Notes Receivable
Balance as of December 31, 2016	\$ 2,047
Additional notes receivable issued	2,000
Accrued interest receivable	54
Change in fair value recognized in earnings	56
Balance as of September 30, 2017	<u>\$ 4,157</u>

Refer to Note 9 "Commitments and Contingencies" of the Notes to Condensed Consolidated Financial Statements for more information on our investment with a privately held company.

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The following tables summarize our financial assets measured at fair value on a recurring basis as of September 30, 2017 and December 31, 2016 (in thousands):

Description	Balance as of September 30, 2017	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	\$ 177,486	\$ 177,486	\$ —	\$ —
Commercial paper	13,295	—	13,295	—
Short-term investments:				
Commercial paper	62,348	—	62,348	—
Corporate bonds	164,631	—	164,631	—
U.S. government agency bonds	7,761	—	7,761	—
U.S. government treasury bonds	78,339	78,339	—	—
Certificates of deposit	3,375	—	3,375	—
Long-term investments:				
U.S. government agency bonds	7,993	—	7,993	—
Corporate bonds	45,837	—	45,837	—
U.S. government treasury bonds	5,012	5,012	—	—
Prepaid expenses and other current assets:				
Israeli funds	3,310	—	3,310	—
Other assets:				
Long-term notes receivable	4,157	—	—	4,157
	<u>\$ 573,544</u>	<u>\$ 260,837</u>	<u>\$ 308,550</u>	<u>\$ 4,157</u>

Description	Balance as of December 31, 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	\$ 87,179	\$ 87,179	\$ —	\$ —
Commercial paper	2,499	—	2,499	—
Corporate bonds	750	—	750	—
Short-term investments:				
Commercial paper	42,391	—	42,391	—
Corporate bonds	122,689	—	122,689	—
Municipal securities	5,847	—	5,847	—
U.S. government agency bonds	28,908	—	28,908	—
U.S. government treasury bonds	45,146	45,146	—	—
Certificates of deposit	6,000	—	6,000	—
Long-term investments:				
U.S. government agency bonds	6,789	—	6,789	—
Corporate bonds	40,812	—	40,812	—
U.S. government treasury bonds	12,005	12,005	—	—
Asset-backed securities	177	—	177	—
Prepaid expenses and other current assets:				
Israeli funds	2,956	—	2,956	—
Other assets:				
Long-term notes receivable	2,047	—	—	2,047
	<u>\$ 406,195</u>	<u>\$ 144,330</u>	<u>\$ 259,818</u>	<u>\$ 2,047</u>

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 associated with certain assets and liabilities. We had no foreign exchange forward contracts outstanding as of September 30, 2017 and no net gain or loss from the settlement of foreign currency forward contracts during the three and nine months ended September 30, 2017. The net gain or loss on forward contracts was not material during the three and nine months ended September 30, 2016.

Note 3. Balance Sheet Components**Inventories**

Inventories consist of the following (in thousands):

	September 30, 2017	December 31, 2016
Raw materials	\$ 15,666	\$ 9,793
Work in process	12,819	10,773
Finished goods	8,456	6,565
Total inventories	<u>\$ 36,941</u>	<u>\$ 27,131</u>

Accrued Liabilities

Accrued liabilities consist of the following (in thousands):

	September 30, 2017	December 31, 2016
Accrued payroll and benefits	\$ 84,418	\$ 79,214
Accrued expenses	38,983	21,811
Accrued income taxes	10,486	4,210
Accrued sales rebate	9,293	10,342
Accrued sales tax and value added tax	8,693	5,032
Accrued professional fees	8,181	3,604
Accrued warranty	5,055	3,841
Other accrued liabilities	8,742	6,278
Total accrued liabilities	<u>\$ 173,851</u>	<u>\$ 134,332</u>

Warranty

We regularly review the accrued 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.

Warranty accrual as of September 30, 2017 and 2016 consists of the following activity (in thousands):

	Nine Months Ended September 30,	
	2017	2016
Balance at beginning of period	\$ 3,841	\$ 2,638
Charged to cost of revenues	5,201	3,440
Actual warranty expenditures	(3,987)	(2,681)
Balance at end of period	<u>\$ 5,055</u>	<u>\$ 3,397</u>

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. The investment is accounted for under an equity method investment and the investee, SDC, is considered a related party.

The investment is reported in our Condensed Consolidated Balance Sheet under equity method investments, and we record our proportional share of SDC's losses within equity in losses of investee, net of tax, in our Condensed Consolidated Statement of Operations. On July 24, 2017, we purchased an additional 2% equity interest in SDC for \$12.8 million. As a result of this purchase, we hold a 19% equity interest in SDC on a fully diluted basis. As of September 30, 2017, the balance of our equity method investments was \$52.9 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 the supply agreement are reported in our Clear Aligner business segment after eliminating outstanding intercompany transactions. As of September 30, 2017, the balance of accounts receivable due from SDC is \$12.7 million.

On July 25, 2016, we entered into a Loan and Security Agreement with SDC where we agreed to provide a loan of up to \$30.0 million in one or more advances to SDC. As of September 30, 2017, \$17.0 million of advances under the Loan Facility were outstanding (Refer to Note 9 "Commitments and Contingencies" of the Notes to Condensed Consolidated Financial Statements for information on the Loan and Security Agreement with SDC).

Note 5. Business Combinations

During the first quarter of 2017, we completed the acquisitions of certain of our distributors for the total estimated cash consideration of approximately \$9.5 million including cash acquired. We preliminarily recorded \$1.8 million of net tangible liabilities, \$8.2 million of identifiable intangible assets and \$3.1 million of goodwill. The preliminary fair values of net tangible liabilities and identifiable intangible assets acquired are based on preliminary valuations, and our estimates and assumptions are subject to change within the measurement period (up to one year from the acquisition date).

The goodwill is primarily related to the benefit we expect to obtain from direct sales as we believe that the transition from our distributor arrangements to a direct sales model will increase our net revenues in the region as we will experience higher average sales prices ("ASP") compared to our discounted ASP under the distribution agreements. The goodwill is not deductible for tax purposes.

Pro forma results of operations for these acquisitions have not been presented as they are not material to our results of operations, either individually or in aggregate, for the three and nine months ended September 30, 2017.

Note 6. Goodwill and Intangible Assets

Goodwill

The change in the carrying value of goodwill for the nine months ended September 30, 2017, all attributable to our Clear Aligner reporting unit, is as follows (in thousands):

	Total
Balance as of December 31, 2016	\$ 61,044
Goodwill from distributor acquisitions	3,247
Adjustments ¹	324
Balance as of September 30, 2017	<u>\$ 64,615</u>

¹ The adjustments to goodwill during the period were related to foreign currency translation and purchase accounting adjustments within the measurement period.

During the fourth quarter of fiscal 2016, we performed the annual goodwill impairment testing and found no impairment as the fair value of our Clear Aligner reporting unit was significantly in excess of the carrying value.

Intangible Long-Lived Assets

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

	Weighted Average Amortization Period (in years)	Gross Carrying Amount as of September 30, 2017	Accumulated Amortization	Accumulated Impairment Loss	Net Carrying Value as of September 30, 2017
Trademarks	15	\$ 7,100	\$ (1,734)	\$ (4,179)	\$ 1,187
Existing technology	13	12,600	(4,563)	(4,328)	3,709
Customer relationships	11	33,500	(14,216)	(10,751)	8,533
Reacquired rights ¹	3	7,500	(749)	—	6,751
Patents	8	6,316	(1,307)	—	5,009
Other	2	618	(352)	—	266
Total intangible assets		\$ 67,634	\$ (22,921)	\$ (19,258)	\$ 25,455

	Weighted Average Amortization Period (in years)	Gross Carrying Amount as of December 31, 2016	Accumulated Amortization	Accumulated Impairment Loss	Net Carrying Value as of December 31, 2016
Trademarks	15	\$ 7,100	\$ (1,631)	\$ (4,179)	\$ 1,290
Existing technology	13	12,600	(4,141)	(4,328)	4,131
Customer relationships	11	33,500	(12,819)	(10,751)	9,930
Patents	8	6,316	(713)	—	5,603
Total intangible assets		\$ 59,516	\$ (19,304)	\$ (19,258)	\$ 20,954

¹ The fair value of reacquired rights obtained from distributor acquisitions during the the first quarter of fiscal year 2017 is valued using the income approach. In addition, we effectively settled the pre-existing relationship with the distributors by assessing whether the distributor agreements include favorable or unfavorable terms compared to current market rates. Based on the assessment, we determined that the distributor agreements had terms that are consistent with market rates and, therefore, no settlement gains or losses are recorded associated with the acquisitions during the first quarter of fiscal year 2017.

The total estimated annual future amortization expense for these acquired intangible assets as of September 30, 2017 is as follows (in thousands):

Remainder of 2017	\$ 2,215
2018	6,002
2019	5,887
2020	3,772
2021	3,349
Thereafter	4,230
Total	\$ 25,455

Amortization for the nine months ended September 30, 2017 was \$4.7 million .

Note 7. Credit Facilities

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 requires us to comply with specific financial conditions and performance requirements. On February 10, 2017, we amended the credit facility and extended the maturity date to March 22, 2018. 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, 2017 , we had no outstanding borrowings under this credit facility and were in compliance with the conditions and performance requirements. On July 24, 2017, we amended the credit facility's negative covenants to allow for a Costa Rica building purchase, an additional equity interest in SDC and an increase in SDC's loan limit (Refer to Note 9 "Equity Method Investments" of the Notes to Condensed Consolidated Financial Statements for information on the additional equity interest in SDC and Refer to Note 9 "Commitments and Contingencies" of the

Notes to Condensed Consolidated Financial Statements for information on the Costa Rica building purchase and SDC loan amendment).

Note 8. 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 and 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. On May 5, 2017, the Ninth Circuit affirmed the district court’s dismissal of the complaint. Plaintiff filed a request for rehearing that was denied by the Ninth Circuit on June 14, 2017. Plaintiff had 90 days following the June 14 Order to file a petition for a writ of certiorari with the United States Supreme Court which has passed and this case has been dismissed without leave to amend.

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. On June 28, 2017, the Court entered an Order dismissing this action with prejudice pursuant to a joint stipulation between the parties.

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

Note 9. Commitments and Contingencies***Operating Leases***

As of September 30, 2017, minimum future lease payments for non-cancelable operating leases are as follows (in thousands):

Fiscal Year Ending December 31,	Operating Leases
Remainder of 2017	\$ 3,072
2018	12,785
2019	11,164
2020	8,503
2021	7,435
Thereafter	13,558
Total minimum future lease payments	\$ 56,517

Other Commitments

On July 25, 2016, we entered into a Loan and Security Agreement (the "Loan Agreement") with SmileDirectClub, LLC ("SDC") where we agreed to provide a loan of up to \$15.0 million in one or more advances to SDC (the "Loan Facility"). On July 24, 2017, we amended the Loan Agreement with SDC to increase the line of credit up to \$30.0 million. 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 collateralized by a security interest in substantially all of SDC's assets. As of September 30, 2017, \$17.0 million of advances under the Loan Facility were outstanding (Refer to Note 4 "Equity Method Investments" of the Notes to 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 was issued on July 14, 2016 for \$2.0 million and a second convertible promissory note was issued on June 5, 2017 for \$2.0 million. Both notes are outstanding as of September 30, 2017. The remaining \$1.0 million available is conditioned upon achievement of certain business milestones. The notes all mature on December 30, 2018 and accrue interest annually at 2.5%.

On June 30, 2017, we entered into a non-cancelable Addendum to the Master Subscription Agreement with a software company to renew our software license subscription for the total price of \$50.0 million over the next three years starting on January 1, 2018.

On July 24, 2017, we entered into a Purchase and Sale Agreement with Belen Business Center CR, S.A. to purchase a building located in the Republic of Costa Rica for a purchase price of \$26.1 million. On July 28, 2017, we made the first payment of \$5.2 million for the purchase.

Off-Balance Sheet Arrangements

As of September 30, 2017, 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, 2017, we did not have any material indemnification claims that were probable or reasonably possible.

Note 10. Stockholders' Equity

Summary of Stock-Based Compensation Expense

As of September 30, 2017, the 2005 Incentive Plan (as amended) has a total reserve of 27,783,379 shares of which 6,920,114 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, 2017 and 2016 is as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Cost of net revenues	\$ 833	\$ 995	\$ 2,526	\$ 2,888
Selling, general and administrative	11,880	10,797	34,814	31,474
Research and development	2,254	1,919	6,684	5,572
Total stock-based compensation	\$ 14,967	\$ 13,711	\$ 44,024	\$ 39,934

Stock Options

We have not granted options since 2011 and all outstanding options were fully vested and associated stock-based compensation expenses were recognized as of December 31, 2015. Activity for the nine months ended September 30, 2017 under the stock option plans is set forth below (in thousands, except years and per share amounts):

	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, 2016	222	\$ 14.90		
Exercised	(110)	16.19		
Cancelled or expired	(4)	18.16		
Outstanding as of September 30, 2017	108	\$ 13.47	0.90	\$ 18,711
Vested and expected to vest at September 30, 2017	108	\$ 13.47	0.90	\$ 18,711
Exercisable at September 30, 2017	108	\$ 13.47	0.90	\$ 18,711

Restricted Stock Units ("RSUs")

The fair value of nonvested RSUs is based on our closing stock price on the date of grant. A summary for the nine months ended September 30, 2017 is as follows (in thousands, except years and per share amounts):

	Shares Underlying RSUs	Weighted Average Grant Date Fair Value	Weighted Remaining Vesting Period (in years)	Aggregate Intrinsic Value
Nonvested as of December 31, 2016	1,789	\$ 58.39		
Granted	456	110.40		
Vested and released	(785)	53.61		
Forfeited	(71)	67.22		
Nonvested as of September 30, 2017	1,389	77.72	1.34	\$ 258,838

As of September 30, 2017, we expect to recognize \$76.6 million of total unamortized compensation cost, net of estimated forfeitures, related to RSUs over a weighted average period of 2.3 years.

Market-performance Based Restricted Stock Units ("MSUs")

On an annual basis, we grant market-performance based restricted stock units ("MSUs") to our executive officers. Each MSU represents the right to one share of Align's common stock. The actual number of MSUs which will be eligible to vest will be based on the performance of Align's stock price relative to the performance of the NASDAQ Composite Index over the vesting period, generally two to three years, up to 200% of the MSUs initially granted.

The following table summarizes the MSU performance for the nine months ended September 30, 2017 (in thousands, except years):

	Number of Shares Underlying MSUs	Weighted Average Grant Date Fair Value	Weighted Average Remaining Vesting Period (in years)	Aggregate Intrinsic Value
Nonvested as of December 31, 2016	520	\$ 60.49		
Granted	201	88.80		
Vested and released	(283)	53.11		
Forfeited	(10)	64.50		
Nonvested as of September 30, 2017	428	78.53	1.22	\$ 79,742

As of September 30, 2017, we expect to recognize \$14.7 million of total unamortized compensation cost, net of estimated forfeitures, related to MSUs over a weighted average period of 1.2 years.

Employee Stock Purchase Plan ("ESPP")

In May 2010, our shareholders 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, 2017, we have 735,301 shares available for future issuance.

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,	
	2017	2016	2017	2016
Expected term (in years)	1.2	1.2	1.2	1.2
Expected volatility	28.8%	27.4%	26.8%	30.5%
Risk-free interest rate	1.2%	0.5%	1.0%	0.7%
Expected dividends	—	—	—	—
Weighted average fair value at grant date	\$ 47.02	\$ 24.44	\$ 31.36	\$ 22.23

As of September 30, 2017, there was \$4.0 million of total unamortized compensation costs related to employee stock purchases which we expect to be recognized over a weighted average period of 0.9 year.

Note 11. 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 Plan") pursuant to which we may purchase up to \$300.0 million of our common stock over the next three years.

During the first quarter of 2017, we repurchased on the open market approximately 0.04 million shares of our common stock at an average price of \$96.37 per share, including commission for an aggregate purchase price of approximately \$3.8 million, completing the April 2014 Repurchase Program. All repurchased shares were retired.

April 2016 Repurchase Program

In April 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 ("April 2016 Repurchase Program").

On May 2, 2017, we entered into an accelerated share repurchase ("ASR") to repurchase \$50.0 million of our common stock ("2017 ASR"). The 2017 ASR was completed on August 3, 2017. 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. We received a total of approximately 0.4 million shares at a weighted average share price of \$146.48 under the 2017 ASR. All repurchased shares were retired. As of September 30, 2017, we have \$250.0 million remaining under the April 2016 Repurchase Plan.

Note 12. Accounting for Income Taxes

Our provision for income taxes was \$ 18.3 million and \$ 11.7 million for the three months ended September 30, 2017 and 2016, respectively, representing effective tax rates of 17.9% and 18.4%, respectively. Our effective tax rate differs from the statutory federal income tax rate of 35% mainly as a result of certain foreign earnings, primarily from the Netherlands and Costa Rica, being taxed at lower tax rates. The decrease in effective tax rate for the three months ended September 30, 2017 compared to the same period in 2016 is primarily attributable to the adoption of ASU 2016-09 in 2017 which requires excess tax benefits related to stock-based compensation to be recognized as a reduction of income tax expense, and certain one-time tax charges recognized as a result of the implementation of the international corporate restructure on July 1, 2016 that is no longer pertinent to the current period.

Our provision for income taxes was \$26.5 million and \$39.2 million for the nine months ended September 30, 2017 and 2016, respectively, representing effective tax rates of 10.5% and 21.6%, respectively. For the nine months ended September 30, 2017, our effective tax rate differs from the statutory federal income tax rate of 35% mainly as a result of certain foreign earnings, primarily from the Netherlands and Costa Rica, being taxed at lower tax rates and the recognition of excess tax benefits related to stock-based compensation in accordance with the adoption of ASU 2016-09. For the nine months ended September 30, 2016, 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 impact from our international corporate restructuring that occurred on July 1, 2016, partially offset by the 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, 2017 compared to the same period in 2016 is primarily attributable to the adoption of ASU 2016-09 in the first quarter of fiscal year 2017 which requires excess tax benefits related to stock-based compensation to be recognized as a reduction of income tax expense. In addition, the effective tax rate for the prior period was higher due to certain one-time tax charges recognized as a result of the implementation of the international corporate restructure during the third quarter of fiscal year 2016.

For the three and nine months ended September 30, 2017, we recognized excess tax benefits of \$1.7 million and \$24.1 million, respectively, in our provision for income taxes.

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 \$46.1 million and \$46.4 million as of September 30, 2017 and December 31, 2016, respectively, all of which would impact our effective tax rate if recognized. Our total interest and penalties accrued as of September 30, 2017 was \$2.6 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 include U.S. federal, the State of California and the Netherlands. 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.

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

In June 2017, the Costa Rica Ministry of Foreign Trade, an agency of the Government of Costa Rica, granted an extension of certain income tax incentives for an additional twelve year period, which was originally granted in 2002 and was set to expire in June 2017. Under these incentives, all of the income in Costa Rica 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 2017 and 2016. For the three and nine months ended September 30, 2017, the reduction in income taxes was minimal primarily due to the new international corporate structure implemented on July 1, 2016. For the three and nine months ended September 30, 2016, income taxes were reduced by \$0.3 million with minimal impact to diluted net income per share and \$17.5 million representing a benefit to diluted net income per share of \$0.21, respectively.

We maintain sufficient cash reserves in the U.S. and do not intend to repatriate our foreign earnings which have not already been subject to U.S. income tax. 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 13. 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 our 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,	
	2017	2016	2017	2016
Numerator:				
Net income	\$ 82,555	\$ 51,367	\$ 221,154	\$ 142,061
Denominator:				
Weighted-average common shares outstanding, basic	80,163	79,977	80,086	79,920
Dilutive effect of potential common stock	1,626	1,489	1,671	1,603
Total shares, diluted	81,789	81,466	81,757	81,523
Net income per share, basic	\$ 1.03	\$ 0.64	\$ 2.76	\$ 1.78
Net income per share, diluted	\$ 1.01	\$ 0.63	\$ 2.71	\$ 1.74

For the three and nine months ended September 30, 2017 and 2016, potentially dilutive shares excluded from diluted net income per share related to RSUs, MSUs, and ESPP were not material.

Note 14. Segments and Geographical Information

Segment Information

Operating segments are defined as components of an enterprise for which separate financial information is available that is evaluated regularly by the Chief Operating Decision Maker (“CODM”), or decision-making group, in deciding how to allocate resources and in assessing performance. Our CODM is our Chief Executive Officer. We report segment information based on the management approach. The management approach designates the internal reporting used by CODM for decision making and performance assessment as the basis for determining our reportable segments. The performance measures of our reportable segments include net revenues and gross profit. In the fourth quarter of 2016, management decided to change the way it internally assesses the performance of our reportable segments by including income from operations measure in the performance metrics. Income from operations for each segment includes all geographic revenues, related cost of net revenues and operating expenses directly attributable to the segment. Certain operating expenses are attributable to operating segments and each allocation is measured differently based on the specific facts and circumstances of the costs being allocated. Costs not specifically allocated to segment income from operations include various corporate expenses such as stock-based compensation and costs related to IT, facilities, human resources and accounting and finance, legal and regulatory, and other separately managed general and administrative costs outside the operating segments. We have included the new performance measure in the prior period presentation to conform to the current year's presentation.

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

- Our Clear Aligner segment consists of Comprehensive Products, Non-Comprehensive Products and Non-Case revenues as defined below:
 - Comprehensive Products include our Invisalign Full, Teen and Assist products.
 - Non-Comprehensive Products include our Express/Lite products in addition to revenues from the sale of aligners to SmileDirectClub (“SDC”) under our supply agreement, which commenced in the fourth quarter of 2016. Revenue from SDC is recorded after eliminating outstanding intercompany transactions.
 - Non-Case includes our Viverra retainers along with our training and ancillary products for treating malocclusion.
- Our Scanner segment consists of intraoral scanning systems and additional services available with the intraoral 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):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Net revenues				
Clear Aligner	\$ 341,611	\$ 243,668	\$ 945,046	\$ 706,802
Scanner	43,656	34,921	107,044	79,869
Total net revenues	\$ 385,267	\$ 278,589	\$ 1,052,090	\$ 786,671
Gross profit				
Clear Aligner	\$ 266,285	\$ 189,270	\$ 737,046	\$ 552,663
Scanner	26,203	19,932	61,984	42,382
Total gross profit	\$ 292,488	\$ 209,202	\$ 799,030	\$ 595,045
Income from operations				
Clear Aligner	\$ 154,614	\$ 102,431	\$ 403,264	\$ 306,789
Scanner	13,525	11,977	28,324	20,333
Unallocated corporate expenses	(69,376)	(52,329)	(187,583)	(146,573)
Total income from operations	\$ 98,763	\$ 62,079	\$ 244,005	\$ 180,549
Depreciation and amortization				
Clear Aligner	\$ 5,643	\$ 3,541	\$ 15,607	\$ 10,163
Scanner	1,130	761	3,248	2,853
Unallocated corporate expenses	3,199	2,599	7,860	3,770
Total depreciation and amortization	\$ 9,972	\$ 6,901	\$ 26,715	\$ 16,786

The following table reconciles total segment income from operations in the table above to net income before provision for income taxes and equity losses of investee (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Total segment income from operations	\$ 168,139	\$ 114,408	\$ 431,588	\$ 327,122
Unallocated corporate expenses	(69,376)	(52,329)	(187,583)	(146,573)
Total income from operations	98,763	62,079	244,005	180,549
Interest and other income (expense), net	3,750	1,463	8,607	1,161
Net income before provision for income taxes and equity in losses of investee	\$ 102,513	\$ 63,542	\$ 252,612	\$ 181,710

Geographical Information

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Net revenues ⁽¹⁾ :				
United States ⁽²⁾	\$ 217,758	\$ 168,501	\$ 608,052	\$ 516,924
The Netherlands ⁽²⁾	127,307	87,051	357,278	191,049
Other International	40,202	23,037	86,760	78,698
Total net revenues	\$ 385,267	\$ 278,589	\$ 1,052,090	\$ 786,671

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

⁽²⁾ Effective July 2016, we implemented a new international corporate structure. This changed the structure of our international procurement and sales operations.

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

	<u>September 30, 2017</u>	<u>December 31, 2016</u>
Long-lived assets ⁽¹⁾ :		
The Netherlands	\$ 142,591	\$ 111,515
United States	125,172	43,278
Mexico	21,537	17,918
Other International	6,601	2,456
Total long-lived assets	<u>\$ 295,901</u>	<u>\$ 175,167</u>

⁽¹⁾ Long-lived assets are attributed to countries based on entity that owns the assets.

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

In addition to historical information, this quarterly report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. These statements include, among other things, our expectations regarding the anticipated impact of our new products and product enhancements will have on doctor utilization and our market share, our expectations regarding product mix and product adoption, our expectations regarding the existence and impact of seasonality, our expectations regarding the financial and strategic benefits of establishing regional order acquisition and treatment planning facilities, as well as the anticipated timing of such facilities being operational, our expectations regarding the continued expansion of our international markets, the level of our operating expenses and gross margins, our expectation that the SmileDirectClub, LLC transaction will be incremental to revenue growth 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.

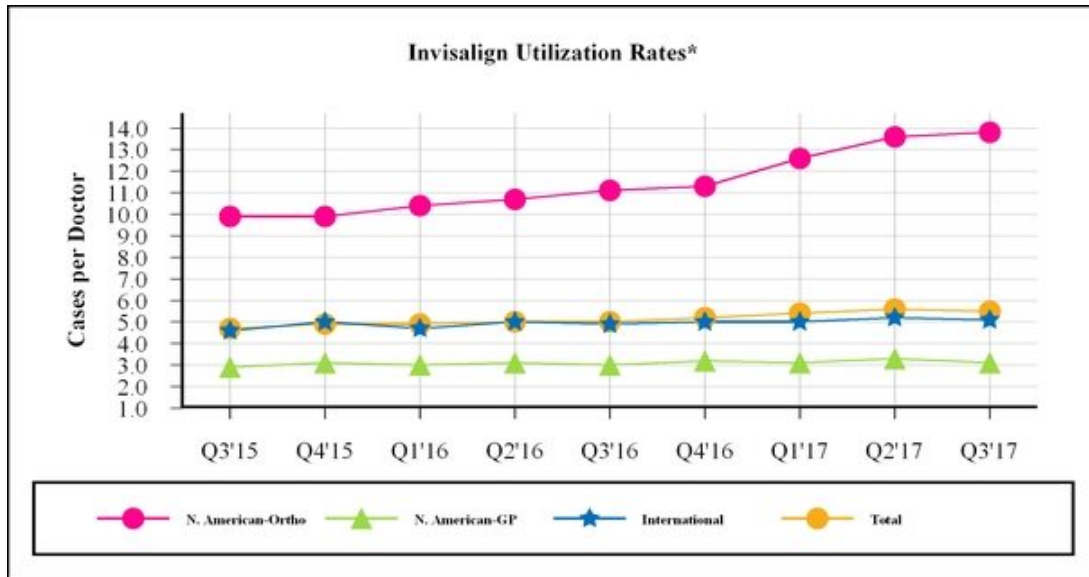
The following discussion and analysis of our financial condition and results of operations should be read together with our condensed consolidated financial statements and related notes included elsewhere in this Quarterly Report on Form 10-Q and with our audited consolidated financial statements included in our Annual Report on form 10-K for the year ended December 31, 2016, 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 in 2017 and beyond may be affected by a number of other factors including:

- *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 treatment in their practices. Our focus is to develop solutions and features to treat a wide range of cases - from simple to complex. Most recently, in March 2017, we announced Invisalign Teen with mandibular advancement, the first clear aligner solution for Class II correction in growing tween and teen patients. This new offering combines the benefits of the most advanced clear aligner system in the world with features for moving the lower jaw forward while simultaneously aligning the teeth. Invisalign Teen with mandibular advancement is now available in Canada, and select Europe, Middle East and Africa ("EMEA") countries, Asia Pacific ("APAC") countries and Latin America ("LATAM") countries. Invisalign Teen with mandibular advancement is pending 510(k) clearance and is not yet available in the United States. We believe that over the long-term, clinical solutions and treatment tools will increase adoption of Invisalign and increase sales of our intraoral scanners; however, it is difficult to predict the rate of adoption which may vary by region and channel.
- *Invisalign 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 last 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 2017 increased to 5.5 cases per doctor compared to 5.0 in the third quarter of 2016.
- *North America:* Utilization among our North American orthodontist customers reached an all time high in the third quarter of 2017 at 13.8 cases per doctor. Compared to 11.1 cases per doctor utilized in the third quarter of 2016, the increase in North America orthodontist utilization in the third quarter of 2017 reflects improvements in product and technology which continues to strengthen our doctors' clinical confidence such that they now utilize Invisalign more often and on more complex cases, including their teenage patients.
- *International:* International doctor utilization is 5.1 cases per doctor in the third quarter of 2017 compared to 4.9 in the third quarter of 2016. The International utilization reflects growth in both the EMEA and APAC regions due to increasing adoption of the product due in part to its ability to treat more complex cases.

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-Trained Doctors.* We continue to expand our Invisalign customer base through the training of new doctors. In 2016, Invisalign clear aligner 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 11,680 new Invisalign doctors, of which 60% were trained internationally. During the third quarter of 2017, we trained 4,280 new Invisalign doctors of which 1,460 were trained in North America and 2,820 in our International regions.
- *International Invisalign Growth.* We will continue to focus our efforts towards increasing Invisalign clear aligner adoption by dental professionals in our direct international markets. On a year over year basis, international Invisalign volume increased 47.4% driven primarily by strong performance in our APAC and EMEA regions. We believe that the introduction of Invisalign treatment with Mandibular Advancement is helping to raise visibility for Invisalign treatment of teenagers and contributed to some of the growth in the APAC market. In 2017, 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 Invisalign 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 of these regions (Refer to Item 1A Risk Factors - "We are exposed to fluctuations in currency exchange rates, which could negatively affect our financial condition and results of operations." for information on related risk factors).

- *Regional Order Acquisition and Treatment Planning Facilities:* We will continue to establish and expand additional order acquisition and treatment planning facilities closer to our international customers in order to improve our operational efficiency and to provide doctors confidence in using Invisalign clear aligners to treat more patients and more often. In June 2017, we opened a new treatment planning facility in Chengdu, China which services and supports our customers within China. It also serves as a clinical education and training center for all of our customers across Asia Pacific. In July 2017, we entered into a Purchase and Sale Agreement with Belen Business Center CR, S.A. to purchase a new Costa Rica treatment planning facility for \$26.1 million. In addition, we opened a treatment planning facility in Cologne, Germany to support our EMEA customers in August 2017. (Refer to Item 1A Risk Factors - "As we continue to grow, we are subject to growth related risks, including risks related to excess or constrained capacity at our existing facilities." for information on related risk factors and Refer to Note 9 "Commitments and Contingencies" of the Notes of Condensed Consolidated Financial Statements for more information on the Purchase Agreement).
- *Operating Expenses.* We expect operating expenses to increase in fiscal year 2017 due in part to:
 - investments in international expansion in new country markets particularly in the APAC, Latin America and Middle East regions;
 - investments in manufacturing to enhance our regional order acquisition and treatment planning capabilities;
 - increases in legal expenses primarily related to the continued protection of our intellectual property rights, including our patents;
 - increases 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.

- *Stock Repurchases: April 2016 Repurchase Program.* On April 28, 2016, we announced that our Board of Directors had authorized a plan to repurchase up to \$300.0 million of our stock. On May 2, 2017, we entered into an accelerated share repurchase ("ASR") to repurchase \$50.0 million of our common stock ("2017 ASR"). The 2017 ASR was completed on August 3, 2017. 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. We received a total of approximately 0.4 million shares at a weighted average share price of \$146.48 under the 2017 ASR. All repurchased shares were retired. As of September 30, 2017, we have \$250.0 million remaining under the April 2016 Repurchase Plan.
- *SmileDirectClub.* On July 24, 2017, we increased the revolving line of credit to SmileDirectClub, LLC ("SDC") from \$15.0 million to \$30.0 million. As of September 30, 2017, \$17.0 million under the Loan Facility was outstanding. On July 24, 2017, we purchased an additional 2% equity interest in SDC for \$12.8 million. As a result of this purchase, we hold a 19% equity interest in SDC on a fully diluted basis (Refer to Note 4 "Equity Method Investments" of the Notes to Condensed Consolidated Financial Statement s for details on accounting treatment). Additionally, we expect the supply agreement to be incremental to revenue growth in 2017.
- *New Corporate Headquarters Office Purchase.* We completed the purchase of our new headquarters on January 26, 2017 for the purchase price of \$44.1 million. In addition, we incurred \$29.7 million in building improvements during 2017 and moved into the facility in August 2017.

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 Comprehensive Products, Non-Comprehensive Products and Non-Case revenues as defined below:
 - Comprehensive Products include our Invisalign Full, Teen and Assist products.

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- Non-Comprehensive Products include our Express/Lite products in addition to revenues from the sale of aligners to SmileDirectClub (“SDC”) under our supply agreement, which commenced in the fourth quarter of 2016. Revenue from SDC is recorded after eliminating outstanding intercompany transactions.
- Non-Case includes our Vivera retainers along with our training and ancillary products for treating malocclusion.
- Our Scanner segment consists of intraoral scanning systems and additional services available with the intraoral 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 and Scanner segment by region for the three and nine months ended September 30, 2017 and 2016 is as follows (in millions):

Net Revenues	Three Months Ended September 30,				Nine Months Ended September 30,			
	2017	2016	Net Change	% Change	2017	2016	Net Change	% Change
Clear Aligner revenues:								
North America	\$ 193.8	\$ 143.8	\$ 50.0	34.8%	\$ 545.1	\$ 423.4	\$ 121.7	28.7%
International	126.6	84.3	42.3	50.2%	340.2	237.9	102.3	43.0%
Non-case	21.2	15.6	5.6	35.9%	59.7	45.5	14.2	31.2%
Total Clear Aligner net revenues	\$ 341.6	\$ 243.7	\$ 97.9	40.2%	\$ 945.0	\$ 706.8	\$ 238.2	33.7%
Scanner net revenues	43.7	34.9	8.8	25.2%	107.0	79.9	27.1	33.9%
Total net revenues	\$ 385.3	\$ 278.6	\$ 106.7	38.3%	\$ 1,052.1	\$ 786.7	\$ 265.4	33.7%

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 Clear Aligner case shipments by region for the three and nine months ended September 30, 2017 and 2016 is as follows (in thousands):

Region	Three Months Ended September 30,				Nine Months Ended September 30,			
	2017	2016	Net Change	% Change	2017	2016	Net Change	% Change
North America	164.2	115.9	48.3	41.7%	455.0	341.3	113.7	33.3%
International	91.2	61.9	29.3	47.3%	251.8	177.2	74.6	42.1%
Total case volume	255.4	177.8	77.6	43.6%	706.7	518.5	188.2	36.3%

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

For the three and nine months ended September 30, 2017, total net revenues increased by \$106.7 million and \$265.4 million as compared to the same periods in 2016 primarily as a result of case volume growth across all regions and most products as well as increased non-case revenues.

Clear Aligner - North America

For the three months ended September 30, 2017, North America net revenues increased by \$50.0 million as compared to the same period in 2016 primarily due to case volume growth across all channels and most products which increased net revenues by \$59.8 million. This increase was offset in part by lower average selling prices (“ASP”) which decreased net revenues by \$9.8 million. The ASP decline is a result of a shift in product mix towards Non-Comprehensive Products, primarily driven by increased SDC revenues which carry a lower ASP and higher promotional discounts, which collectively reduced revenues by \$19.6 million. These factors contributing to the decline in ASP were offset in part by an increase in additional aligner revenue, which contributed \$6.7 million to net revenues, as well as price increases on our Comprehensive Products effective April 1, 2017, which contributed \$4.5 million to net revenues.

For the nine months ended September 30, 2017, North America net revenues increased by \$121.7 million as compared to the same period in 2016 primarily due to case volume growth across all channels and products which increased net revenues by \$141.0 million. This increase was offset in part by lower ASP which decreased net revenues by \$19.3 million. The ASP decline is a result

of a shift in product mix towards Non-Comprehensive Products, primarily driven by increased SDC revenues which carry a lower ASP and higher Invisalign promotional discounts, which collectively reduced revenues by \$34.1 million. These factors contributing to the decline in ASP were offset in part by an increase in additional aligner revenue, which contributed \$10.0 million to net revenues, as well as price increases on our Comprehensive Products effective on April 1 of 2016 and 2017, which contributed \$6.9 million to net revenues.

Clear Aligner - International

For the three months ended September 30, 2017, International net revenues increased by \$ 42.3 million as compared to the same period in 2016 primarily driven by case volume growth across all channels and products which increased net revenues by \$40.0 million. This increase resulted in higher ASP which increased net revenues by \$2.3 million. The increase in ASP is primarily a result of price increases in our Comprehensive Products effective July 1, 2017, a favorable impact of foreign exchange rates and the impact from acquiring a distributor as we now recognize direct sales at full ASP rather than the discounted ASP, all of which collectively contributed \$6.6 million to net revenues. These factors contributing to the increase in ASP were offset in part by \$4.9 million related to higher promotional discounts and increased net deferrals.

For the nine months ended September 30, 2017, International net revenues increased by \$102.3 million as compared to the same period in 2016 primarily driven by case volume growth across all channels and products which increased net revenues by \$102.5 million. This increase was offset in part by slightly lower ASP. The ASP decline was primarily due to higher promotional discounts and the impact of foreign exchange rates, offset in part by price increases in our Comprehensive Products effective on July 1 of 2016 and 2017, the impact from acquiring certain distributors as we now recognize direct sales at full ASP rather than the discounted ASP, as well as an increase in additional aligner revenue.

Clear Aligner - Non-Case

For the three and nine months ended September 30, 2017, non-case net revenues, consisting of training fees and ancillary product revenues, increased by \$5.6 million and \$14.2 million as compared to the same periods in 2016 primarily due to increased Viverra volume in both North America and International.

Scanner

For the three and nine months ended September 30, 2017, scanner and services net revenues increased by \$ 8.8 million and \$27.1 million as compared to the same periods in 2016. Scanner and services net revenues increased for the three and nine months ended September 30, 2017 as compared to the same periods in 2016 primarily as a result of an increase in the number of scanners recognized and higher volume of CAD/CAM services resulting from a larger installed base of scanners, offset in part by a decrease in scanner ASP.

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

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2017	2016	Change	2017	2016	Change
Clear Aligner						
Cost of net revenues	\$ 75.3	\$ 54.4	\$ 20.9	\$ 208.0	\$ 154.1	\$ 53.9
<i>% of net segment revenues</i>	22.1%	22.3%		22.0%	21.8%	
Gross profit	\$ 266.3	\$ 189.3	\$ 77.0	\$ 737.0	\$ 552.6	\$ 184.4
<i>Gross margin %</i>	77.9%	77.7%		78.0%	78.2%	
Scanner						
Cost of net revenues	\$ 17.5	\$ 15.0	\$ 2.5	\$ 45.1	\$ 37.5	\$ 7.6
<i>% of net segment revenues</i>	40.0%	42.9%		42.1%	46.9%	
Gross profit	\$ 26.2	\$ 20.0	\$ 6.2	\$ 62.0	\$ 42.4	\$ 19.6
<i>Gross margin %</i>	60.0%	57.1%		57.9%	53.1%	
Total cost of net revenues	\$ 92.8	\$ 69.4	\$ 23.4	\$ 253.1	\$ 191.6	\$ 61.5
<i>% of net revenues</i>	24.1%	24.9%		24.1%	24.4%	
Gross profit	\$ 292.5	\$ 209.2	\$ 83.3	\$ 799.0	\$ 595.0	\$ 204.0
<i>Gross margin %</i>	75.9%	75.1%		75.9%	75.6%	

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 personnel-related costs including payroll and stock-based compensation for staff involved in the production process, the cost of materials, packaging, shipping costs, depreciation on capital equipment and facilities used in the production process, amortization of acquired intangible assets and training costs.

Clear Aligner

For the three months ended September 30, 2017, gross margin percentage increased as compared to the same period in 2016 primarily driven by lower costs per case.

For the nine months ended September 30, 2017, gross margin percentage declined as compared to the same period in 2016 primarily due to an increase in aligners per case driven by additional aligners and lower ASP.

Scanner

For the three ended September 30, 2017, gross margin increased compared to the same period in 2016 primarily driven by lower service costs. This was partially offset by a lower ASP.

For the nine months ended September 30, 2017, gross margin increased compared to the same period in 2016 primarily due to a favorable product mix shift to our lower cost iTero Element scanner.

Selling, general and administrative (in millions):

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2017	2016	Change	2017	2016	Change
Selling, general and administrative	\$ 169.5	\$ 126.7	\$ 42.8	\$ 483.6	\$ 360.4	\$ 123.2
<i>% of net revenues</i>	44.0%	45.5%		46.0%	45.8%	

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, marketing and administration in addition to media and advertising expenses, clinical education, trade shows and industry events, product marketing, outside consulting services, equipment and maintenance costs, depreciation and amortization expense and allocations of corporate overhead expenses including facilities and IT.

For the three months ended September 30, 2017, selling, general and administrative expense increased compared to the same period in 2016 primarily due to higher compensation related costs of \$23.8 million mainly as a result of increased headcount. We also incurred higher expenses from equipment and maintenance costs of \$6.6 million, advertising and marketing of \$5.5 million, and outside services costs of \$4.2 million.

For the nine months ended September 30, 2017, selling, general and administrative expense increased compared to the same period in 2016 primarily due to higher compensation related costs of \$57.9 million mainly as a result of increased headcount. We also incurred higher expenses from advertising and marketing of \$23.9 million, equipment and maintenance costs of \$17.5 million, and outside services costs of \$15.4 million.

Research and development (in millions):

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2017	2016	Change	2017	2016	Change
Research and development	\$ 24.2	\$ 20.4	\$ 3.8	\$ 71.4	\$ 54.1	\$ 17.3
% of net revenues	6.3%	7.3%		6.8%	6.9%	

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

Research and development expense includes the personnel-related costs including payroll and 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.

For the three and nine months ended September 30, 2017, research and development expense increased compared to the same periods in 2016 primarily due to higher compensation costs as a result of increased headcount.

Income from operations (in millions):

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2017	2016	Change	2017	2016	Change
Clear Aligner						
Income from operations	\$ 154.6	\$ 102.4	\$ 52.2	\$ 403.3	\$ 306.8	\$ 96.5
Operating margin %	45.3%	42.0%		42.7%	43.4%	
Scanner						
Income from operations	\$ 13.5	\$ 12.0	\$ 1.5	\$ 28.3	\$ 20.3	\$ 8.0
Operating margin %	31.0%	34.3%		26.5%	25.5%	
Total income from operations ⁽¹⁾	\$ 98.8	\$ 62.1	\$ 36.7	\$ 244.0	\$ 180.5	\$ 63.5
Operating margin %	25.6%	22.3%		23.2%	23.0%	

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

⁽¹⁾ Refer to Note 14 "Segments and Geographical Information" of the Notes to Condensed Consolidated Financial Statements for details on unallocated corporate expenses and the reconciliation to consolidated income from operations.

Clear Aligner

For the three months ended September 30, 2017, operating margin percentage increased compared to the same period in 2016 primarily due to greater Invisalign revenues and higher operating margin from sales to SDC, lower costs per case, partially offset by higher compensation related costs and marketing expenses.

For the nine months ended September 30, 2017, operating margin percentage declined compared to the same period in 2016 due to higher marketing spend and, to a lesser extent, lower ASP, partially offset by a higher operating margin from sales to SDC.

Scanner

For the three ended September 30, 2017, operating margin percentage decreased compared to the same period in 2016 due to higher operating expenses along with a lower ASP. This was partially offset by lower service costs.

For the nine months ended September 30, 2017, operating margin percentage increased compared to the same period in 2016 due to a favorable product mix shift to our lower cost iTero Element scanner.

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

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2017	2016	Change	2017	2016	Change
Interest and other income (expenses), net	\$ 3.8	\$ 1.5	\$ 2.3	\$ 8.6	\$ 1.2	\$ 7.4

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 revaluation 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.

For the three and nine months ended September 30, 2017, interest and other income (expenses), net increased compared to the same periods in 2016 mainly due to higher foreign exchange gains as a result of the Euro strengthening to the U.S. dollar.

Equity in losses of investee, net of tax (in millions):

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2017	2016	Change	2017	2016	Change
Equity in losses of investee, net of tax	\$ 1.6	\$ 0.5	\$ 1.1	\$ 5.0	\$ 0.5	\$ 4.5

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

For the three and nine months ended September 30, 2017, equity in losses of investee, net of tax increased compared to the same periods in 2016 due to higher losses attributable to equity method investments including a higher share due to an additional investment in the third quarter of 2017 (Refer to Note 4 "Equity Method Investments" of the Notes to Condensed Consolidated Financial Statements for details on equity method investments).

Income tax (in millions):

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2017	2016	Change	2017	2016	Change
Provision for income taxes	\$ 18.3	\$ 11.7	\$ 6.6	\$ 26.5	\$ 39.2	\$ (12.7)
Effective tax rates	17.9%	18.4%		10.5%	21.6%	

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For the three months ended September 30, 2017 and 2016, provision for income taxes was \$18.3 million and \$11.7 million, respectively, representing effective tax rates of 17.9% and 18.4%, respectively. Our provision for income taxes was \$26.5 million and \$39.2 million for the nine months ended September 30, 2017 and 2016, respectively, representing effective tax rates of 10.5% and 21.6%, respectively. The decrease in effective tax rate for the three months ended September 30, 2017 compared to the same period in 2016 is primarily attributable to the adoption of ASU 2016-09 in 2017 which requires excess tax benefits related to stock-based compensation to be recognized as a reduction of income tax expense, and certain one-time tax charges recognized as a result of the implementation of the international corporate restructure on July 1, 2016 that is no longer pertinent to the current period. The decrease in effective tax rate for the nine months ended September 30, 2017 compared to the same period in 2016 is primarily attributable to the adoption of ASU 2016-09 in the first quarter of fiscal year 2017, which requires excess tax benefits related to stock-based compensation to be recognized as a reduction of income tax expense. In addition, the effective tax rate for the prior period was increased due to certain one-time tax charges recognized as a result of the implementation of the international corporate restructure during the third quarter of fiscal year 2016. For the three and nine months ended September 30, 2017, we recognized excess tax benefits of \$1.7 million and \$24.1 million, respectively, in our provision for income taxes.

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

In June 2017, the Costa Rica Ministry of Foreign Trade, an agency of the Government of Costa Rica, granted an extension of certain income tax incentives for an additional twelve year period, which were originally granted in 2002 and was set to expire in June 2017. Under these incentives, all of the income in Costa Rica 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 2017 and 2016. For the three and nine months ended September 30, 2017, the reduction in income taxes was minimal primarily due to the new international corporate structure implemented on July 1, 2016. For the three and nine months ended September 30, 2016, income taxes were reduced by \$0.3 million with minimal impact to diluted net income per share and \$17.5 million representing a benefit to diluted net income per share of \$0.21, respectively (Refer to Note 12 "Accounting for Income Taxes" for details on income taxes).

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, 2017 and December 31, 2016, we had the following cash, cash equivalents, and short-term and long-term marketable securities (in thousands):

	September 30, 2017	December 31, 2016
Cash and cash equivalents	\$ 362,613	\$ 389,275
Short-term marketable securities	316,454	250,981
Long-term marketable securities	58,842	59,783
Total	<u>\$ 737,909</u>	<u>\$ 700,039</u>

Cash flows (in thousands):

	Nine Months Ended September 30,	
	2017	2016
Net cash flow provided by (used in):		
Operating activities	\$ 276,213	\$ 166,674
Investing activities	(228,620)	142,859
Financing activities	(79,036)	(57,619)
Effect of exchange rate changes on cash and cash equivalents	4,781	320
Net increase (decrease) in cash and cash equivalents	<u>\$ (26,662)</u>	<u>\$ 252,234</u>

As of September 30, 2017, we had \$737.9 million in cash, cash equivalents and short-term and long-term marketable securities. Cash equivalents and marketable securities are comprised of money market funds and highly liquid debt instruments which primarily include commercial paper, corporate bonds, U.S. government agency bonds, U.S. government treasury bonds and certificates of deposit.

As of September 30, 2017, approximately \$501.6 million of cash, cash equivalents and short-term and long-term marketable securities was held by our foreign subsidiaries. Amounts held by foreign subsidiaries are generally subject to U.S. income taxation on repatriation to the U.S. The costs to repatriate our foreign earnings to the U.S. would likely be material; however, our intent is to permanently reinvest our earnings from foreign operations, and our current plans do not require us to repatriate them to fund our U.S. operations as we generate sufficient domestic operating cash flow and have access to external funding under our current revolving line of credit.

Stock Repurchases

Refer to Note 11 "Common Stock Repurchase Program" of the Notes to Condensed Consolidated Financial Statements for details on stock repurchase program.

April 2016 Repurchase Program. On April 28, 2016, we announced that our Board of Directors had authorized a plan to repurchase up to \$300.0 million of our stock. On May 2, 2017, we entered into an accelerated share repurchase ("ASR") to repurchase \$50.0 million of our common stock ("2017 ASR"). The 2017 ASR was completed on August 3, 2017. 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. We received a total of approximately 0.4 million shares at a weighted average share price of \$146.48 under the 2017 ASR. All repurchased shares were retired. As of September 30, 2017, we have \$250.0 million remaining under the April 2016 Repurchase Plan.

Operating Activities

For the nine months ended September 30, 2017, cash flows from operations of \$276.2 million resulted primarily from our net income of approximately \$221.2 million as well as the following:

Significant non-cash activities

- Stock-based compensation was \$44.0 million related to equity incentive compensation granted to employees and directors,
- Depreciation and amortization of \$26.7 million related to our property, plant and equipment and intangible assets, and
- Net change in deferred tax assets of \$5.5 million.

Significant changes in working capital

- Increase of \$84.4 million in accounts receivable which is primarily a result of the increase in net revenues,
- Increase of \$53.2 million in deferred revenues corresponding to the increases in case shipments, and
- Increase of \$19.0 million in accrued and other long-term liabilities due to timing of payments and activities.

Investing Activities

Net cash used in investing activities was \$228.6 million for the nine months ended September 30, 2017 primarily consisted of purchases of marketable securities of \$356.9 million, property and plant and equipment purchases of \$126.2 million, of which \$63.0 million is related to the purchase of our new headquarters along with building improvements, \$23.0 million of loan advances to equity investee and \$9.0 million paid for certain distributor acquisitions, net of cash received. These outflows were partially offset by maturities and sales of marketable securities of \$292.8 million and loan repayment from equity investee of \$6.0 million.

For the remainder of 2017, we expect to invest an additional \$55.0 million to \$60.0 million on capital expenditures primarily related to additional manufacturing capacity to support our international expansion. 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 \$79.0 million for the nine months ended September 30, 2017 primarily resulting from common stock repurchases of \$53.8 million and payroll taxes paid for vesting of restricted stock units through share withholdings of \$39.1 million. These outflows were offset in part by \$13.9 million from proceeds from the issuance of common stock.

Contractual Obligations

Our contractual obligations have not significantly changed since December 31, 2016 as disclosed in our Annual Report on Form 10-K, other than obligations described in the Form 10-Q herein. 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.

Off-Balance Sheet Arrangements

As of September 30, 2017, 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.

Critical Accounting Policies and Estimates

Management's discussion and analysis of our financial condition and results of operations is based upon our Condensed Consolidated Financial Statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of condensed consolidated financial statements requires management to make estimates and judgments that affect the reported amounts of assets and liabilities, 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, stock-based compensation, goodwill and finite-lived assets and related impairment, 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 and estimates affect our more significant judgments 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, 2016:

- 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, 2017, we had approximately \$566.1 million invested in available-for-sale marketable securities. An immediate 10% change in interest rates would not have a material adverse impact on our future operating results and cash flows.

We do not enter into investments for trading or speculative purposes and have not used any derivative financial instruments to manage our interest rate risk exposure. We do not have interest bearing liabilities as of September 30, 2017, and, therefore, we are not subject to risks from immediate interest rate increases.

Currency Rate Risk

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 currency hedging transactions in an effort to cover some of our exposure to foreign currency exchange 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, 2017, we did not have any outstanding foreign exchange forward contracts.

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, 2017, 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 Securities and Exchange Commission rules and forms.

Changes in internal control over financial reporting.

There were no changes in our internal control over financial reporting during the quarter ended September 30, 2017 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

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 (*Refer to Note 8 "Legal Proceedings" of the Notes to Condensed Consolidated Financial Statement s* for details on legal proceedings).

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 for any reason, including as a result of a shift in product mix towards lower priced products, our operating results would be harmed.

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, Dentsply Sirona Inc., Straumann Group and 3M, have substantially greater financial resources and manufacturing and marketing experience than we do. In addition, as a result of the expiration of certain key patents owned by us, commencing in 2017, we expect that these existing competitors as well as new entrants into the clear aligner market will begin offering an orthodontic system more similar to ours in the near future. Several of these competitors will likely have greater resources as well as the ability to leverage their existing channels in the dental market to compete directly with us, and therefore our share of the clear aligner market could decline which would likely have a material adverse effect on our business, results of operation and financial condition. In addition, corresponding foreign patents will start to expire in 2018 which will likely result in increased competition in some of the markets outside the U.S. Large consumer product companies may also enter the orthodontic supply market. Furthermore, we also face competition from companies that now offer clear aligner therapy directly to the consumer eliminating the need for the consumer to visit a dental office. In addition, we may also 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 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.

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. 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, and we also have order acquisition for the EMEA region at our facility in Amsterdam, the Netherlands. We will continue to establish additional order acquisition and treatment planning facilities closer to our international customers in order to improve our operational efficiency. In addition to the research and development efforts conducted in our North America facilities, we also carry out research and development in Moscow, Russia. We also have customer-care, accounts receivable, credit and collections, customer event registration and accounts payable organizations located at our facility in San Jose, Costa Rica. In addition, we have operations in Israel where the design and wand are assembled and our intraoral scanner is 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;
- 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.

In addition, President Donald Trump and his administration have made statements regarding the possibility of changing the way in which international operations of U.S. companies are taxed, including through the implementation of a border tax, tariff or increase in custom duties on products manufactured in countries outside of the U.S., such as Mexico, and imported into the U.S. In the event such taxes, tariffs, increased custom duties or other measures are implemented, they could have a materially adverse effect on our business and or operating results, and we may have to consider relocating some of our international operations.

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.

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

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 certain countries within 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, which could materially impact our international operations and adversely affect our business as a whole.

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 intraoral 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 change the volume-based discount accounting that affects our average selling 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; or 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.

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 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 are establishing additional order acquisition and treatment planning facilities closer to our international customers in order to improve our operational efficiency and provide doctors with a better experience to further improve their confidence in using Invisalign to treat more patients, more often. Our ability to plan, construct and equip additional order acquisition, treatment planning and manufacturing facilities is subject to significant risk and uncertainty, including risks inherent in the establishment of a 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 these additional facilities 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 facility 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 intraoral 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 not in the past and may not in the future 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 including limited visibility into the number of aligners purchased by SmileDirectClub, LLC ("SDC") under the supply agreement from quarter to quarter;
- weakness in consumer spending as a result of the slowdown in the U.S. economy and global economies;
- changes in relationships with our distributors;

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- 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;
- 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 intraoral 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 of our agreement to manufacture clear aligners for SDC, including market acceptance of the SDC business model and product, possible adverse customer reaction and negative publicity about us and our products;
- impairments in the value of our strategic investments in SDC and other privately held companies could be material;
- 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;
- changes in accounting standards, policies and estimates including changes made by our equity investee; and
- our ability to successfully hedge against a portion of our foreign currency-denominated assets and liabilities.

To respond to these and other factors, we may need to make business decisions that could adversely affect our operating results such as modifications to our pricing policy, business structure or operations. Most of our expenses, such as employee compensation

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

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

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

- correctly identify customer needs and preferences and predict future needs and preferences;
- include functionality and features that address customer requirements;
- 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.

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 time frame 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 primarily 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 corporate 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 a multi-year, company-wide program to transform certain business processes or extend established processes which includes the transition to a new enterprise resource planning ("ERP") software system. 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, if we are not able to accurately forecast expenses 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 or our cloud-based software servers hosted by third party and misappropriate our confidential information or that of third parties, create system disruptions or cause shutdowns. Furthermore, sophisticated hardware and operating system software and applications that we either internally develop or procure from third parties which we depend upon may contain defects in design and manufacture, including "bugs" and other problems that can unexpectedly interfere with the operation of the system. The costs to eliminate or alleviate security problems, viruses and bugs could be significant, and the efforts to address these problems could result in interruptions that may have a material adverse impact on our operations, net revenues and operating results.

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

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. We have experienced such breaches in the past and our security measures may be inadequate to prevent security breaches, and our business operations and profitability would be adversely affected by, among other things, loss of customers and potential criminal and civil sanctions if they are not prevented.

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

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

We retain confidential customer and patient information in our processing centers. Therefore, it is critical that our facilities and infrastructure remain secure and that our facilities and infrastructure are perceived by the marketplace and our customers to be secure. Despite the implementation of security measures, we have experienced such breaches in the past and 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 customer and patient's expectations regarding the security of healthcare information, we could be liable for damages and our reputation could be impaired. In addition, patient care could suffer, and we could be liable if our systems fail to deliver correct information in a timely manner. Our insurance may not protect us from this risk.

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

Our success will depend in part on our ability to maintain existing intellectual property and to obtain and maintain further intellectual property protection for our products, both in the U.S. and in other countries. Our inability to do so could harm our competitive position. As of September 30, 2017, we had issued 454 U.S. patents, 447 foreign issued patents, and 402 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, interferences, oppositions, inter partes reviews or other proceedings are, have been and may in the future be necessary in some instances to determine the validity and scope of certain of our proprietary rights, and in other instances to determine the validity, scope or non-infringement of certain patent rights claimed by third parties to be pertinent to the manufacture,

use or sale of our products. Litigation, interference, oppositions, inter partes reviews, administrative challenges or other similar types of proceedings are unpredictable and may be protracted, expensive and distracting to management. The outcome of such proceedings could adversely affect the validity and scope of our patent or other proprietary rights, hinder our ability to manufacture and market our products, require us to seek a license for the infringed product or technology or result in the assessment of significant monetary damages. 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 including our transition of further business operations into our ERP software system, and, as a result, the degree of compliance of our internal control over financial reporting with the existing policies or procedures may become ineffective. Establishing, testing and maintaining an effective system of internal control over financial reporting requires significant resources and time commitments on the part of our management and our finance staff, may require additional staffing and infrastructure investments and would increase our costs of doing business. If we are unable to assert that our internal control over financial reporting is effective in any future period (or if our auditors are unable to express an opinion on the effectiveness of our internal controls or conclude that our internal controls are ineffective), we could lose investor confidence in the accuracy and completeness of our financial reports, which could have an adverse effect on our stock price.

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

We are highly dependent on the key employees in our clinical engineering, technology development, sales, training and marketing personnel and management teams. The loss of the services provided by those individuals may significantly delay or prevent the achievement of our product development and other business objectives and could harm our business. Our future success will also depend on our ability to identify, recruit, train and retain additional qualified personnel, including orthodontists. Few orthodontists are accustomed to working in a manufacturing environment since they are generally trained to work in private practices, universities and other research institutions. Thus, we may be unable to attract and retain personnel with the advanced qualifications necessary for the further development of our business. Furthermore, we may not be successful in retaining our key personnel or their services. If we are unable to attract and retain key personnel, our business could be materially harmed.

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 intraoral 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 intraoral 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 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.

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, 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, Congress passed health care reform legislation that was 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.

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.

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.

We are subject to risks associated with our strategic investments. Impairments in the value of our investments and related loan could negatively impact our financial results.

We have invested in SmileDirectClub, LLC ("SDC") and other privately held companies for strategic reasons and to support key business initiatives, and we may not realize a return on our strategic investments. Many of such companies generate net losses and the market for their products, services or technologies may be slow to develop. Further, valuations of privately held companies are inherently complex due to the lack of readily available market data. If we determine that our investments and related loan in SDC or other privately held companies have experienced a decline in value, we may be required to record impairments, which could be material and could have an adverse impact on our financial results.

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 stock-based compensation, 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 an 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, new or changes to accounting pronouncements, 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-based compensation, settlement of income tax audits, and changes in overall levels of pretax earnings. With the adoption of ASU 2016-09, we also anticipate our first quarter effective tax rate to vary significantly due to the timing of when majority of our equity compensation vests each year. Other quarters can also be impacted depending on the timing of equity vests. Our subsidiary in Israel is under audit by the local tax authorities for calendar years 2006 through 2013.

In addition, our tax rate may be impacted by tax holidays or incentives. In June 2017, the Costa Rica Ministry of Foreign Trade, an agency of the Government of Costa Rica, granted an extension of certain income tax incentives for an additional twelve year period, which was originally granted in 2002 and was set to expire in June 2017. 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 2017 and 2016. For the three and nine months ended September 30, 2017, the new corporate structure implemented on July 1, 2016 had a minimal impact on income taxes. For the three and nine months ended September 30, 2016, income taxes were reduced by \$0.3 million with minimal impact to diluted net income per share and \$17.5 million representing a benefit to diluted net income per share of \$0.21, 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 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.

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, 2017 :

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, 2017 through July 31, 2017	—	\$ —	—	\$ 250,000,000
August 1, 2017 through August 31, 2017	80,387	\$ 186.60	80,387	\$ 250,000,000
September 1, 2017 through September 30, 2017	—	\$ —	—	\$ 250,000,000

⁽¹⁾ On April 28, 2016, we announced that our Board of Directors had authorized a plan to repurchase up to \$300.0 million of our stock under our April 2016 Repurchase Program. On May 2, 2017, we entered into an accelerated share repurchase ("ASR") to repurchase \$50.0 million of our common stock ("2017 ASR"). The 2017 ASR was completed on August 3, 2017. 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. We received a total of approximately 0.4 million shares at a weighted average share price of \$146.48 under the 2017 ASR. All repurchased shares were retired. As of September 30, 2017, we have \$250.0 million remaining under the April 2016 Repurchase Plan.

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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<u>Exhibit Number</u>	<u>Description</u>	<u>Filing</u>	<u>Date</u>	<u>Exhibit Number</u>	<u>Filed here with</u>
10.1	Purchase and Sale Agreement dated July 24, 2017 between Align Technology de Costa Rica, S.R.L. and Belan Business Center, S.A.	Form 8-K	7/27/2017	10.1	
10.2	Membership Interest Purchase Agreement dated July 24, 2017 between Align Technology, Inc. and SmileDirectClub, LLC.	Form 8-K	7/27/2017	10.2	
10.3	First Amendment to Loan and Security Agreement dated July 24, 2017 between Align Technology, Inc. and SmileDirectClub, LLC.	Form 8-K	7/27/2017	10.3	
10.4	Sixth Amendment to Credit Agreement dated July 24, 2017 between Align Technology, Inc. and Wells Fargo Bank, National Association	Form 8-K	7/27/2017	10.4	
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 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				*

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 2, 2017

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

By: _____
/s/ JOHN F. MORICI
John F. Morici
Chief Financial Officer

EXHIBIT INDEX

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CERTIFICATION

I, Joseph M. Hogan, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Align Technology, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 2, 2017

/s/ JOSEPH M. HOGAN

Joseph M. Hogan
President and Chief Executive Officer

CERTIFICATION

I, John F. Morici, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Align Technology, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 2, 2017

/s/ JOHN F. MORICI

John F. Morici

Chief Financial Officer

