

ALIGN TECHNOLOGY INC  
Form 10-Q  
October 29, 2015  
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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, 2015  
OR

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

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

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

Delaware  
(State or other jurisdiction of incorporation or organization)  
2560 Orchard Parkway  
San Jose, California 95131  
(Address of principal executive offices)  
(408) 470-1000  
(Registrant's telephone number, including area code)

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

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

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

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

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

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

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

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## PART I—FINANCIAL INFORMATION

## ITEM 1 FINANCIAL STATEMENTS

## ALIGN TECHNOLOGY, INC.

## CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per share data)

(unaudited)

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

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

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ALIGN TECHNOLOGY, INC.

## CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

(in thousands)

(unaudited)

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

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

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

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

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

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

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

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ALIGN TECHNOLOGY, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(unaudited)

Note 1. Summary of Significant Accounting Policies

Basis of presentation

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

The results of operations for the three and nine months ended September 30, 2015 are not necessarily indicative of the results that may be expected for the year ending December 31, 2015 or any other future period, and we make no representations related thereto. The information included in this Quarterly Report on Form 10-Q should be read in conjunction with “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” “Quantitative and Qualitative Disclosures About Market Risk” and the Consolidated Financial Statements and notes thereto included in Items 7, 7A and 8, respectively, in our Annual Report on Form 10-K for the year ended December 31, 2014.

Use of estimates

The preparation of financial statements in conformity with generally accepted accounting principles (“GAAP”) in the United States of America (“U.S.”) requires our management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. Actual results could differ materially from those estimates. On an ongoing basis, we evaluate our estimates, including those related to the fair values of financial instruments, long-lived assets and goodwill, useful lives of intangible assets and property and equipment, revenue recognition, stock-based compensation, income taxes, and contingent liabilities, among others. We base our estimates on historical experience and on various other assumptions that are believed to be reasonable, the results of which form the basis for making judgments about the carrying values of assets and liabilities.

Revenue Recognition

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

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



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

#### Derivative Financial Instruments

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

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

## Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2014-09, "Revenue from Contracts with Customers," requiring an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers. The updated standard will replace most existing revenue recognition guidance in U.S. GAAP when it becomes effective and permits the use of either the retrospective or cumulative effect transition method. In July 2015, the FASB voted to defer the effective date for annual reporting periods beginning after December 15, 2017 (including interim reporting periods within those periods) and permitted early adoption of the standard, but not before the original effective date of December 15, 2016. We expect the updated standard to become effective for us in the first quarter of fiscal 2018. We have not yet selected a transition method and we are currently evaluating the effect that the updated standard will have on our consolidated financial statements and related disclosures.

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

## Note 2. Marketable Securities and Fair Value Measurements

As of September 30, 2015 and December 31, 2014, the estimated fair value of our short-term and long-term marketable securities, classified as available for sale, are as follows (in thousands):

## Short-term

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

## Long-term

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

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

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## Short-term

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

## Long-term

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

For the three and nine months ended September 30, 2015 and 2014, realized gains were immaterial. Unrealized gains and losses for our available for sale securities as of September 30, 2015 and December 31, 2014 were also immaterial. Cash and cash equivalents are not included in the table above as the gross unrealized gains and losses are not material. We have no material short-term or long-term investments that have been in a continuous unrealized loss position for greater than twelve months as of September 30, 2015 and December 31, 2014. Amounts reclassified to earnings from accumulated other comprehensive income related to unrealized gain or losses were immaterial for the three and nine months ended September 30, 2015 and 2014.

Our fixed-income securities investment portfolio consists of corporate bonds, certificates of deposits, U.S. dollar dominated foreign corporate bonds, commercial paper, municipal securities, U.S. government agency bonds, U.S. government treasury bonds and asset-backed securities that have a maximum maturity of 27 months. The securities that we invest in are generally deemed to be low risk based on their credit ratings from the major rating agencies. The longer the duration of these securities, the more susceptible they are to changes in market interest rates and bond yields. As interest rates increase, those securities purchased at a lower yield show a mark-to-market unrealized loss. The unrealized losses are due primarily to changes in credit spreads and interest rates. We expect to realize the full value of all these investments upon maturity or sale. The weighted average remaining duration of these securities was approximately 10 and 11 months as of September 30, 2015 and December 31, 2014, respectively.

As the carrying value approximates the fair value for our short-term and long-term marketable securities shown in the tables above, the following table summarizes the fair value of our short-term and long-term marketable securities classified by maturity as of September 30, 2015 and December 31, 2014 (in thousands):

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

### Fair Value Measurements

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

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an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. The three levels of inputs that may be used to measure fair value:

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

Our Level 1 assets consist of money market funds and U.S. government treasury bonds.

Level 2 — Observable inputs other than quoted prices included in Level 1, such as quoted prices for similar assets or liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the asset or liability.

Our Level 2 assets consist of commercial paper, corporate bonds, certificates of deposits, U.S. government agency bonds, asset-backed securities, municipal securities, U.S. dollar dominated foreign corporate bonds and our Israeli funds that are mainly invested in insurance policies and foreign currency forward contracts. We obtain fair values for Level 2 investments from our asset manager for each of our portfolios. Our custody bank and asset managers independently use professional pricing services to gather pricing data which may include quoted market prices for identical or comparable financial instruments, or inputs other than quoted prices that are observable either directly or indirectly, and we are ultimately responsible for these underlying estimates. The foreign currency forward contracts are valued using observable inputs such as quotations on forward foreign exchange rates.

Level 3 — Unobservable inputs to the valuation methodology that are supported by little or no market activity and that are significant to the measurement of the fair value of the assets or liabilities. Level 3 assets and liabilities include those whose fair value measurements are determined using pricing models, discounted cash flow methodologies or similar valuation techniques, as well as significant management judgment or estimation.

#### Recurring Fair Value Measurements

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

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

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

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

## Derivative Financial Instruments

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

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

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



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

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## Note 3. Balance Sheet Components

## Inventories

Inventories consist of the following (in thousands):

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

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

## Accrued liabilities

Accrued liabilities consist of the following (in thousands):

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

## Warranty

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

## Clear Aligner

We warrant our Invisalign products against material defects until the Invisalign case is complete. We accrue for warranty costs in cost of net revenues upon shipment of products. The amount of accrued estimated warranty costs is primarily based on historical experience as to product failures as well as current information on replacement costs.

## Scanners

We warrant our scanners for a period of one year from the date of training and installation. We accrue for these warranty costs which includes materials and labor based on estimated historical repair costs. Extended service

packages may be purchased for additional fees.

Warranty accrual as of September 30, 2015 and 2014 consists of the following activity (in thousands):

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

## Note 4. Goodwill and Long-lived Assets

## Goodwill

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

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

Balance as of December 31, 2014	Clear Aligner \$61,369
Adjustments <sup>1</sup>	(391
Balance as of September 30, 2015	\$60,978

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

During the fourth quarter of fiscal 2014, we performed the annual goodwill impairment testing and found no impairment events as the fair value of our Clear Aligner reporting unit was significantly in excess of the carrying value.

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

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

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

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

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

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

## Note 5. Credit Facilities

On March 22, 2013, we entered into a credit facility, which provides for a \$50.0 million revolving line of credit, with a \$10.0 million letter of credit sublimit, and has a maturity date on March 22, 2016. The credit facility also requires us to maintain a minimum unrestricted cash balance of \$50.0 million and comply with specific financial conditions and performance requirements. The loan bears interest, at our option, at a fluctuating rate per annum equal to the daily one-month adjusted LIBOR rate plus a spread of 1.75% or an adjusted LIBOR rate (based on one, three, six or twelve-month interest periods) plus a spread of 1.75%. As of September 30, 2015, we had no outstanding borrowings under this credit facility; however, we were not in compliance with certain negative covenants. As a result, on October 15, 2015, we received a waiver for our non-compliance and also amended the credit facility in regards to these negative covenants.

## Note 6. Legal Proceedings

## Securities Class Action Lawsuit

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

### Shareholder Derivative Lawsuit

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

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entered staying this derivative lawsuit until an initial ruling on our first motion to dismiss the Securities Action. On January 15, 2014, an Order was entered staying this derivative lawsuit until an initial ruling on our second motion to dismiss the Securities Action. On October 14, 2014, an Order was entered staying this derivative lawsuit until a ruling by the Ninth Circuit in the Securities Action discussed above. Align is currently unable to predict the outcome of this complaint and therefore cannot determine the likelihood of loss nor estimate a range of possible losses.

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

## Note 7. Commitments and Contingencies

## Operating Leases

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

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

## Off-balance Sheet Arrangements

As of September 30, 2015, we had no off-balance sheet arrangements that have, or are reasonably likely to have, a current or future material effect on our consolidated financial condition, results of operations, liquidity, capital expenditures or capital resources.

## Indemnification Provisions

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

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



indemnification claims arise in the future, future payments by us could be significant and could have a material adverse effect on our results of operations or cash flows in a particular period. As of September 30, 2015, we did not have any material indemnification claims that were probable or reasonably possible.

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## Note 8. Stock-based Compensation

## Summary of stock-based compensation expense

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

Stock-based compensation is based on the estimated fair value of awards, net of estimated forfeitures, and recognized over the requisite service period. Estimated forfeitures are based on historical experience at the time of grant and may be revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. The stock-based compensation related to all of our stock-based awards and employee stock purchases for the three and nine months ended September 30, 2015 and 2014 is as follows (in thousands):

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

## Options

Activity for the nine months ended September 30, 2015 under the stock option plans is set forth below (in thousands, except years and per share amounts):

	Stock Options Number of Shares Underlying Stock Options	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Term (in years )	Aggregate Intrinsic Value
Outstanding as of December 31, 2014	668	\$ 15.57		
Granted	—	—		
Exercised	(129	) 16.47		
Cancelled or expired	—	—		
Outstanding as of September 30, 2015	539	\$ 15.36	2.28	\$22,300
Vested and expected to vest at September 30, 2015	539	\$ 15.36	2.28	\$22,300
Exercisable at September 30, 2015	539	\$ 15.36	2.28	\$22,300

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

## Restricted Stock Units (“RSU”)

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

Number of Shares Underlying RSU	Weighted Average Grant	Weighted Remaining	Aggregate Intrinsic
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		Date Fair Value	Contractual Period (in years)	Value
Nonvested as of December 31, 2014	2,124	\$42.08		
Granted	835	57.72		
Vested and released	(661	) 36.77		
Forfeited	(80	) 47.48		
Nonvested as of September 30, 2015	2,218	\$49.39	1.34	\$125,883

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

We have granted market-performance based restricted stock units ("MSU") to our executive officers. Each MSU represents the right to one share of Align's common stock and will be issued through our amended 2005 Incentive Plan. The actual number of MSU which will be eligible to vest will be based on the performance of Align's stock price relative to the performance of the NASDAQ Composite Index over the vesting period, generally two to three years, up to 150% of the MSU initially granted.

The following table summarizes the MSU activity for the nine months ended September 30, 2015 (in thousands, except years):

	Number of Shares Underlying MSU	Weighted Average Grant Date Fair Value	Weighted Average Remaining Contractual Period (in years )	Aggregate Intrinsic Value
Nonvested as of December 31, 2014	498	\$42.00		
Granted	289	61.73		
Vested and released	(162	) 30.28		
Forfeited	(14	) 53.69		
Nonvested as of September 30, 2015	611	\$51.41	1.55	\$34,689

As of September 30, 2015, the total unamortized compensation costs related to the MSU, net of estimated forfeitures, was \$16.2 million, which we expect to recognize over a weighted average period of 1.6 years.

## Employee Stock Purchase Plan ("ESPP")

In May 2010, our stockholders approved the 2010 Employee Stock Purchase Plan ("2010 Purchase Plan") which will continue until terminated by either the Board of Directors or its administrator. The maximum number of shares available for purchase under the 2010 Purchase Plan is 2,400,000 shares. As of September 30, 2015, there remains 1,133,749 shares available for purchase under the 2010 Purchase Plan.

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

	Three Months Ended September 30,		Nine Months Ended September 30,		
	2015	2014	2015	2014	
Expected term (in years)	1.2	1.3	1.2	1.2	
Expected volatility	27.9	% 35.8	% 31.1	% 38.8	%
Risk-free interest rate	0.41	% 0.24	% 0.29	% 0.20	%
Expected dividends	—	—	—	—	
Weighted average fair value at grant date	\$17.10	\$16.44	\$16.19	\$17.15	

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

## Note 9. Common Stock Repurchase

On April 23, 2014, we announced that our Board of Directors had authorized a stock repurchase program pursuant to which we may purchase up to \$300.0 million of our common stock over the next three years, with \$100.0 million

authorized over the first 12 months. Any purchases under this stock repurchase program may be made, from time-to-time, pursuant to open market purchases (including pursuant to Rule 10b5-1 plans), privately-negotiated transactions, accelerated stock repurchases, block trades or derivative contracts or otherwise in accordance with applicable federal securities laws, including Rule 10b-18 of the Securities Exchange Act of 1934.

As part of our \$300.0 million stock repurchase program, on April 28, 2014, we entered into an accelerated share repurchase agreement ("2014 ASR") to repurchase \$70.0 million of our common stock which was completed in July 2014. We received a total of approximately 1.4 million shares under the 2014 ASR for an average purchase price per share of \$51.46, which all shares

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were retired. The final number of shares repurchased was based on our volume-weighted average stock price during the term of the transaction, less an agreed upon discount.

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

In January 2015, our Board of Directors authorized the repurchase of the next \$100.0 million under the repurchase program which we anticipate completing within twelve months. On April 28, 2015, we entered into an accelerated share purchase agreement ("2015 ASR") to repurchase \$70.0 million of our common stock. Under the terms of the 2015 ASR, we paid \$70.0 million on April 29, 2015 and received an initial delivery of approximately 0.8 million shares. The 2015 ASR was completed on July 23, 2015 with a final delivery of approximately 0.3 million shares. We received a total of approximately 1.2 million shares under the 2015 ASR for an average share price of \$60.52, which all shares were retired. The final number of shares repurchased was based on our volume-weighted average stock price during the term of the transaction, less an agreed upon discount.

During the three months ended September 30, 2015, we repurchased on the open market approximately 0.3 million shares of our common stock at an average price of \$57.04 per share, including commissions, for an aggregate purchase price of approximately \$18.8 million. All repurchased shares were retired. As of September 30, 2015, we have \$111.2 million remaining under the April 2014 stock repurchase program, \$11.2 million of which we expect to purchase within the next six months.

Note 10. Accounting for Income Taxes

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

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

We exercise significant judgment in regards to estimates of future market growth, forecasted earnings and projected taxable income in determining the provision for income taxes, and for purposes of assessing our ability to utilize any future benefit from deferred tax assets.

As of September 30, 2015, we maintained a valuation allowance of \$32.8 million against deferred tax assets primarily related to Israel and California operating loss carryforwards and Australia capital loss carryforwards. These net operating and capital loss carryforwards would result in an income tax benefit if we were to conclude it is more likely than not that the related deferred tax assets will be realized.

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Our total gross unrecognized tax benefits was \$37.8 million and \$33.1 million as of September 30, 2015 and December 31, 2014, respectively, all of which would impact our effective tax rate if recognized. We have elected to recognize interest and penalties related to unrecognized tax benefits as a component of income taxes. The change in accrued interest and penalties during the three and nine months ended September 30, 2015 was not material. We do not expect any significant changes to the amount of unrecognized tax benefit within the next twelve months.

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

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

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years beginning in 2017. Under these incentives, all of the income in Costa Rica during these twelve year incentive periods is subject to reduced rate of Costa Rica income tax. In order to receive the benefit of these incentives, we must hire specified numbers of employees and maintain certain minimum levels of fixed asset investment in Costa Rica. If we do not fulfill these conditions for any reason, our incentive could lapse, and our income in Costa Rica would be subject to taxation at higher rates, which could have a negative impact on our operating results. The Costa Rica corporate income tax rate that would apply, absent the incentives, is 30% for 2015 and 2014. Income taxes were reduced by \$8.2 million and \$7.7 million for the three months ended September 30, 2015 and 2014, respectively, representing a benefit to diluted net income per share of \$0.10 and \$0.09 in 2015 and 2014, respectively. As a result of these incentives, our income taxes were reduced by \$24.6 million and \$22.8 million for the nine months ended September 30, 2015 and 2014, respectively, representing a benefit to diluted net income per share of \$0.30 and \$0.28 in 2015 and 2014, respectively.

## Note 11. Net Income Per Share

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

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

	Three Months Ended, September 30,		Nine Months Ended, September 30,	
	2015	2014	2015	2014
Numerator:				
Net income	\$27,616	\$38,247	\$95,143	\$106,291
Denominator:				
Weighted-average common shares outstanding, basic	79,808	80,629	80,173	80,924
Dilutive effect of potential common stock	1,284	1,385	1,403	1,519
Total shares, diluted	81,092	82,014	81,576	82,443
Net income per share, basic	\$0.35	\$0.47	\$1.19	\$1.31
Net income per share, diluted	\$0.34	\$0.47	\$1.17	\$1.29

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

## Note 12. Segments and Geographical Information

## Segment Information

Operating segments are defined as components of an enterprise for which separate financial information is available that is evaluated regularly by the Chief Operating Decision Maker (“CODM”), or decision-making group, in deciding how to allocate resources and in assessing performance. Our CODM is our Chief Executive Officer. We report segment information based on the management approach. The management approach designates the internal reporting used by CODM for decision making and performance assessment as the basis for determining our reportable segments. The performance measures of our reportable segments include net revenues and gross profit.



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

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

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

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

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2015	2014	2015	2014
Net Revenues				
Clear Aligner	\$198,292	\$178,138	\$586,138	\$526,112
Scanner	9,344	11,738	29,072	36,941
Total net revenues	\$207,636	\$189,876	\$615,210	\$563,053
Gross profit				
Clear Aligner	\$156,205	\$141,117	\$461,502	\$415,903
Scanner	1,371	3,937	5,798	11,878
Total gross profit	\$157,576	\$145,054	\$467,300	\$427,781

## Geographical Information

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

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2015	2014	2015	2014
Net revenues: <sup>(1)</sup>				
U.S.	\$143,933	\$134,244	\$429,005	\$396,837
the Netherlands	37,427	34,538	118,295	113,828
Other international	26,276	21,094	67,910	52,388
Total net revenues	\$207,636	\$189,876	\$615,210	\$563,053

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

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

	September 30, 2015	December 31, 2014
Long-lived assets: <sup>(2)</sup>		
United States	\$97,789	\$76,511
Mexico	14,655	6,229
Other International	8,294	7,385
Total long-lived assets	\$120,738	\$90,125

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

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

In addition to historical information, this quarterly report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. These statements include, among other things, our expectations regarding the anticipated impact that our new products and product enhancements will have on doctor utilization and our market share, our expectation that the policy simplification "Additional Aligners at No Charge" will help increase Invisalign utilization and volume as well as the expected impact this policy change will have on Invisalign Clear Aligner net revenues in the fourth quarter of 2015 and beyond, our expectations regarding product mix and product adoption, our expectations regarding the existence and impact of seasonality, our expectations regarding the financial and strategic benefits of the Scanner and Services ("Scanner") business, our expectations to increase our investment in manufacturing capacity, our expectations regarding the continued expansion of our international markets, the anticipated number of new doctors trained, the expected date our iTero Element Intraoral Scanner will be available, the effectiveness of our new training course and its impact on volumes, our expectations regarding our stock repurchase program, the level of our operating expenses and gross margins, and other factors beyond our control, as well as other statements regarding our future operations, financial condition and prospects and business strategies. These statements may contain words such as "expects," "anticipates," "intends," "plans," "believes," "estimates," or other words indicating future results. These forward-looking statements are subject to certain risks and uncertainties that could cause actual results to differ materially from those reflected in the forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in Item 2 "Management's Discussion and Analysis of Financial Condition and Results of Operations", and in particular, the risks discussed below in Part II, Item 1A "Risk Factors". We undertake no obligation to revise or update these forward-looking statements. Given these risks and uncertainties, readers are cautioned not to place undue reliance on such forward-looking statements.

The following discussion and analysis of our financial condition and results of operations should be read together with our Condensed Consolidated Financial Statements and related notes included elsewhere in this Quarterly Report on Form 10-Q.

Overview

Align Technology, Inc. is a global medical device company that advanced the invisible orthodontics market with the introduction of the Invisalign System in 1999. Today, we are focused on designing, manufacturing and marketing innovative technology-rich products to help dental professionals achieve the clinical results they expect and deliver effective, convenient cutting-edge dental treatment options to their patients. Align Technology was founded in March 1997 and is headquartered in San Jose, California with offices worldwide. Our international headquarters are located in Amsterdam, the Netherlands. We have two operating segments: (1) Clear Aligner, known as the Invisalign System; and (2) Scanner and Services ("Scanner"), known as the iTero intraoral scanners and OrthoCAD services.

We received FDA clearance in 1998 and began our first commercial sales of Invisalign to U.S. orthodontists in 1999 followed by U.S. General Practitioner Dentists ("GPs") in 2002. Over the next decade, we introduced Invisalign to the European market and Japan, added distribution partners in Asia Pacific, Latin America, and Europe Middle East and Africa ("EMEA"), and introduced a full range of treatment options including Invisalign Express 10, Invisalign Teen, Invisalign Assist, and Vivera Retainers. By 2011, we launched significant new aligner and software features across all Invisalign products that make it easier for doctors to use Invisalign on more complex cases, and introduced Invisalign to the People's Republic of China. In 2013, we launched SmartTrack, the next generation of Invisalign clear aligner material, which became the new standard aligner material for Invisalign products in North America, Europe and other international markets where we have obtained regulatory approval. Over the last several years' we have continued to build upon our technology and expertise to deliver enhanced clinical innovations aimed at helping our customers treat some of the most challenging cases. These innovations, both launched in early 2014, include Invisalign G5,

specifically designed for treatment of deep bite malocclusion, as well as ClinCheck Pro, the next generation Invisalign treatment software tool designed to help Invisalign providers achieve their treatment goals. Most recently, we began the initial commercialization of Invisalign G6 clinical innovations for first premolar extraction during the first quarter of 2015.

We also sell iTero intra-oral scanners and provide computer-aided design and computer-aided manufacturing ("CAD/CAM") services. Intra-oral scanners provide a dental "chair-side" platform for accessing valuable digital diagnosis and treatment tools, with potential for enhancing accuracy of records, treatment efficiency, and the overall patient experience. We believe there are numerous benefits for customers and the opportunity to accelerate the adoption of Invisalign through interoperability with our intra-oral scanners. The use of digital technologies such as CAD/CAM for restorative dentistry or in-office restorations has been growing rapidly and intra-oral scanning is a critical part of enabling these new digital technologies and procedures in dental practices. In late 2012, we commercially launched the Invisalign Outcome Simulator, the first Invisalign chair-side application

powered by the iTero scanner. The interactive application provides dentists and orthodontists an enhanced platform for patient education and is designed to increase treatment acceptance by helping patients visualize the benefits possible with Invisalign treatment. In March 2015, we announced our next generation iTero Element Intraoral Scanner which features a more compact footprint, enhanced wand and multi-touch display and is engineered to enable faster scan speeds for more efficient, real-time clinical evaluation.

We believe in an open systems approach to our technologies and are committed to working with other intra-oral scanning companies interested in developing interoperability for use with Invisalign treatment. In January 2014, we announced that the 3M™ True Definition scanner was qualified for use with Invisalign case submissions. This qualification enables Invisalign providers with a True Definition scanner to submit a digital impression in place of a traditional PVS impression as part of the Invisalign case submission process. In March 2015, we announced that the Sirona CEREC Omnicam with the new CEREC Ortho software 1.1 was qualified for use with Invisalign case submissions. The new CEREC Ortho software was available in select markets in the summer of 2015. The 3M True Definition scanner and Sirona CEREC Omnicam scanner are the only third-party scanners that have been qualified for use with Invisalign treatment.

The Invisalign System is offered in more than 90 countries and has been used to treat more than 3.4 million patients. Our iTero intraoral scanner, which is primarily sold in North America, provides dental professionals with an open choice to send digital impressions to any laboratory-based CAD/CAM system or to any of the more than 3,160 dental labs worldwide.

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

The successful execution of our business strategy and our results in 2015 and beyond may be affected by a number of other factors including:

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

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

**New Products, Feature Enhancements and Technology Innovation.** Product innovation drives greater treatment predictability and clinical applicability, and ease of use for our customers, which supports adoption of Invisalign in their practices. Increasing applicability and treating more complex cases requires that we move away from individual features to more comprehensive solutions so that Invisalign providers can more predictably treat the whole case, such as with Invisalign G5 for deep bite treatment. Launched in February 2014, Invisalign G5 was engineered to help doctors achieve even better clinical outcomes when treating patients with deep bites - a prevalent orthodontic problem. In North America, in February 2014 and Internationally in the first quarter of 2015, we launched ClinCheck Pro, the next generation Invisalign treatment software tool, designed to provide more precise control over final tooth position and to help Invisalign providers achieve their treatment goals. Invisalign G6 clinical innovations for premolar extraction became available to Invisalign-trained providers beginning in the first quarter of 2015 with limited commercialization. Full commercialization of Invisalign G6 in Europe, Middle East and Africa ("EMEA"), Asia

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

protrusion. Most recently, in March 2015, we announced the next generation iTero Element Intraoral Scanner with improved imaging technology that is designed to enable significantly faster scan speed, accuracy, intuitive operation, and visualization capabilities. We began shipping the iTero Element Intraoral Scanner in September 2015 and expect to ramp up our production over the next few quarters accordingly; however, if we are unable to scale production of our iTero Element scanner to meet customer demand, our financial results may be negatively impacted. We believe that over the long-term, clinical solutions and treatment tools will increase adoption of Invisalign and increase sales of our intraoral scanners; however, it is difficult to predict the rate of adoption which may vary by region and channel. Invisalign Utilization rates. Our goal is to establish Invisalign as the treatment of choice for treating malocclusion ultimately driving increased product adoption and frequency of use by dental professionals, also known as "utilization rates." Our quarterly utilization rates for the previous 9 quarters are as follows:

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

Total utilization in the third quarter of 2015 increased to 4.7 cases per doctor compared to 4.4 in the third quarter of 2014. Utilization among our North American orthodontist customers reached an all time high of 9.9 cases per doctor in the third quarter of 2015 compared to 8.8 in the third quarter of 2014. International doctor utilization increased to 4.6 in the third quarter of 2015 from 4.3 in the third quarter of 2014. North American GP doctor utilization increased slightly to 2.9 in the third quarter of 2015 from 2.8 in the third quarter of 2014. The increase in North America orthodontist utilization reflects improvements in product and technology, which continues to strengthen our doctors' clinical confidence in the use of Invisalign such that they now utilize Invisalign more often and on more complex cases, including their teenage patients. Increased International utilization reflects growth in both the EMEA and Asia Pacific regions driven by go-to-market and sales coverage investments, improving clinical education and support as well as ongoing technology innovation. We expect that over the long-term our utilization rates will gradually improve as a result of advancements in product and technology, which continue to strengthen our doctors' clinical confidence in the use of Invisalign, along with the implementation of our Go-To-Market strategy (as discussed below); however, we expect that our utilization rates may fluctuate from period to period due to a variety of factors, including seasonal trends in our business along with adoption rates of new products and features.

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

Consequently, we expect that our Invisalign volume in the fourth quarter of 2015 will be up compared to the third quarter.

Number of new Invisalign doctors trained. We continue to expand our Invisalign customer base through the training of new doctors. In 2014, Invisalign growth was driven primarily by increased utilization by our North American orthodontist doctors and International doctors as well as by the continued expansion of our customer base as we trained a total of 9,440 new Invisalign doctors, of which 56% were trained internationally. GPs are one of the keys to driving growth in the adult segment, and, in 2014, we launched Invisalign Fundamentals, a new training course, designed to improve practice integration and increase utilization for newly trained doctors. The Invisalign Fundamentals program has been implemented across North America, and we will look for opportunities to adjust our international training programs as we work to help our GP practices worldwide more successfully adopt Invisalign into their practices. We believe that this new training approach, together with our go-to market strategy which includes dedicated focus, pre-and post training, has the potential to increase the number of doctors submitting cases 90-days post-training, as well as the number of cases submitted per doctor. During the third quarter of 2015, we trained 2,260 new Invisalign doctors.

International Clear Aligner. We will continue to focus our efforts towards increasing adoption of our products by dental professionals in our direct international markets. On a year over year basis, international volume increased 35.1% driven primarily due to strong performance in the Asia Pacific region as well as growth in Europe. In 2015, we are continuing to expand in our existing markets through targeted investments in sales coverage and professional marketing and education programs, along with consumer marketing in selected country markets. We expect international revenues to continue to grow at a faster rate than North America for the foreseeable future due to our continued investment in international market expansion, the size of the market opportunity, and our relatively low market penetration in this region. In addition, as we plan for further international expansion over the next several years, we must provide better support to our customers in these regions and be geographically closer to their practices. Accordingly, we intend to make further investments in our manufacturing over the next few years to enhance our regional capabilities.

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

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

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

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

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



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

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

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

Stock Repurchase Authorization. On April 23, 2014, we announced that our Board of Directors had authorized a stock repurchase program pursuant to which we may purchase up to \$300.0 million of our common stock over the next three years, with \$100.0 million authorized to be purchased over the first twelve months. Any purchases under this stock repurchase program may be made, from time-to-time, pursuant to open market purchases (including pursuant to Rule 10b5-1 plans), privately-negotiated transactions, accelerated stock repurchases, block trades or derivative contracts or otherwise in accordance with applicable federal securities laws, including Rule 10b-18 of the Securities Exchange Act of 1934. The program does not obligate Align to acquire any particular amount of common stock and depending on market conditions or other factors these purchases may be commenced or suspended at any time, or from time-to-time without prior notice. The authorization or continuance of any repurchases under stock repurchase programs is contingent on a variety of factors, including our financial condition, results of operations, business requirements, and our Board of Directors' continuing determination that such stock repurchases are in the best interests of our stockholders and in compliance with all laws and applicable agreements. Additionally, there can be no assurance that our stock repurchase program will have a beneficial impact on our stock price.

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

## Results of Operations

### Net revenues by Reportable Segment

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

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

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

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Net revenues for our Clear Aligner segment by region and product and our Scanner segment by region for the three and nine months ended September 30, 2015 and 2014 is as follows (in millions):

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

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

## Clear Aligner Case Volume by Region

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

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

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

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

## Clear Aligner - North America

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

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

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

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

Clear Aligner - International

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

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

Clear Aligner - Invisalign Non-Case

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

Scanner and Services

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

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

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

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

Cost of net revenues for our Clear Aligner and Scanner segments includes salaries for staff involved in the production process, the cost of materials, packaging, shipping costs, depreciation on capital equipment used in the production process, amortization of acquired intangible assets from Cadent, training costs and stock-based compensation.

**Clear Aligner**

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

**Scanner**

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

**Selling, General and administrative (in millions):**

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

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

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

Selling, general and administrative expense includes personnel-related costs including payroll, commissions and stock-based compensation for our sales force, marketing and administration in addition to media and advertising expenses, clinical education, trade shows and industry events, product marketing, outside consulting services, legal expenses, depreciation and amortization expense, the medical device excise tax ("MDET") and allocations of corporate overhead expenses including facilities and IT.

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



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

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

Research and development (in millions):

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

Changes and percentages are based on actual values. Certain tables may not sum or recalculate due to rounding. Research and development expense includes the personnel-related costs including stock-based compensation and outside consulting expenses associated with the research and development of new products and enhancements to existing products and allocations of corporate overhead expenses including facilities and IT.

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

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

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

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

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

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

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

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

Income tax (in millions):

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

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

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

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

We exercise significant judgment in regards to estimates of future market growth, forecasted earnings and projected taxable income in determining the provision for income taxes, and for purposes of assessing our ability to utilize any future benefit from deferred tax assets.

As of September 30, 2015, we maintained a valuation allowance of \$32.8 million against deferred tax assets primarily related to Israel and California operating loss carryforwards and Australia capital loss carryforwards. These net operating and capital loss carryforwards would result in an income tax benefit if we were to conclude it is more likely than not that the related deferred tax assets will be realized.

Our total gross unrecognized tax benefits was \$37.8 million and \$33.1 million as of September 30, 2015 and December 31, 2014, respectively, all of which would impact our effective tax rate if recognized. We have elected to recognize interest and penalties related to unrecognized tax benefits as a component of income taxes. The change in accrued interest and penalties during the three and nine months ended September 30, 2015 was not material. We do not expect any significant changes to the amount of unrecognized tax benefit within the next twelve months.

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

In June 2009, the Costa Rica Ministry of Foreign Trade, an agency of the Government of Costa Rica, granted a twelve year extension of certain income tax incentives, which were previously granted in 2002. The incentive tax rates will expire in various years beginning in 2017. Under these incentives, all of the income in Costa Rica during these twelve year incentive periods is subject to reduced rate of Costa Rica income tax. In order to receive the benefit of these incentives, we must hire specified numbers of employees and maintain certain minimum levels of fixed asset investment in Costa Rica. If we do not fulfill these conditions for any reason, our incentive could lapse, and our income in Costa Rica would be subject to taxation at higher rates, which could have a negative impact on our operating results. The Costa Rica corporate income tax rate that would apply, absent the incentives, is 30% for 2015 and 2014. Income taxes were reduced by \$8.2 million and \$7.7 million for the three months ended September 30, 2015 and 2014, respectively, representing a benefit to diluted net income per share of \$0.10 and \$0.09 in 2015 and 2014, respectively. As a result of these incentives, our income taxes were reduced by \$24.6 million and \$22.8 million for the nine months ended September 30, 2015 and 2014, respectively, representing a benefit to diluted net income per share of \$0.30 and \$0.28 in 2015 and 2014, respectively.

## Liquidity and Capital Resources

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

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

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Cash flows (in thousands):

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

As of September 30, 2015, we had \$630.0 million of cash, cash equivalents and short-term and long-term marketable securities. Cash equivalents and marketable securities are comprised of money market funds and debt instruments which include corporate bonds, U.S. dollar dominated foreign corporate bonds, commercial paper, municipal securities, U.S. government agency bonds, U.S. government treasury bonds and asset-backed securities. We do not enter into investments for trading or speculative purposes.

As of September 30, 2015, approximately \$417.4 million of cash, cash equivalents and short-term and long-term marketable securities was held by our foreign subsidiaries. Amounts held by foreign subsidiaries are generally subject to U.S. income taxation on repatriation to the U.S. The costs to repatriate our foreign earnings to the U.S. would likely be material; however, our intent is to permanently reinvest our earnings from foreign operations, and our current plans do not require us to repatriate them to fund our U.S. operations as we generate sufficient domestic operating cash flow and have access to external funding under our current revolving line of credit.

On April 23, 2014, we announced that our Board of Directors had authorized a stock repurchase program pursuant to which we may purchase up to \$300.0 million of our common stock over the next three years, with \$100.0 million authorized over the first twelve months. Any purchases under this stock repurchase program may be made, from time-to-time, pursuant to open market purchases (including pursuant to Rule 10b5-1 plans), privately-negotiated transactions, accelerated stock repurchases, block trades or derivative contracts or otherwise in accordance with applicable federal securities laws, including Rule 10b-18 of the Securities Exchange Act of 1934.

As part of our \$300.0 million stock repurchase program, on April 28, 2014, we entered into an accelerated share repurchase agreement ("2014 ASR") to repurchase \$70.0 million of our common stock which was completed on July 2014. We received a total of approximately 1.4 million shares under the 2014 ASR for an average purchase price per share of \$51.46, which all shares were retired. The final number of shares repurchased was based on our volume-weighted average stock price during the term of the transaction, less an agreed upon discount.

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

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

purchase price of \$18.8 million. All repurchased shares were retired. We have \$111.2 million remaining under the April 2014 stock repurchase program, \$11.2 million of which we expect to purchase within the next six months. We expect to finance future stock repurchases with current cash on hand.

On March 22, 2013, we entered into a credit facility for a \$50.0 million revolving line of credit, with a \$10.0 million letter of credit sublimit, and has a maturity date on March 22, 2016. The credit facility also requires us to maintain a minimum unrestricted cash balance of \$50.0 million and comply with specific financial conditions and performance requirements. The loan bears interest, at our option, at a fluctuating rate per annum equal to the daily one-month adjusted LIBOR rate plus a spread of 1.75% or an

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

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

### Operating Activities

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

Significant non-cash activities:

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

Significant changes in working capital:

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

### Investing Activities

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

For the remainder of 2015, we expect to spend an additional \$18.0 million to \$23.0 million on capital expenditures for estimated total capital expenditures of \$55.0 million to \$60.0 million for 2015 primarily for additional manufacturing capacity and infrastructure including a project to implement a new enterprise resource planning system. Although we believe our current investment portfolio has little risk of impairment, we cannot predict future market conditions or market liquidity and can provide no assurance that our investment portfolio will remain unimpaired.

### Financing Activities

Net cash used in financing activities was \$89.0 million for the nine months ended September 30, 2015 primarily resulting from \$90.6 million for the repurchase of our common stock and \$17.6 million related to payroll taxes paid for vesting of restricted stock units through share withholdings. These outflows were offset in part by \$10.6 million in proceeds from issuance of common stock and \$8.7 million from excess tax benefits from our share-based compensation arrangements.



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### Contractual Obligations

Our contractual obligations have not significantly changed since December 31, 2014 as disclosed in our Annual Report on Form 10-K. We believe that our current cash, cash equivalents and short-term marketable securities combined with our existing borrowing capacity will be sufficient to fund our operations for at least the next 12 months. If we are unable to generate adequate operating cash flows and need more funds beyond those available under our credit facility, we may need to suspend our stock repurchase program or seek additional sources of capital through equity or debt financing, collaborative or other arrangements with other companies, bank financing and other sources in order to realize our objectives and to continue our operations. There can be no assurance that we will be able to obtain additional debt or equity financing on terms acceptable to us, or at all. If adequate funds are not available, we may need to make business decisions that could adversely affect our operating results such as modifications to our pricing policy, business structure or operations. Accordingly, the failure to obtain sufficient funds on acceptable terms when needed could have a material adverse effect on our business, results of operations and financial condition.

### Off-Balance Sheet Arrangements

As of September 30, 2015, we had no off-balance sheet arrangements that have, or are reasonably likely to have, a current or future material effect on our consolidated financial condition, results of operations, liquidity, capital expenditures or capital resources.

### Indemnification Provisions

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

It is not possible to make a reasonable estimate of the maximum potential amount under these indemnification agreements due to the unique facts and circumstances involved in each particular agreement. Additionally, we have a limited history of prior indemnification claims and the payments we have made under such agreements have not had a material adverse effect on our results of operations, cash flows, or financial position. However, to the extent that valid indemnification claims arise in the future, future payments by us could be significant and could have a material adverse effect on our results of operations or cash flows in a particular period. As of September 30, 2015, we did not have any material indemnification claims that were probable or reasonably possible.

### Critical Accounting Policies and Estimates

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

We believe the following critical accounting policies reflect our most significant estimates, judgments and assumptions used in the preparation of our consolidated financial statements. These critical accounting policies and

related disclosures appear in our Annual Report on Form 10-K for the year ended December 31, 2014:

• Revenue recognition;

• Stock-based compensation expense;

• Goodwill and finite-lived acquired intangible assets,

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

• Accounting for income taxes.

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### Revenue Recognition

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

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

### Recent Accounting Pronouncements

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

## ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

### Interest Rate Risk

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

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

### Currency Rate Risk

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

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

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

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

ITEM 4.CONTROLS AND PROCEDURES

Evaluation of disclosure controls and procedures.

Under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, we have evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of the end of the period covered by this Quarterly Report on Form 10-Q. Based upon that evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that our disclosure controls and procedures are effective as of September 30, 2015, to provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our Chief Executive Officer and our Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure, and that such information is recorded, processed, summarized and reported within the time periods specified in the SEC rules and forms.

Changes in internal control over financial reporting.

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

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PART II—OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

Securities Class Action Lawsuit

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

Shareholder Derivative Lawsuit

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

In addition, in the course of Align's operations, Align is involved in a variety of claims, suits, investigations, and proceedings, including actions with respect to intellectual property claims, patent infringement claims, government investigations, labor and employment claims, breach of contract claims, tax, and other matters. Regardless of the outcome, these proceedings can have an adverse impact on us because of defense costs, diversion of management resources, and other factors. Although the results of complex legal proceedings are difficult to predict and Align's

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

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ITEM 1A.RISK FACTORS

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

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

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

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

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

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

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

We provide volume based discount programs to our doctors. In addition, we sell a number of products at different list prices. If we introduce any price reductions or consumer rebate programs; if we expand our discount programs in the future or participation in these programs increases; if our product mix shifts to lower priced products or products that have a higher percentage of deferred revenue, our average selling prices would be adversely affected and our net



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

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

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

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

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

We are subject to growth related risks, including excess or constrained capacity and pressure on our internal systems and personnel. In order to manage current operations and future growth effectively, we will need to continue to implement and improve our operational, financial and management information systems and to hire, train, motivate, manage and retain employees. We may be unable to manage such growth effectively. Any such failure could have a material adverse impact on our business, operations and prospects. In addition, in order to meet the demands from expected volumes, we purchased a second manufacturing facility in Juarez, Mexico. We began manufacturing aligners in this second facility in September 2015 while continuing to manufacture Aligners at our existing facility in Juarez. Our ability to plan, construct and equip additional manufacturing facilities is subject to significant risk and uncertainty, including risks inherent in the establishment of a new manufacturing facility, such as hiring and retaining employees and delays and cost overruns as a result of a number of factors, any of which may be out of our control. If the transition into this additional facility is significantly delayed or demand for our product exceeds our current expectations, we may not be able to fulfill orders timely, which may negatively impact our financial results and overall business. In addition, because we cannot immediately adapt our production capacity and related cost structures to changing market conditions, our manufacturing capacity may at times exceed or fall short of our production requirements. In addition, if product demand decreases or we fail to forecast demand accurately, we could be required to write off inventory or record excess capacity charges, which would lower our gross margin. Any or all of these problems could result in the loss of customers, provide an opportunity for competing products to gain market acceptance and otherwise harm our business and financial results.

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

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

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

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

- limited visibility into and difficulty predicting the level of activity in our customers' practices from quarter to quarter;
- weakness in consumer spending as a result of the slowdown in the U.S. economy and global economies;
- changes in relationships with our distributors;

changes in the timing of receipt of Invisalign case product orders during a given quarter which, given our cycle time and the delay between case receipts and case shipments, could have an impact on which quarter revenue can be recognized;

fluctuations in currency exchange rates against the U.S. dollar;

changes in product mix;

our inability to predict from period to period the number of trainers or the availability of doctors required to complete intra-oral scanner installations, which may impact the timing of when revenue is recognized;

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

if participation in our customer rebate or discount programs increases our average selling price will be adversely affected;

seasonal fluctuations in the number of doctors in their offices and their availability to take appointments;

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- success of or changes to our marketing programs from quarter to quarter;
- our reliance on our contract manufacturers for the production of sub-assemblies for our intra-oral scanners;
- timing of industry tradeshows;
- changes in the timing of when revenue is recognized, including as a result of the introduction of new products or promotions, modifications to our terms and conditions or as a result of changes to critical accounting estimates or new accounting pronouncements;
- changes to our effective tax rate;
- unanticipated delays in production caused by insufficient capacity or availability of raw materials;
- any disruptions in the manufacturing process, including unexpected turnover in the labor force or the introduction of new production processes, power outages or natural or other disasters beyond our control;
- the development and marketing of directly competitive products by existing and new competitors;
- major changes in available technology or the preferences of customers may cause our current product offerings to become less competitive or obsolete;
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