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Form 10-Q
May 02, 2019
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us-gaap:CorporateAndOtherMember 2019-01-01 2019-03-31 0001097149 us-gaap:AllOtherSegmentsMember
2019-01-01 2019-03-31 0001097149 us-gaap:AllOtherSegmentsMember 2018-01-01 2018-03-31 0001097149
us-gaap:CorporateAndOtherMember 2018-01-01 2018-03-31 0001097149 algn:ScannersAndServicesMember
2018-01-01 2018-03-31 0001097149 algn:ClearAlignerMember 2018-01-01 2018-03-31 0001097149
algn:ScannersAndServicesMember 2019-01-01 2019-03-31 iso4217:EUR xbrli:pure iso4217:CNY algn:floor
iso4217:USD xbrli:shares iso4217:USD algn:Lawsuit iso4217:JPY iso4217:AUD iso4217:GBP iso4217:CAD
algn:patent iso4217:MXN iso4217:BRL xbrli:shares algn:segment

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2019

OR

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

For the transition period from to

Commission file number: 0-32259

ALIGN TECHNOLOGY, INC.

(Exact name of registrant as specified in its charter)

Delaware	**94-3267295**

(State or other jurisdiction of incorporation or organization) **(I.R.S. Employer Identification Number)**
2820 Orchard Parkway
San Jose, California 95134
(Address of principal executive offices)
(408) 470-1000
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, $0.0001 par value	ALGN	The NASDAQ Stock Market LLC (NASDAQ Global Market)

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted 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 such files). Yes x No ¨

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

Large accelerated filer	x	Accelerated filer	¨
Non-accelerated filer	o	Smaller reporting company	¨
Emerging growth company	o		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13 (a) of the Exchange Act.

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

The number of shares outstanding of the registrant's Common Stock, $0.0001 par value, as ofApril 26, 2019 was 80,004,892.

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

	Three Months Ended March 31,	
	2019	2018
Net revenues	$548,971	$436,924
Cost of net revenues	146,875	109,516
Gross profit	402,096	327,408
Operating expenses:		
Selling, general and administrative	247,110	199,625
Research and development	37,503	29,591
Impairments and other charges	29,782	—
Total operating expenses	314,395	229,216
Income from operations	87,701	98,192
Interest income	2,633	2,176
Other income (expense), net	(5,746)	177
Net income before provision for income taxes and equity in losses of investee	84,588	100,545
Provision for income taxes	8,796	2,902
Equity in losses of investee, net of tax	3,944	1,777
Net income	$71,848	$95,866
Net income per share:		
Basic	$0.90	$1.20
Diluted	$0.89	$1.17
Shares used in computing net income per share:		
Basic	79,860	80,036
Diluted	80,687	81,628

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 March 31,	
	2019	**2018**
Net income	$71,848	$95,866
Net change in foreign currency translation adjustment	409	1,042
Change in unrealized gains (losses) on investments, net of tax	84	(129)
Other comprehensive income	493	913
Comprehensive income	$72,341	$96,779

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)
(unaudited)

	March 31, 2019	December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	$588,001	$636,899
Marketable securities, short-term	144,540	98,460
Equity method investments	41,969	—
Accounts receivable, net of allowance for doubtful accounts of $3,567 and $2,378, respectively	479,281	439,009
Inventories	68,489	55,641
Prepaid expenses and other current assets	116,833	72,470
Total current assets	1,439,113	1,302,479
Marketable securities, long-term	—	9,112
Property, plant and equipment, net	575,267	521,329
Operating lease right-of-use assets	56,384	—
Equity method investments	—	45,913
Goodwill and intangible assets, net	80,329	81,949
Deferred tax assets	57,151	64,689
Other assets	26,186	26,987
Total assets	$2,234,430	$2,052,458
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$62,512	$64,256
Accrued liabilities	252,754	234,679
Finance lease liabilities	56,100	—
Deferred revenues	433,518	393,138
Total current liabilities	804,884	692,073
Income tax payable	93,463	78,008
Operating lease liabilities	59,307	—
Other long-term liabilities	21,072	29,486
Total liabilities	978,726	799,567
Commitments and contingencies (Notes 9 and 10)		
Stockholders' equity:		
Preferred stock, $0.0001 par value (5,000 shares authorized; none issued)	—	—
Common stock, $0.0001 par value (200,000 shares authorized; 80,000 and 79,778 issued and outstanding, respectively)	8	8
Additional paid-in capital	855,956	877,514
Accumulated other comprehensive income (loss), net	(2,281)	(2,774)
Retained earnings	402,021	378,143
Total stockholders' equity	1,255,704	1,252,891
Total liabilities and stockholders' equity	$2,234,430	$2,052,458

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 STOCKHOLDERS' EQUITY
(in thousands)
(unaudited)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss), Net	Retained Earnings	Total
	Shares	Amount				
Balance as of December 31, 2018	79,778	$ 8	$877,514	$ (2,774)	$378,143	$1,252,891
Net income	—	—	—	—	71,848	71,848
Net change in unrealized gains (losses) from investments	—	—	—	84	—	84
Net change in foreign currency translation adjustment	—	—	—	409	—	409
Issuance of common stock relating to employee equity compensation plans	427	—	9,609	—	—	9,609
Tax withholdings related to net share settlements of restricted stock units	—	—	(50,181)	—	—	(50,181)
Common stock repurchased and retired	(205)	—	(2,030)	—	(47,970)	(50,000)
Stock-based compensation	—	—	21,044	—	—	21,044
Balance as of March 31, 2019	80,000	$ 8	$855,956	$ (2,281)	$402,021	$1,255,704

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss), Net	Retained Earnings	Total
	Shares	Amount				
Balances at December 31, 2017	80,040	$ 8	$886,435	$ 571	$267,274	$1,154,288
Net income	—	—	—	—	95,866	95,866
Net change in unrealized gains (losses) from investments	—	—	—	(129)	—	(129)
Net change in foreign currency translation adjustment	—	—	—	1,042	—	1,042
Issuance of common stock relating to employee equity compensation plans	500	—	8,020	—	—	8,020
Tax withholdings related to net share settlements of restricted stock units	—	—	(47,842)	—	—	(47,842)
Common stock repurchased and retired	(396)	—	(3,811)	—	(96,189)	(100,000)
Stock-based compensation	—	—	15,830	—	—	15,830
Other					385	385
Balance as of March 31, 2018	80,144	$ 8	$858,632	$ 1,484	$267,336	$1,127,460

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)

	Three Months Ended March 31,	
	2019	**2018**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net income	$71,848	$95,866
Adjustments to reconcile net income to net cash provided by operating activities:		
Deferred taxes	7,586	4,069
Depreciation and amortization	22,678	11,434
Impairments on long-lived assets	28,498	—
Impairment on equity investment	3,975	—
Stock-based compensation	21,044	15,830
Equity in losses of investee	3,944	1,777
Other non-cash operating activities	5,101	474
Changes in assets and liabilities:		
Accounts receivable	(42,743)	(36,026)
Inventories	(13,280)	(4,002)
Prepaid expenses and other assets	(35,033)	(15,873)
Accounts payable	1,470	5,599
Accrued and other long-term liabilities	(5,183)	(35,466)
Long-term income tax payable	4,808	5,259
Deferred revenues	42,494	28,391
Net cash provided by operating activities	117,207	77,332
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property, plant and equipment	(35,261)	(57,578)
Purchase of marketable securities	(125,823)	—
Proceeds from maturities of marketable securities	80,306	126,825
Proceeds from sales of marketable securities	8,727	9,560
Loan repayment from equity investee	—	30,000
Other investing activities	(2,367)	462
Net cash (used in) provided by investing activities	(74,418)	109,269
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock	9,609	8,020
Common stock repurchases	(50,000)	(100,000)
Employees' taxes paid upon the vesting of restricted stock units	(50,181)	(47,842)
Other financing activities	(2,190)	—
Net cash used in financing activities	(92,762)	(139,822)
Effect of foreign exchange rate changes on cash, cash equivalents, and restricted cash	1,089	1,715
Net (decrease) increase in cash, cash equivalents, and restricted cash	(48,884)	48,494
Cash, cash equivalents, and restricted cash at beginning of the period	637,566	450,125
Cash, cash equivalents, and restricted cash at end of the period	$588,682	$498,619

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 contains all adjustments, including normal recurring adjustments, necessary to state fairly our results of operations for the three months ended March 31, 2019 and 2018, our comprehensive income for the three months ended March 31, 2019 and 2018, our financial position as of March 31, 2019, our stockholders’ equity for the three months ended March 31, 2019 and 2018, and our cash flows for the three months ended March 31, 2019 and 2018. The Condensed Consolidated Balance Sheet as of December 31, 2018 was derived from the December 31, 2018 audited financial statements. It does not include all disclosures required by accounting principles generally accepted in the United States of America (“U.S.”).

We adopted Accounting Standards Update (“ASU”) 2016-02, “*Leases*” (Topic 842) in the first quarter of fiscal year 2019 by electing the transition method issued in ASU 2018-11 and the package of practical expedients available in the standard. The standard had a material impact on our Condensed Consolidated Balance Sheet as of March 31, 2019 as we recognized assets and liabilities related to our leases. The adoption did not have an impact to prior periods.

The results of operations for the three months ended March 31, 2019 are not necessarily indicative of the results that may be expected for the year ending December 31, 2019 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, 2018.

Use of Estimates

The preparation of financial statements in conformity with generally accepted accounting principles (“GAAP”) in the 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, valuation of investments in privately held companies, useful lives of intangible assets and property and equipment, revenue recognition, stock-based compensation, long-lived assets and goodwill, 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.

Significant Accounting Policies

Our significant accounting policies are described in Note 1 “Summary of Significant Accounting Policies” of the Notes to Consolidated Financial Statements included in our Annual Report on Form 10-K. Significant changes to the Lease policy is discussed below:

Lease

We lease office and retail spaces, vehicles and office equipment with original lease periods of up to 10 years. We determine if an arrangement is a lease at inception under ASC 842. Operating lease right-of-use ("ROU") assets represent our right to use an underlying asset for the lease term and lease liabilities represent our obligation to make lease payments arising from the lease. ROU assets and liabilities are recognized at commencement date based on the present value of lease payments over the lease term. If a lease arrangement does not provide an implicit rate, we use our incremental borrowing rate based on the information available at commencement date in determining the present value of lease payments. We use the implicit rate when readily determinable. Our lease terms may include options to extend or terminate the lease which we include in our lease term when it is reasonably certain that we will exercise that option. We have lease agreements with lease and non-lease components which are accounted for as a single lease component. Leases with an initial term of 12 months or less are not recorded on the balance sheet.

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Recent Accounting Pronouncements

(i) New Accounting Updates Recently Adopted

In February 2016, the Financial Accounting Standards Board ("FASB") issued ASU 2016-02, "*Leases*" (Topic 842) to increase transparency and comparability among organizations by recognizing lease assets and lease liabilities on the balance sheet and disclosing key information about leasing arrangements. The updated guidance is effective for annual periods beginning after December 15, 2018, including interim periods within those fiscal years. In July 2018, the FASB issued ASU 2018-11, "*Leases-Targeted Improvements,*" which provides an additional transition method by allowing entities to initially apply the new leases standard at the adoption date and recognize a cumulative-effect adjustment to the opening balance of retained earnings. We adopted the guidance in the first quarter of fiscal year 2019 by electing the transition method issued in ASU 2018-11 and the package of practical expedients available in the standard. The standard had a material impact on our Condensed Consolidated Balance Sheet as of March 31, 2019 as we recognized assets and liabilities related to our leases. The adoption did not have an impact to prior periods.

In February 2018, the FASB issued ASU 2018-02, *"Income Statement - Reporting Comprehensive Income (Topic 220): Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income,"* which gives entities the option to reclassify to retained earnings the tax effects resulting from the U.S. Tax Cuts and Jobs Act (the "TCJA") related to items in accumulated other comprehensive income. The amendments are effective for fiscal years and interim periods within those years beginning after December 15, 2018 on a retrospective basis and early adoption is permitted. We adopted the standard in the first quarter of fiscal year 2019 which did not have a material impact on our consolidated financial statements and related disclosures. The TCJA did not affect our accumulated other comprehensive income (loss), net, and therefore we did not reclassify any income tax effects from accumulated other comprehensive income (loss), net to our retained earnings.

(ii) Recent Accounting Updates Not Yet Effective

In June 2016, the FASB issued ASU 2016-13, "*Financial Instruments - Credit Losses*" (Topic 326). The FASB issued this update to provide financial statement users with more decision-useful information about the expected credit losses on financial instruments and other commitments to extend credit held by a reporting entity at each reporting date. The amendments in this update replace the existing guidance of incurred loss impairment methodology with an approach that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information to inform credit loss estimates. In November 2018, the FASB issued ASU 2018-19, "*Codification Improvements to Topic 326, Financial Instruments - Credit Losses*" which clarifies the scope of guidance in the ASU 2016-13. The updated guidance is effective for annual periods beginning after December 15, 2019, including interim periods within those fiscal years. Early adoption of the update is permitted in fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. We are currently evaluating the impact of this guidance on our consolidated financial statements and related disclosures.

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

In August 2018, the FASB issued ASU 2018-13, "*Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement,"* to modify the disclosure

requirements on fair value measurements in Topic 820, *Fair Value Measurement*. The amendments are effective for fiscal years and interim periods within those years beginning after December 15, 2019 on a prospective basis and early adoption is permitted. We are currently evaluating the impact of this guidance on our related disclosures.

In August 2018, the FASB issued ASU 2018-15, "*Intangibles—Goodwill and Other—Internal-Use Software (Subtopic 350-40) Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract,"* to clarify the guidance on the costs of implementing a cloud computing hosting arrangement that is a service contract. Under the amendments, the entity is required to follow the guidance in Subtopic 350-40, *Internal-Use Software*, to determine which implementation costs under the service contract to be capitalized as an asset and which costs to expense. The amendments are effective for fiscal years and interim periods within those years beginning after December 15, 2019 either on a retrospective or prospective basis and early adoption is permitted. We are currently evaluating the impact of this guidance on our consolidated financial statements and related disclosures.

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Note 2. Investments and Fair Value Measurements

Marketable Securities

As of March 31, 2019 and December 31, 2018, 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

March 31, 2019	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Commercial paper	$38,234	$ —	$ —	$38,234
Corporate bonds	33,240	8	(2)	33,246
U.S. government agency bonds	14,253	—	(31)	14,222
U.S. government treasury bonds	45,854	7	(3)	45,858
Foreign bonds	12,960	3	(3)	12,960
Certificates of deposit	20	—	—	20
Total marketable securities, short-term	$144,561	$ 18	$ (39)	$144,540

There are no long-term marketable securities as of March 31, 2019.

Short-term

December 31, 2018	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Commercial paper	$17,793	$ —	$ —	$17,793
Corporate bonds	45,100	—	(48)	45,052
U.S. government agency bonds	19,981	—	(77)	19,904
U.S. government treasury bonds	15,292	—	(1)	15,291
Certificates of deposit	420	1	(1)	420
Total marketable securities, short-term	$98,586	$ 1	$ (127)	$98,460

Long-term

December 31, 2018	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Corporate bonds	$4,957	$ 5	$ (2)	$4,960
U.S. government agency bonds	1,399	8	—	1,407
U.S. government treasury bonds	2,235	9	—	2,244
Certificates of deposit	500	1	—	501
Total marketable securities, long-term	$9,091	$ 23	$ (2)	$9,112

Cash equivalents are not included in the tables above as the gross unrealized gains and losses are not material. We have no short-term or long-term investments that have been in a continuous material unrealized loss position for greater than twelve months as of March 31, 2019 and December 31, 2018. Amounts reclassified to earnings from accumulated other comprehensive income (loss), net related to unrealized gains or losses were not material for the three months ended March 31, 2019 and 2018. For the three months ended March 31, 2019 and 2018, realized gains or losses were not material.

Our fixed-income securities investment portfolio consists of investments that can have a maximum effective maturity of up to 40 months on any individual security. 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

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full value of all these investments upon maturity or sale. The weighted average remaining duration of these securities was approximately five months and four months as of March 31, 2019 and December 31, 2018, 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 contractual maturity as of March 31, 2019 and December 31, 2018 (in thousands):

	March 31, 2019	December 31, 2018
One year or less	$144,540	$98,460
Due in greater than one year	—	9,112
Total available for sale short-term and long-term marketable securities	$144,540	$107,572

Investments in Privately Held Companies

Our investments in privately held companies as of March 31, 2019 and December 31, 2018 are as follows (in thousands):

	March 31, 2019	December 31, 2018
Equity securities under the equity method investment [1]	$41,969	$45,913
Equity securities without readily determinable fair values [2]	$5,887	$9,862

[1] *Refer to Note 5 "Equity Method Investments" of the Notes to Condensed Consolidated Financial Statements* for more information

[2] The equity securities are reported as a nonrecurring investment within other assets in our Condensed Consolidated Balance Sheet. During the three months ended March 31, 2019, there was approximately $4.0 million of impairment resulting from an observable price change.

Fair Value Measurements

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

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

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. We obtain fair values for our Level 2 investments. Our custody bank and asset managers independently use professional pricing services to gather pricing data which may include quoted market prices for identical or comparable financial instruments, or inputs other than quoted prices that are observable either directly or indirectly, and we are ultimately responsible for these underlying estimates.

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.

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The following tables summarize our financial assets measured at fair value on a recurring basis as of March 31, 2019 and December 31, 2018 (in thousands):

Description	Balance as of March 31, 2019	Level 1	Level 2
Cash equivalents:			
Money market funds	$369,896	$369,896	$—
Commercial paper	7,978	—	7,978
Corporate bonds	6,809	—	6,809
Short-term investments:			
Commercial paper	38,234	—	38,234
Corporate bonds	33,246	—	33,246
U.S. government treasury bonds	45,858	45,858	—
U.S. government agency bonds	14,222	—	14,222
Foreign bonds	12,960	—	12,960
Certificates of deposit	20	—	20
Prepaid expenses and other current assets:			
Israeli funds	3,031	—	3,031
	$532,254	$415,754	$116,500

Description	Balance as of December 31, 2018	Level 1	Level 2
Cash equivalents:			
Money market funds	$431,081	$431,081	$—
Commercial paper	4,681	—	4,681
U.S. government treasury bonds	2,195	2,195	—
Corporate bonds	3,880	—	3,880
Short-term investments:			
Commercial paper	17,793	—	17,793
Corporate bonds	45,052	—	45,052
U.S. government agency bonds	19,904	—	19,904
U.S. government treasury bonds	15,291	15,291	—
Certificates of deposit	420	—	420
Long-term investments:			
U.S. government agency bonds	1,407	—	1,407
Corporate bonds	4,960	—	4,960
U.S. government treasury bonds	2,244	2,244	—
Certificates of deposit	501	—	501
Prepaid expenses and other current assets:			
Israeli funds	3,047	—	3,047
	$552,456	$450,811	$101,645

Derivative Financial Instruments

We enter into foreign currency forward contracts to minimize the short-term impact of foreign currency exchange rate fluctuations on certain trade and intercompany receivables and payables. These forward contracts are classified within

Level 2 of the fair value hierarchy. The gain from the settlement of foreign currency forward contracts during the three months ended March 31, 2019 was not material. There was no net gain or loss from the settlement of foreign currency forward contracts during the three months ended March 31, 2018. As of March 31, 2019, the fair value of foreign exchange forward contracts outstanding was not material.

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The following table presents the gross notional value of all our foreign exchange forward contracts outstanding as of March 31, 2019 and December 31, 2018 (in thousands):

	March 31, 2019	
	Local Currency Amount	Notional Contract Amount (USD)
Euro	€73,000	$82,059
Chinese Yuan	¥540,000	80,380
Canadian Dollar	C$33,500	25,105
British Pound	£16,500	21,508
Japanese Yen	¥2,100,000	18,962
Brazilian Real	R$69,000	17,660
Mexican Peso	M$115,000	5,942
Australian Dollar	A$3,000	2,128
		$253,744

	December 31, 2018	
	Local Currency Amount	Notional Contract Amount (USD)
Euro	€62,000	$71,095
Chinese Yuan	¥375,000	54,515
Brazilian Real	R$81,000	20,858
Canadian Dollar	C$27,000	19,808
British Pound	£13,000	16,635
Japanese Yen	¥1,700,000	15,357
Australian Dollar	A$3,000	2,114
		$200,382

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Note 3. Balance Sheet Components

Inventories

Inventories consist of the following (in thousands):

	March 31, 2019	December 31, 2018
Raw materials	$29,002	$ 26,119
Work in process	19,710	13,784
Finished goods	19,777	15,738
Total inventories	$68,489	$ 55,641

Other Assets

Other assets consist of the following (in thousands):

	March 31, 2019	December 31, 2018
Capitalized commissions	$10,747	$ 9,185
Equity securities	5,887	9,862
Security deposits	5,038	5,162
Other long-term assets	4,514	2,778
Total other assets	$26,186	$ 26,987

Accrued Liabilities

Accrued liabilities consist of the following (in thousands):

	March 31, 2019	December 31, 2018
Accrued payroll and benefits	$87,603	$ 127,109
Accrued expenses	44,343	39,323
Deferred litigation settlement gain	35,000	—
Accrued customer credits and deposits	18,094	12,439
Current operating lease liabilities	15,592	—
Accrued warranty	10,233	8,551
Accrued property, plant and equipment	9,901	8,193
Accrued sales return reserve	8,202	6,534
Accrued sales rebate	6,612	5,668
Accrued sales tax and value added tax	5,893	6,276
Accrued professional fees	4,955	6,752
Accrued income taxes	2,255	5,752
Other accrued liabilities	4,071	8,082
Total accrued liabilities	$252,754	$ 234,679

Warranty

We regularly review the balance for accrued warranty and update 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.

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Warranty accrual as of March 31, 2019 and 2018 consists of the following activity (in thousands):

	Three Months Ended March 31,	
	2019	2018
Balance at beginning of period	$8,551	$5,929
Charged to cost of revenues	3,133	2,359
Actual warranty expenditures	(1,451)	(1,631)
Balance at end of period	$10,233	$6,657

Deferred Revenues

Deferred revenues consist of the following (in thousands):

	March 31, 2019	December 31, 2018
Deferred revenues - current	$433,518	$393,138
Deferred revenues - long-term [1]	19,166	17,051

[1] Included in other long-term liabilities within our Condensed Consolidated Balance Sheets

During the three months ended March 31, 2019 and March 31, 2018, we recognized $549.0 million and $436.9 million of revenue, respectively, of which $68.4 million and $47.3 million was included in the deferred revenues balance at December 31, 2018, and December 31, 2017, respectively. Our unfilled performance obligations as of March 31, 2019 were $483.8 million. These performance obligations are expected to be recognized over the next one to five years. Align has revised certain previous disclosed amounts within this footnote. Management has concluded that the changes are not material to the current or prior period financial statements.

Note 4. Leases

We have operating and finance leases for office and retail spaces, vehicles and office equipment.

The supplemental balance sheet information consists of following (in thousands):

Leases	March 31, 2019
Operating leases:	
Operating lease right-of-use assets[1]	$56,384
Accrued liabilities	$15,592
Operating lease liabilities	59,307
Total operating lease liabilities	$74,899
Finance leases:	
Property, plant and equipment, net	$50,655
Finance lease liabilities	$56,100

[1] The balance is net of impairment charges recorded in the first quarter of 2019. *Refer to Note 8"Impairments and Other Charges" of the Notes to Condensed Consolidated Financial Statements* for more information

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The components of lease expenses consists of following (in thousands):

Lease Cost	Three Months Ended March 31, 2019
Operating lease cost[1]	$5,301
Finance lease cost:	
Amortization of leased assets[1]	$409
Interest on lease liabilities[2]	392
Total finance lease cost	$801

[1] Included in operating expenses on our Condensed Consolidated Statement of Operations
[2] Included in other income (expense), net on our Condensed Consolidated Statement of Operations

Remaining Lease Term and Discount Rate	March 31, 2019	
Weighted average remaining lease term (in years)		
Operating leases	5.8	
Finance leases[1]	0	
Weighted average discount rate		
Operating leases	4.7	%
Finance leases	4.2	%

[1] On April 5, 2019, we paid the balance of the $56.0 million purchase price and closed the Purchase and Sale Agreement. *Refer to Note 10"Commitments and Contingencies" of the Notes to Condensed Consolidated Financial Statements* for more information

Maturities of operating lease liabilities as of March 31, 2019 are as follows (in thousands):

Fiscal Year Ending December 31,	Operating Leases	Finance Leases
Remainder of 2019	$15,709	$56,100
2020	18,148	—
2021	16,398	—
2022	11,915	—
2023	8,899	—
Thereafter	13,302	—
Total lease payments	$84,371	$56,100
Less: Interest	(9,472)	—
Total lease liabilities	$74,899	$56,100

As of March 31, 2019, we had additional operating leases that have not yet commenced of $9.2 million. These operating leases will commence between fiscal year 2019 to 2022 with lease terms of 3 years to 5 years.

Minimum future lease payments previously disclosed under ASC 840 in our Annual Report on Form 10-K for the year ended December 31, 2018 (in thousands) are as follows:

Fiscal Year Ending December 31,	Operating Leases
2019	$ 21,429
2020	20,483

2021	18,897
2022	15,096
2023	12,400
Thereafter	18,371
Total minimum lease payments	$ 106,676

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Note 5. Equity Method Investments

On July 25, 2016, we acquired a 17% equity interest, on a fully diluted basis, in SmileDirectClub, LLC ("SDC") for $46.7 million. On July 24, 2017, we purchased an additional 2% equity interest in SDC for $12.8 million. The investment is accounted for as an equity method investment and the investee, SDC, is considered a related party. The investment is reported in our Condensed Consolidated Balance Sheets under equity method investments which was reclassed to short-term asset as of March 31, 2019 due to arbitration ordered to tender our interest by April 3, 2019. We record our proportional share of SDC's losses within equity in losses of investee, net of tax, in our Condensed Consolidated Statement of Operations. As of March 31, 2019 and December 31, 2018, the balance of our equity method investments was $42.0 million and $45.9 million, respectively.

Concurrently with the investment on July 25, 2016, we also entered into a supply agreement with SDC to manufacture clear aligners for SDC's doctor-led, at-home program for simple teeth straightening. The term of the supply agreement expires on December 31, 2019. The sale of aligners to SDC and the income from the supply agreement are reported in our Clear Aligner business segment. We eliminate unrealized profit on outstanding intercompany transactions. As of March 31, 2019 and December 31, 2018, the balance of accounts receivable due from SDC was $18.0 million and $16.3 million, respectively. For the three months ended March 31, 2019 and 2018, net revenues recognized from SDC was $5.7 million and $5.3 million, respectively.

On July 25, 2016, we entered into a Loan and Security Agreement (the "Loan Agreement") with SDC and amended on July 24, 2017 where we agreed to provide SDC a loan of up to $30.0 million in one or more advances. On February 7, 2018, $30.0 million of outstanding loan advances and related accrued interest were repaid in full, and the Loan Agreement was terminated.

As a result of the arbitrator's decision regarding SDC announced on March 5, 2019, Align was ordered to tender its SDC equity interest by April 3, 2019 for a purchase price equal to the "capital account" balance as of October 31, 2017 under the terms of the investment. In April 2019, based on "capital account" value provided by SDC, Align entered into unsecured promissory note receivable with SDC to receive approximately $54.2 million through February 1, 2021 in exchange for equity interest. As a result, we expect to record a gain of approximately $16 million in the second quarter of 2019 as other income in our Condensed Consolidated Statement of Operation. Although we tendered our members interests pursuant to the arbitrators decision, the parties did not agree on the amount of SDC's "capital account" balance as of October 31, 2017 or the appropriate repurchase price for the membership units. We intend to seek a re-valuation of Align's "capital account" balance as of October 31, 2017, which may increase the amount of the unsecured promissory note and recognize additional other income (*Refer to Note 9 "Legal Proceedings" of the Notes to Condensed Consolidated Financial Statements* for SDC legal proceedings discussion).

Note 6. Goodwill and Intangible Assets

Goodwill

The change in the carrying value of goodwill for the three months ended March 31, 2019, all attributable to our Clear Aligner reporting unit, is as follows (in thousands):

	Total
Balance as of December 31, 2018	$64,029
Adjustments [1]	(22)
Balance as of March 31, 2019	$64,007

[1] The adjustments to goodwill during the period were a result of foreign currency translation

During the fourth quarter of fiscal 2018, we performed the annual goodwill impairment testing and found no impairment as the fair value of our Clear Aligner reporting unit was significantly in excess of the carrying value.

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Intangible Long-Lived Assets

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

	Weighted Average Amortization Period (in years)	Gross Carrying Amount as of March 31, 2019	Accumulated Amortization	Accumulated Impairment Loss	Net Carrying Value as of March 31, 2019
Trademarks	15	$7,100	$(1,942)	$(4,179)	$ 979
Existing technology	13	12,600	(5,408)	(4,328)	2,864
Customer relationships	11	33,500	(17,008)	(10,751)	5,741
Reacquired rights	3	7,500	(5,066)	—	2,434
Patents	8	6,796	(2,542)	—	4,254
Other	2	618	(568)	—	50
Total intangible assets		$68,114	$(32,534)	$(19,258)	$ 16,322

	Weighted Average Amortization Period (in years)	Gross Carrying Amount as of December 31, 2018	Accumulated Amortization	Accumulated Impairment Loss	Net Carrying Value as of December 31, 2018
Trademarks	15	$ 7,100	$(1,907)	$(4,179)	$ 1,014
Existing technology	13	12,600	(5,268)	(4,328)	3,004
Customer relationships	11	33,500	(16,542)	(10,751)	6,207
Reacquired rights	3	7,500	(4,341)	—	3,159
Patents	8	6,796	(2,334)	—	4,462
Other	2	618	(544)	—	74
Total intangible assets		$ 68,114	$(30,936)	$(19,258)	$ 17,920

The total estimated annual future amortization expense for these acquired intangible assets as of March 31, 2019 is as follows (in thousands):

Fiscal Year Ending December 31,	Amortization
Remainder of 2019	$ 4,544
2020	3,838
2021	3,389
2022	2,116
2023	1,495
Thereafter	940
Total	$ 16,322

Amortization for the three months ended March 31, 2019 and 2018 was $1.5 million and $1.4 million, respectively.

Note 7. Credit Facilities

On February 27, 2018, we entered into a new credit facility for a $200.0 million revolving line of credit, with a $50.0 million letter of credit sublimit, and a maturity date of February 27, 2021, replacing the existing credit facility which provided for a $50.0 million revolving line of credit with a $10.0 million letter of credit. The credit facility requires us to comply with specific financial conditions and performance requirements. The loans bear interest, at our option, at either a rate based on the reserve adjusted LIBOR for the applicable interest period or a base rate, in each case plus a margin. The base rate is the highest of the credit facility's publicly announced prime rate, the federal funds rate plus

0.50% and one month LIBOR plus 1.0%. The margin ranges from 1.25% to 1.75% for LIBOR loans and 0.25% to 0.75% for base rate loans. Interest on the loans is payable quarterly in arrears with respect to base rate loans and at the end of an interest period (and at three month intervals if the interest period exceeds three months) in the case of LIBOR loans. Principal, together with accrued and unpaid interest, is due on the maturity date. As of March 31, 2019, we had no outstanding borrowings under this credit facility and were in compliance with the conditions and performance requirements.

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Note 8. Impairments and Other Charges

On March 5, 2019, we announced the outcome of the arbitration regarding SDC (*Refer to Note 9 "Legal Proceedings" of the Notes to Condensed Consolidated Financial Statements* for SDC legal proceedings discussion) which required Align to close its Invisalign stores and tender Align's equity interest in SDC by April 3, 2019. Accordingly, Align evaluated the ongoing value of the Invisalign stores' operating lease right-of-use assets and related leasehold improvements and other fixed assets in accordance with ASC 360, *Property, Plant and Equipment*. Based on the evaluation, Align determined that the carrying value of these assets were not recoverable. Align evaluated the fair value of these assets in accordance with ASC 820, *Fair Value Measurement,* and we considered the market participant's ability to generate economic benefits by using these assets in its highest and best use or by selling it to another market participant that would use the asset in its highest and best use. As a result, Align recorded impairment losses of $14.2 million for operating lease right-of-use assets and $14.3 million of leasehold improvements and other fixed assets. In addition, we also recorded $1.3 million of employee severance costs and other charges.

Note 9. Legal Proceedings

Securities Class Action Lawsuit

On November 5, 2018, a class action lawsuit against Align, and three of our executive officers, was filed in the U.S. District Court for the Northern District of California on behalf of a purported class of purchasers of our common stock between July 25, 2018 and October 24, 2018. The complaint generally alleges claims under the federal securities laws and seeks monetary damages in an unspecified amount and costs and expenses incurred in the litigation. On December 12, 2018, a similar lawsuit was filed in the same court on behalf of a purported class of purchasers of our common stock between April 25, 2018 and October 24, 2018 (together with the first lawsuit, the "Securities Actions"). The Court appointed a lead plaintiff on March 22, 2019 and that lead plaintiff is expected to file a consolidated complaint on May 10, 2019. Align believes these claims are without merit and intends to vigorously defend itself. Align is currently unable to predict the outcome of these lawsuits and therefore cannot determine the likelihood of loss nor estimate a range of possible loss.

Shareholder Derivative Lawsuit

In January 2019, three derivative lawsuits were also filed in the U.S. District Court for the Northern District of California, purportedly on behalf of Align, naming as defendants the members of our Board of Directors along with certain of our executive officers. The allegations in the complaints are similar to those presented in the Securities Action, but the complaints assert various state law causes of action, including for breaches of fiduciary duty, insider trading, and unjust enrichment, among others. The complaints seek unspecified monetary damages on behalf of Align, which is named solely as a nominal defendant against whom no recovery is sought, as well as disgorgement and the costs and expenses associated with the litigation, including attorneys' fees. On February 26, 2019, the three lawsuits were consolidated. On April 10, 2019, the Court stayed the consolidated action pending final disposition of the Securities Action.

On April 12, 2019, a derivative lawsuit was also filed in California Superior Court for Santa Clara County, purportedly on behalf of Align, naming as defendants the members of our Board of Directors along with certain of our executive officers. The allegations in this complaint are similar to those in the derivative suits described above.

Align is currently unable to predict the outcome of these lawsuits and therefore cannot determine the likelihood of loss nor estimate a range of possible loss.

3Shape Litigation

On November 14, 2017, Align filed six patent infringement lawsuits asserting 26 patents against 3Shape, a Danish corporation, and a related U.S. corporate entity, asserting that 3Shape's Trios intraoral scanning system and Dental System software infringe Align patents. Align filed two Section 337 complaints with the U.S. International Trade Commission ("ITC") alleging that 3Shape violates U.S. trade laws by selling for importation and importing its infringing Trios intraoral scanning system and Dental System software. Align's ITC complaints seek cease and desist orders and exclusion orders prohibiting the importation of 3Shape's Trios scanning system and Dental System software products into the U.S. Align also filed four separate complaints in the U.S. District Court for the District of Delaware alleging patent infringement by 3Shape's Trios intraoral scanning system and Dental System software. Two of those cases are stayed pending the ITC determinations, and the other two cases are currently active in discovery. The ITC conducted hearings in September and November 2018. On March 1, 2019, the Administrative Law Judge issued an Initial Determination in one of the Section 337 investigations, finding no violation of Section 337 by 3Shape. Align and 3Shape each petitioned the Commission for review of the Initial Determination, and the Commission has not yet ruled on those petitions. On

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April 26, 2019, the Administrative Law Judge issued an Initial Determination in the second Section 337 investigations, finding no violation of Section 337 by 3Shape. Petitions for review by the Commission, if any, are due May 10, 2019. The target dates for completion of the investigations is July 1 and August 26, 2019.

On May 9, 2018, 3Shape filed a complaint in the U.S. District Court for the District of Delaware alleging patent infringement by Align's iTero Element scanner of a single 3Shape patent; the case was subsequently stayed. On June 14, 2018, 3Shape filed another complaint in the U.S. District Court for the District of Delaware alleging patent infringement by Align's iTero Element scanner of a single 3Shape patent, which remains an active case.

On August 28, 2018, 3Shape filed a complaint against Align in the U.S. District Court for the District of Delaware alleging antitrust violations and seeking monetary damages and injunctive relief relating to Align's market activities, including Align's assertion of its patent portfolio, in the clear aligner and intraoral scanning markets. Align filed a motion to dismiss 3Shape's complaint on October 17, 2018, which the Court has yet to rule on. Align has also moved to stay the litigation pending the outcome of its motion to dismiss and/or the patent litigations involving 3Shape.

On December 10, 2018, Align filed three additional patent infringement lawsuits asserting 10 additional patents against 3Shape. Align filed one Section 337 complaint with the ITC alleging that 3Shape violates U.S. trade laws through unfair competition by selling for importation and importing the infringing TRIOS intraoral scanning system, Trios Lab Scanners and TRIOS software, TRIOS Module software, Dental System software, and Ortho System Software. On December 11, 2018, Align filed two separate complaints in the U.S. District Court for the District of Delaware alleging patent infringement by 3Shape's Trios intraoral scanning system, Lab Scanners and Dental and Ortho System Software. The ITC instituted the investigation, and one of the District Court cases was stayed pending the ITC determination.

3Shape has sought to invalidate certain of Align's patents through petitions for inter partes review proceedings. Align disputes 3Shape's positions and intends to vigorously defend the validity of its patent rights.

Each of the District Court patent infringement complaints seek monetary damages and injunctive relief against further infringement. We are currently unable to predict the outcome of this dispute and therefore cannot determine the likelihood of loss, if any, nor estimate a range of possible loss.

SDC Dispute

In February 2018, we received a communication on behalf of SDC Financial LLC, SmileDirectClub LLC, and the Members of SDC Financial LLC other than the Company (collectively, the SDC Entities) alleging that the launch and operation of the Invisalign store pilot program constitutes a breach of non-compete provisions applicable to the members of SDC Financial LLC, including Align. As a result of this alleged breach, SDC Financial LLC notified us that its members (other than Align) seek to exercise a right to repurchase all of Align's SDC Financial LLC membership interests for a purchase price equal to the current "capital account" balance of Align. The SDC Entities' communication also alleged that Align breached confidentiality provisions applicable to the SDC Financial LLC members and demanded that Align cease all activities related to the Invisalign store pilot project, close existing Invisalign stores and cease using SDC's confidential information. In April 2018, the SDC Entities instigated confidential arbitration proceedings and filed a complaint in the Chancery Court of Davidson County, State of Tennessee that sought, among other forms of relief, to preliminarily and permanently enjoin all activities related to the Invisalign store pilot project, require Align to close existing Invisalign stores, prohibit Align from opening any additional stores, and allow the SDC Entities to exercise a right to repurchase all of Align's SDC Financial LLC membership interests for a purchase price equal to Align's current "capital account" balance.
On June 29, 2018, the Chancery Court of Davidson County, State of Tennessee denied the SDC Entities' request for a temporary injunction to prevent Align from opening additional Invisalign stores. During December 2018, the parties

participated in binding arbitration proceedings and presented closing arguments on January 23, 2019. The arbitrator issued his decision (the Award) on March 4, 2019. The arbitrator found that Align breached the non-compete provision applicable to the members of SDC Financial LLC, including that Align misused the SDC Entities' confidential information and violated fiduciary duties to SDC Financial LLC. The arbitrator ordered Align to close its Invisalign stores by April 3, 2019, and enjoined Align from opening new Invisalign stores or providing certain services in physical retail establishments in connection with the marketing and sale of clear aligners, and enjoined Align from using the SDC Entities' confidential information. The arbitrator extended the expiration date of the non-compete provision to August 18, 2022. The arbitrator also ordered Align to tender its SDC Financial LLC membership interests to the SDC Entities for a purchase price equal to the "capital account" balance as of October 31, 2017, a price which is significantly below the current fair market value of such investment. No financial damages were awarded to the SDC Entities. The SDC Entities filed a motion to confirm the Award, which Align did not oppose, in the Circuit Court for Cook County, Illinois. The motion to confirm the Award is under submission.

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As required by the Award, on April 3, 2019, Align closed its Invisalign stores, returned SDC's alleged confidential information, and tendered its memberships interests to certain SDC Entities for a purchase price that SDC claims to be Align's "capital account" balance as of October 31, 2017. Align disputes the "capital account" balance as of October 31, 2017 as provided by the SDC Entities and anticipate that there may be additional litigation with the SDC Entities regarding the "capital account" balance and other issues relating to the Award and the parties' relationship.

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.

Straumann Group Litigation Settlement

In March 2019, we entered into an agreement with Straumann Group to settle all outstanding patent disputes in the U.S., the U.K., and Brazil, including those involving ClearCorrect, a subsidiary of Straumann Group. Under the terms of the settlement, Straumann Group paid Align $35 million on March 29, 2019 and it was recorded as a deferred litigation settlement gain in accrued liabilities in our Condensed Consolidated Balance Sheet due to certain contingencies which made the payment refundable as of March 31, 2019. We expect to recognize most of this gain in operating income in our Condensed Consolidated Statement of Operation in the second quarter of 2019. In addition, we also signed a non-binding letter of intent with Straumann Group for a 5-year global development and distribution agreement whereby Straumann would distribute 5,000 iTero Element scanners which would be fully integrated into the Straumann/Dental Wings CARES®/DWOS® workflow. This device would offer users access to the Straumann CARES digital workflow, Straumann's CoDiagnostix guided implant surgery and ClearCorrect, in addition to the Invisalign workflow. If for any reason the companies choose not to enter into the development and distribution agreement by July 2, 2019 or by a mutually agreed extended date, Straumann Group will pay Align an additional $16 million in lieu of the development and distribution agreement.

Note 10. Commitments and Contingencies

Other Commitments

On January 15, 2019, we entered into a Purchase Agreement to purchase five floors of a building under construction in Petach Tivka, Israel (the "Property") for a purchase price of approximately $27.0 million with an option to purchase additional three floors. The purchase price will be paid in six installments according to construction milestones and the delivery of the Property throughout 2019 and 2020.

On January 29, 2019, we entered into a Purchase and Sale Agreement to purchase our current finance lease building located in Morrisville, North Carolina for a purchase price of $58.1 million subject to adjustments. In January 2019, we paid a $2.0 million deposit and in April 2019, we paid the remaining balance of the $56.0 million and closed the Purchase and Sale Agreement.

Off-Balance Sheet Arrangements

As of March 31, 2019, we had no material 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 other than certain items disclosed in Note 9 “Commitments and Contingencies” of the Notes to Consolidated Financial Statements included in our Annual Report on Form 10-K.

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.

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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 March 31, 2019, we did not have any material indemnification claims that were probable or reasonably possible.

Note 11. Stockholders' Equity

Summary of Stock-Based Compensation Expense

As of March 31, 2019, the 2005 Incentive Plan (as amended) has a total reserve of 27,783,379 shares of which 5,297,058 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 months ended March 31, 2019 and 2018 is as follows (in thousands):

	Three Months Ended March 31,	
	2019	2018
Cost of net revenues	$1,112	$881
Selling, general and administrative	16,890	12,578
Research and development	3,042	2,371
Total stock-based compensation	$21,044	$15,830

Stock Options

We have not granted options since 2011 and all outstanding options were fully vested and associated stock-based compensation expenses was recognized as of December 31, 2015. During the three months ended March 31, 2019, 7,800 stock options were exercised at a weighted average exercise price of $7.89 per share. As of March 31, 2019, options outstanding and exercisable were not material.

Restricted Stock Units ("RSUs")

The fair value of RSUs is based on our closing stock price on the date of grant. A summary for the three months ended March 31, 2019 is as follows:

	Number of Shares Underlying RSUs (in thousands)	Weighted Average Grant Date Fair Value	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Nonvested as of December 31, 2018	931	$129.39		
Granted	255	253.84		
Vested and released	(356)	95.18		
Forfeited	(20)	155.77		
Nonvested as of March 31, 2019	810	$183.06	1.67	$230,206

As of March 31, 2019, we expect to recognize $125.3 million of total unamortized compensation cost, net of estimated forfeitures, related to RSUs over a weighted average period of 2.6 years.

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

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We grant MSUs to our executive officers. Each MSU represents the right to one share of Align's common stock. The actual number of MSUs which will be eligible to vest will be based on the performance of Align's stock price relative to the performance of a stock market index over the vesting period, and certain MSU grants are also based on Align's stock price at the end of the performance period. Generally, the vesting period of MSUs is three years. For MSUs granted during the three months ended March 31, 2019, the maximum number of MSUs which will be eligible to vest are 250% of the MSUs initially granted.

The following table summarizes the MSU performance for the three months ended March 31, 2019:

	Number of Shares Underlying MSUs (in thousands)	Weighted Average Grant Date Fair Value	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Nonvested as of December 31, 2018	324	$215.07		
Granted	133	245.69		
Vested and released	(179)	72.74		
Forfeited	(5)	265.42		
Nonvested as of March 31, 2019	273	$322.53	1.84	$77,513

As of March 31, 2019, we expect to recognize $58.0 million of total unamortized compensation cost, net of estimated forfeitures, related to MSUs over a weighted average period of 1.8 years.

Employee Stock Purchase Plan ("ESPP")

In May 2010, our shareholders approved the 2010 Employee Stock Purchase Plan (the "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 March 31, 2019, we have 490,417 shares available for future issuance.

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

	Three Months Ended March 31,	
	2019	2018
Expected term (in years)	1.4	1.3
Expected volatility	48.6 %	35.7 %
Risk-free interest rate	2.5 %	1.9 %
Expected dividends	—	—
Weighted average fair value at grant date	$90.36	$78.38

As of March 31, 2019, there was $10.3 million of total unamortized compensation costs related to employee stock purchases which we expect to be recognized over a weighted average period of 1.0 year.

Note 12. Common Stock Repurchase Programs

April 2016 Repurchase Program

In April 2016, we announced that our Board of Directors had authorized a plan to repurchase up to $300.0 million of our common stock ("April 2016 Repurchase Program").

In 2017, we entered into an accelerated share repurchase agreement ("2017 ASR") to repurchase $50.0 million of our common stock which was completed in August 2017. We received a total of approximately 0.4 million shares for an average share price of $146.48. During 2017, we repurchased on the open market approximately 0.2 million shares of our common stock at an average price of $243.40 per share, including commissions, for an aggregate purchase price of approximately $50.0 million.

In 2018, we repurchased on the open market approximately 0.7 million shares of our common stock at an average price of $293.21 per share, including commissions, for an aggregate purchase price of approximately $200.0 million, completing the April 2016 Repurchase Program.

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May 2018 Repurchase Program

In May 2018, we announced that our Board of Directors had authorized a plan to repurchase up to $600.0 million of our common stock ("May 2018 Repurchase Program").

In 2018, we repurchased on the open market approximately 0.1 million shares of our common stock at an average price of $356.54 per share, including commissions, for an aggregate purchase price of approximately $50.0 million. In 2018, we entered into an accelerated stock repurchase agreement ("2018 ASR") to repurchase $50.0 million of our common stock which was completed in December 2018. We received a total of approximately 0.2 million shares for an average share price of $213.18.

In February 2019, we purchased on the open market approximately 0.2 million shares of our common stock at an average price of $243.42 per share, including commission for an aggregate purchase price of $50.0 million. As of March 31, 2019, we have $450.0 million remaining under the May 2018 Repurchase Program.

Note 13. Accounting for Income Taxes

Our provision for income taxes was $8.8 million and $2.9 million for the three months ended March 31, 2019 and 2018, respectively, representing effective tax rates of 10.4% and 2.9%, respectively. Our effective tax rate differs from the statutory federal income tax rate of 21% for the three months ended March 31, 2019 and 2018, respectively, mainly as a result of the recognition of excess tax benefits related to stock-based compensation and certain foreign earnings, primarily from the Netherlands and Costa Rica, being taxed at lower tax rates.

The increase in effective tax rate for the three months ended March 31, 2019 compared to the same period in 2018 is primarily attributable to reduction in excess tax benefits related to stock-based compensation resulting from the unfavorable tax impact of IRS Notice 2018-68 issued in August 2018, which limited our officers' stock compensation deductions. For the three months ended March 31, 2019 and 2018, we recognized excess tax benefits of $11.9 million and $23.3 million, respectively, in our provision for income taxes.

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

We file U.S. federal, U.S. state, and non-U.S. income tax returns. Our major tax jurisdictions include U.S. federal, the State of California and the Netherlands. For U.S. federal and state tax returns, we are no longer subject to tax examinations for years before 2015. We are currently under examination by the IRS for tax years 2015 and 2016. With few exceptions, we are no longer subject to examination by foreign tax authorities for years before 2010.

Our total gross unrecognized tax benefits, excluding interest and penalties, was $38.0 million and $33.3 million as of March 31, 2019 and December 31, 2018, respectively, a material amount of which would impact our effective tax rate if recognized. Our total interest and penalties accrued as of March 31, 2019 was not material. We have elected to recognize interest and penalties related to unrecognized tax benefits as a component of income taxes. The timing and resolution of income tax examinations is uncertain, and the amounts ultimately paid, if any, upon resolution of issues raised by the taxing authorities may differ materially from the amounts accrued for each year. Although it is possible that our balance of gross unrecognized tax benefits could materially change in the next 12 months, given the uncertainty in the development of ongoing income tax examinations, we are unable to estimate the full range of possible adjustments to this balance.

As of December 31, 2018, undistributed earnings of the Company's foreign subsidiaries totaled $533.5 million. As a result of the TCJA, during the year ended December 31, 2017, we provided for U.S. income taxes on undistributed foreign earnings through December 31, 2017, and we have reassessed our capital needs and investment strategy with regard to the indefinite reinvestment, determining that certain of those are no longer indefinitely reinvested. Of the total undistributed foreign earnings as of December 31, 2018, the amount that is not indefinitely reinvested is $239.2 million. The remaining amount of undistributed foreign earnings of approximately $294.3 million continues to be indefinitely reinvested in our international operations. Since U.S. income taxes have already been provided under the GILTI provisions of the TCJA, the additional tax impact of the distribution of such foreign earnings to the U.S. parent company would be limited to withholding taxes and is not significant.

In June 2017, the Costa Rica Ministry of Foreign Trade, an agency of the Government of Costa Rica, granted an extension of certain income tax incentives for an additional twelve year period. Under these incentives, all of the income in Costa Rica is subject to a reduced tax rate. In order to receive the benefit of these incentives, we must hire specified numbers of employees and maintain certain minimum levels of fixed asset investment in Costa Rica. If we do not fulfill these conditions for any reason, our

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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 2019 and 2018. For the three months ended March 31, 2019, the reduction in income taxes due to the reduced tax rate was minimal.

Note 14. 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 RSUs, MSUs, stock options and our ESPP.

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

	Three Months Ended March 31,	
	2019	2018
Numerator:		
Net income	$71,848	$95,866
Denominator:		
Weighted average common shares outstanding, basic	79,860	80,036
Dilutive effect of potential common stock	827	1,592
Total shares, diluted	80,687	81,628
Net income per share, basic	$0.90	$1.20
Net income per share, diluted	$0.89	$1.17

For the three months ended March 31, 2019 and 2018, potentially anti-dilutive shares excluded from diluted net income per share related to RSUs, MSUs and ESPP were not material.

Note 15. Supplemental Cash Flow Information

The supplemental cash flow information consists of the following (in thousands):

	Three Months Ended March 31,	
	2019	2018
Non-cash investing and financing activities:		
Fixed assets acquired with accounts payable or accrued liabilities	$13,113	$18,739
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	$3,820	$—
Financing cash flows from finance leases	$2,190	$—
Right-of-use assets obtained in exchange for lease obligations:		
Operating leases	$15,984	$—
Finance leases	$51,064	$—

Note 16. 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

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include net revenues, gross profit and income from operations. Income from operations for each segment includes all geographic revenues, related cost of net revenues and operating expenses directly attributable to the segment. Certain operating expenses are attributable to operating segments and each allocation is measured differently based on the specific facts and circumstances of the costs being allocated. Costs not specifically allocated to segment income from operations include various corporate expenses such as stock-based compensation and costs related to IT, facilities, human resources, accounting and finance, legal and regulatory, and other separately managed general and administrative costs outside the operating segments.

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

- Our Clear Aligner segment consists of Comprehensive Products, Non-Comprehensive Products and Non-Case revenues as defined below:
- Comprehensive Products include, but not limited to, our Invisalign Comprehensive (formerly known as Invisalign Full and Invisalign Teen), Invisalign Assist and Invisalign First.

- Non-Comprehensive Products include, Invisalign Express 10, Invisalign Express 5, Express Package, Lite Package and Invisalign Go products in addition to revenues from the sale of aligners to SDC under our supply agreement.

- Non-Case includes, but not limited to, Vivera retainers along with our training and ancillary products for treating malocclusion.

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

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

	Three Months Ended March 31,	
Net revenues	2019	2018
Clear Aligner	$469,205	$385,505
Scanner	79,766	51,419
Total net revenues	$548,971	$436,924
Gross profit		
Clear Aligner	$351,358	$296,976
Scanner	50,738	30,432
Total gross profit	$402,096	$327,408
Income from operations		
Clear Aligner	$158,641	$161,454
Scanner	28,259	16,082
Unallocated corporate expenses	(99,199)	(79,344)
Total income from operations	$87,701	$98,192
Depreciation and amortization		
Clear Aligner	$11,135	$6,384
Scanner	2,097	1,104
Unallocated corporate depreciation and amortization	9,446	3,946
Total depreciation and amortization	$22,678	$11,434
Impairments and other charges		
Clear Aligner	$29,782	$—

Scanner	—	—
Unallocated corporate impairments and other charges	—	—
Total impairments and other charges	$29,782	$—

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

	Three Months Ended March 31,	
	2019	2018
Total segment income from operations	$186,900	$177,536
Unallocated corporate expenses	(99,199)	(79,344)
Total income from operations	87,701	98,192
Interest income	2,633	2,176
Other income (expense), net	(5,746)	177
Net income before provision for income taxes and equity in losses of investee	$84,588	$100,545

Geographical Information

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

	Three Months Ended March 31,	
	2019	2018
Net revenues [1]:		
United States	$279,005	$237,103
The Netherlands	174,744	139,531
China	42,616	25,586
Other International	52,606	34,704
Total net revenues	$548,971	$436,924

[1] Net revenues are attributed to countries based on location of where revenues are recognized.

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

	March 31, 2019	December 31, 2018
Long-lived assets [2]:		
The Netherlands	$211,302	$206,679
United States	175,167	139,239
Costa Rica	82,138	80,218
China	55,676	36,249
Mexico	33,734	33,240
Other International	73,634	25,704
Total long-lived assets	$631,651	$521,329

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

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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 of our new products and product enhancements will have on doctor utilization and our market share, our expectations regarding product mix and product adoption, our expectations regarding the existence and impact of seasonality, our expectations regarding the sales growth of our intra-oral scanner sales in international markets, our belief that technology features and functionality of our iTero scanners will increase adoption of Invisalign and increase sales of our intra-oral scanners, our expectations regarding the financial and strategic benefits of establishing regional order acquisition, treatment planning and manufacturing facilities, our intention to hire more sales representatives in 2019 and their expected impact on our sales, our expectations regarding the continued expansion of our international markets, including our expectation that international revenues will grow at a faster rate then Americas for the foreseeable future,our expectation to incur additional costs related to the planned corporate structure reorganization, 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 2, Item 1A "Risk Factors." We undertake no obligation to revise or update these forward-looking statements. Given these risks and uncertainties, readers are cautioned not to place undue reliance on such forward-looking statements.

The following discussion and analysis of our financial condition and results of operations should be read together with our condensed consolidated financial statements and related notes included elsewhere in this Quarterly Report on Form 10-Q and with our audited consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2018 as filed with the Securities and Exchange Commission.

Overview

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

The successful execution of our business strategy in 2019 and beyond may be affected by a number of other factors including:

- *New Invisalign Product Portfolio and Pricing*. In July 2018, we launched a new expanded Invisalign product portfolio which includes new options and greater flexibility to treat a broader range of patients. The new Invisalign product portfolio offers doctors more choices by extending desirable features across the entire portfolio and creating new Invisalign treatment packages, as well as new options to treat young patients with early mixed dentition (with a mixture of primary/baby and permanent teeth). The new end-to-end Invisalign product portfolio includes clear aligner product offerings for almost every patient age group and case complexity to make it easier for our doctors to tailor treatment planning to the needs of each patient. Pricing and availability for the new Invisalign product offerings and the associated terms and conditions vary by region.

- *New Invisalign Products and Feature Enhancements*. Product innovation drives greater treatment predictability, clinical applicability and ease of use for our customers which supports adoption of Invisalign treatment in their practices. Our focus is to develop solutions and features to treat a wide range of cases from simple to complex.

In March 2017, we announced Invisalign treatment with Mandibular Advancement, the first clear aligner solution for Class II correction in growing tween and teen patients. This offering combines the benefits of our clear aligner system with features for moving the lower jaw forward while simultaneously aligning the teeth. Invisalign treatment with Mandibular Advancement is available in Canada, select Europe, Middle East and Africa ("EMEA"), Asia Pacific ("APAC") and Latin America ("LATAM") countries and, in the U.S.

In April 2018, we announced a new Invisalign Go product with more user-friendly iTero digital chairside experience and greater flexibility to treat a wider range of mild to moderate cases, such as crowded or gap teeth that require teeth straightening prior to restorative treatments. Invisalign Go is available to Invisalign-trained

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doctors in the U.S., the majority of European countries as well as in select APAC markets. Invisalign Go also incorporates new data-driven clinical protocols for predictable tooth movement and automated case assessments that leverages our Invisalign patients treated to date. These improvements make it easier for general practitioner dentists to tailor their treatment plans to the individual needs of each patient.

Beginning July 2018, Invisalign First clear aligners, a treatment option designed with features specifically for younger patients with early mixed dentition, are available to Invisalign-trained doctors in the U.S., Canada, Australia, New Zealand, Japan, and the EMEA region. Invisalign First clear aligners are designed specifically to address a broad range of younger patients' malocclusions, including shorter clinical crowns, management of erupting dentition and predictable dental arch expansion. Phase 1 treatment is an early interceptive orthodontic treatment for young patients, traditionally done through arch expanders, or partial metal braces, before all permanent teeth have erupted, typically at ages seven through ten years.

- *New iTero Products and Technology Innovation.* The iTero scanner is an important component to our customer experience and is central to a digital approach as well as overall customer utilization of Invisalign.

In April 2018, we expanded the iTero Element portfolio with the launch of the iTero Element 2 and the iTero Element Flex scanners, building on the existing high precision, full-color imaging and fast scan times of the iTero Element portfolio while streamlining orthodontic and restorative workflows. The next-generation iTero Element 2 is designed for greater performance with 2X faster start-up and 25% faster scan processing time compared to the iTero Element. The new iTero Element Flex wand-only configuration is a portable scanner for easy transport from office to office. iTero Element 2 and iTero Element Flex are currently available in Canada, the United States, majority of EMEA and select APAC countries. The existing iTero Element scanner will continue to be available in all markets.

In April 2018, we announced that we received market approval for the iTero Element intra-oral scanner from the China Food and Drug Administration, and we began offering this scanner in China. The iTero Element scanner launch in China not only supports growth of our base Invisalign clear aligner business but also represents a major milestone for digital dentistry in China. As we continue to expand into markets where we sell our intra-oral scanners, we expect continued growth for the foreseeable future due to the size of the market opportunities and our relatively low market penetration in these regions.

In February 2019, we announced the launch of iTero Element 5D Imaging System for comprehensive, preventative and restorative oral care. The iTero Element 5D Imaging System provides a new comprehensive approach to clinical applications, workflows and user experience that expands the suite of existing high-precision, full color imaging and fast scan times of the iTero Element portfolio. The iTero Element 5D Imaging System is available in the majority of EMEA and APAC regions. The iTero Element 5D Imaging System is not yet available in the United States or Latin America.

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.

The use of iTero and other digital scanners for Invisalign case submission in place of PVS impressions continues to grow and remains a positive catalyst for Invisalign utilization. For the first quarter of 2019, total Invisalign cases submitted with a digital scanner in the Americas increased to 76.0%, up from 73.5% in the fourth quarter of 2018. International scans increased to 59.3%, up from 57.5% in the fourth quarter of 2018. We believe that over the long-term, technology innovation and added features and functionality of our iTero scanners 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.

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- *Invisalign Adoption.* Our goal is to establish Invisalign as the treatment of choice for treating malocclusion ultimately driving increased product adoption and frequency of use by dental professionals, also known as "utilization rates." Our quarterly utilization rates for the last five quarters are as follows:

* Invisalign utilization rates = # of cases shipped divided by # of doctors cases were shipped to. Beginning in the first quarter of 2018, we report International region to include EMEA and APAC. LATAM is excluded from above chart as it is not material. Our historical utilization numbers have been recast to reflect this classification.

Total utilization in the first quarter of 2019 increased to 6.2 cases per doctor compared to 5.8 in the first quarter of 2018.

North America: Utilization among our North American orthodontist customers reached an all time high in the first quarter of 2019 at 18.3 cases per doctor. Compared to 15.3 cases per doctor utilized in the first quarter of 2018. The increase in North American orthodontist utilization in the first quarter of 2019 reflects improvements in product and technology which continues to strengthen our doctors' clinical confidence such that they now utilize Invisalign more often and on more complex cases, including their teenage patients.

International: International doctor utilization was 5.5 cases per doctor in the first quarter of 2019 compared to 5.4 in the first quarter of 2018. The increase in International utilization reflects increased utilization and continued expansion of our customer base in both EMEA and APAC regions due to increasing adoption of the product due in part to its ability to treat more complex cases.

We expect that over the long-term, our utilization rates will gradually improve as a result of advancements in product and technology, which continue to strengthen our doctors' clinical confidence in the use of Invisalign. In addition, since the teenage and younger market makes up 75% of the approximately 12 million total orthodontic case starts each year, and as we continue to drive adoption of teenage and younger patients through sales and marketing programs, we expect our utilization rate to improve. Our utilization rates, however, may fluctuate from period to period due to a variety of factors, including seasonal trends in our business along with adoption rates of new products and features.

- *Number of New Invisalign Doctors Trained.* We continue to expand our Invisalign customer base through the training of new doctors. During the three months ended March 31, 2019, we trained 4,135 new Invisalign doctors of which 1,725 were trained in the Americas region and 2,410 in the International region. In 2018, we trained a total of 19,655 new Invisalign doctors, of which 7,885 were trained in the Americas region and 11,770 in the International region.

- *International Invisalign Growth.* We continue to focus our efforts towards increasing Invisalign clear aligner adoption by dental professionals in the EMEA and APAC markets. On a year-over-year basis, our International Invisalign volume increased 38.5% driven primarily by increased adoption as well as expansion of our customer base in both the EMEA

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and APAC regions. We continue to see growth from our international orthodontists and general practitioner ("GP") customers and are seeing more positive traction in the GP channel as we continue to segment our sales and marketing resources and programs specifically around each customer channel. In addition, we believe that continuous product introductions and feature improvements, such as Invisalign treatment with mandibular advancement, provide our customers with continued confidence in treating complex cases as well as teen-aged patients with Invisalign clear aligners. In 2019, 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 select country markets. We expect International revenues to continue to grow at a faster rate than the Americas for the foreseeable future due to our continued investment in international market expansion, the size of the market opportunities, and our relatively low market penetration of these regions. Our future growth is dependent upon the continued growth of Invisalign adoption and international market penetration (Refer to *Item 1A Risk Factors - "We are exposed to fluctuations in currency exchange rates, which could negatively affect our financial condition and results of operations."* for information on related risk factors).

- *Establish Regional Order Acquisition, Treatment Planning and Manufacturing Operations.* We will continue to establish and expand additional order acquisition, treatment planning and manufacturing operations closer to our international customers in order to improve our operational efficiency and to provide doctors confidence in using Invisalign clear aligners to treat more patients and more often. In the fourth quarter of 2018, we began fabricating our aligners in our new manufacturing facility in Ziyang, China, our first aligner fabrication facility outside of Juarez, Mexico. We expect that it will take several quarters to ramp this facility up to full capacity and as a result manufacturing labor and overhead in this facility will be underutilized during this transition period (Refer to *Item 1A Risk Factors - "As we continue to grow, we are subject to growth related risks, including risks related to excess or constrained capacity at our existing facilities."* for information on related risk factors).
- *Increased Sales Force.* In order to provide more comprehensive sales and service coverage, in the fourth quarter of 2018, we increased our sales force in the Americas by adding approximately 100 sales team members. We intend to continue to invest in expanding our sales force to allow us to pursue the growth opportunities within and outside of our existing geographic markets (Refer to *Item 1A Risk Factors - "We primarily rely on our direct sales force to sell our products, and any failure to maintain our direct sales force could harm our business"* for information on related risk factors).
- *Corporate Structure Reorganization.* Given our continued growth and expansion internationally, during the year, we intend to reorganize our corporate structure and intercompany relationships to more closely align with the international nature of our business activities. The proposed corporate structure may also allow us to obtain financial and operational efficiencies after they are implemented. As part of this corporate structure reorganization, we intend to relocate our European headquarters from the Netherlands to Switzerland. We expect the relocation to be completed in early 2020. As a result, we will incur expenses in the near term and expect to realize the related benefits in subsequent years. The implementation of this reorganization plan may be disruptive to our business, and, following completion of the reorganization plan, our business may not be more efficient or effective than prior to implementation of the plan. Our reorganization activities, including any related expenses and the impact from affected employees, could have a material adverse effect on our business, operating results, and financial condition (Refer to *Item 1A Risk Factors - "We may experience unexpected issues and expenses associated with the corporate structure reorganization, including the relocation of our European headquarters to Switzerland"* for information on related risk factors).
- *Straumann Group Litigation Settlement.* In March 2019, we entered into an agreement with Straumann Group to settle all outstanding patent disputes in the U.S., the U.K., and Brazil, including those involving ClearCorrect, a subsidiary of Straumann Group. Under the terms of the settlement, Straumann Group paid Align $35 million on March 29, 2019 and it was recorded as a deferred litigation settlement gain in accrued liabilities in our Condensed Consolidated Balance Sheet due to certain contingencies which made the payment refundable as of March 31, 2019. We expect to recognize most of this gain in operating income in our Condensed Consolidated Statement of Operation in the second quarter of 2019. In addition, we also signed a non-binding letter of intent with Straumann Group for a 5-year global development and distribution agreement whereby Straumann would distribute 5,000 iTero Element scanners which

would be fully integrated into the Straumann/Dental Wings CARES®/DWOS® workflow. This device would offer users access to the Straumann CARES digital workflow, Straumann's CoDiagnostix guided implant surgery and ClearCorrect, in addition to the Invisalign workflow. If for any reason the companies choose not to enter into the development and distribution agreement by July 2, 2019 or by a mutually agreed extended date, Straumann Group will pay Align an additional $16 million in lieu of the development and distribution agreement (*Refer to Note 9 "Legal Proceedings" of the Notes to Consolidated Financial Statements* for details).

- *SmileDirectClub.* In March 2019, we announced the outcome of the arbitration of the claims asserted against us by SDC Financial LLC, SmileDirectClub LLC, and the members of SDC Financial LLC other than the company (collectively,

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the SDC Entities). As previously disclosed, the arbitration concluded on January 23, 2019. The arbitrator issued his decision on March 4, 2019. The arbitrator ordered us to close our Invisalign stores by April 3, 2019,enjoined us from opening new Invisalign stores or providing certain services in physical retail establishments, and enjoined us from using the SDC Entities' confidential information. The arbitrator extended the expiration date of the non-compete provision to August 18, 2022. The arbitrator also ordered us to tender our SDC Financial LLC membership interests to the SDC Entities for a purchase price equal to the "capital account" balance of Align as of October 31, 2017, a price which is significantly below the current fair market value of such investment. No financial damages were awarded to the SDC Entities. In the first quarter of 2019, we recorded charges related to the store closures of approximately $30 million, composed of impairments related to the right of use lease assets, leasehold improvements and other fixed assets along with employee severance expenses. These amounts represent estimates which are subject to change as management finalizes its assessment. Changes to these estimates may be material. On April 3, 2019, we closed all Invisalign stores and returned all of SDC's confidential information. In addition, we tendered our members interests to the SDC Entities for a purchase price that SDC claims to be the "capital account" balance of Align as of October 31, 2017 and, as a result, we expect to record a gain of approximately $16 million in the second quarter of 2019 as other income in our Condensed Consolidated Statement of Operation. Although we tendered our members interests pursuant to the arbitrators decision, we dispute that the amount paid by the SDC entities is the correct amount of our "capital account" balance as of October 31, 2017. We anticipate that there may be additional litigation with the SDC Entities regarding the "capital account" balance and other issues relating to the Award and the parties' relationship. (*Refer to Note 9 "Legal Proceedings" of the Notes to Consolidated Financial Statements* for details on SDC dispute and *Refer to Note 8 "Impairments and Other Charges" of the Notes to Consolidated Financial Statements* for details on impairments).

- *Expenses.* We expect expenses to increase in 2019 due in part to:

Investments in manufacturing capacity and facilities to enhance our regional capabilities;
Investments in international expansion in new country markets;
Investments in expansion of number of direct sales force personnel;
Increase in sales, marketing and customer support resources;
Product and technology innovation to enhance product efficiency and operational productivity;
Increases in legal expenses, primarily related to the continued protection of our intellectual property rights, including our patents along with the additional costs related to the planned corporate structure reorganization.

We believe that these investments will position us to increase our revenues and continue to grow our market share, but will negatively impact results of operations, particularly in the near term.

- *Stock Repurchases.* In February 2019, we purchased $50.0 million of our common stock on the open market under a $600.0 million repurchase plan approved by our Board of Directors in May 2018. As of March 31, 2019, we have $450.0 million remaining under the May 2018 Repurchase Program (*Refer to Note 12 "Common Stock Repurchase Programs" of the Notes to Condensed Consolidated Financial Statements* for details on our stock repurchase programs).

Results of Operations

Net Revenues by Reportable Segment

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

- Our Clear Aligner segment consists of Comprehensive Products, Non-Comprehensive Products and Non-Case revenues as defined below:

- Comprehensive Products include, but are not limited to, Invisalign Comprehensive (formerly known as Invisalign Full and Invisalign Teen), Invisalign Assist and Invisalign First.

- Non-Comprehensive Products include, but are not limited to, Invisalign Express 10, Invisalign Express 5, Express Package, Lite Package and Invisalign Go in addition to revenues from the sale of aligners to SmileDirectClub (“SDC”) under our supply agreement.

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- Non-Case includes, but is not limited to, Vivera retainers along with our training and ancillary products for treating malocclusion.

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

Net revenues for our Clear Aligner and Scanner segments by region for the three months ended March 31, 2019 and 2018 are as follows (in millions):

	Three Months Ended March 31,			
Net Revenues	**2019**	**2018**	**Net Change**	**% Change**
Clear Aligner revenues:				
Americas	$245.3	$209.6	$35.8	17.1%
International	194.9	151.7	43.2	28.5%
Non-case	29.0	24.2	4.8	19.7%
Total Clear Aligner net revenues	$469.2	$385.5	$83.7	21.7%
Scanner net revenues	79.8	51.4	28.3	55.1%
Total net revenues	$549.0	$436.9	$112.0	25.6%

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

Clear Aligner Case Volume by Region

Case volume data which represents Clear Aligner case shipments by region for the three months ended March 31, 2019 and 2018 is as follows (in thousands):

	Three Months Ended March 31,			
Region	**2019**	**2018**	**Net Change**	**% Change**
Americas	213.2	176.5	36.7	20.8%
International	146.3	105.6	40.7	38.5%
Total case volume	359.5	282.1	77.4	27.4%

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

For the three months ended March 31, 2019, total net revenues increased by $112.0 million as compared to the same period in 2018 primarily as a result of Clear Aligner case and scanner volume growth across all regions.

Clear Aligner - Americas

For the three months ended March 31, 2019, Americas net revenues increased by $35.8 million as compared to the same period in 2018 primarily due to case volume growth across all channels and products which increased net revenues by $43.5 million. This increase was offset in part by lower average selling prices (“ASP”) which was mainly the result of higher promotional discounts which reduced net revenues by $7.6 million, increased net revenue deferrals by $3.5 million, and unfavorable foreign exchange rates which reduced net revenues by $2.4 million. This ASP decline was partially offset by higher prices from the new products introduced in July 2018 which increased net revenues by $8.7 million.

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Clear Aligner - International

For the three months ended March 31, 2019, International net revenues increased by $43.2 million as compared to the same period in 2018 primarily driven by case volume growth across all channels and products which increased net revenues by $58.5 million. This increase was partially offset by lower ASP which reduced net revenues by $15.3 million. The ASP decline was mainly the result of unfavorable foreign exchange rates which reduced net revenue by $11.5 million, higher promotional discounts which reduced net revenues by $9.1 million, and a product mix shift towards lower priced products which reduced net revenues by $6.7 million. These were partially offset by $6.5 million due to the higher prices related to our new products effective July 2018, along with a benefit from going direct in several additional countries, and therefore, we now recognize direct sales at full ASP rather than the discounted distributor ASP, which increased net revenue by $3.3 million.

Clear Aligner - Non-Case

For the three months ended March 31, 2019, non-case net revenues, consisting of Vivera Retainers, training fees and other product revenues, increased by $4.8 million as compared to the same period in 2018. This was primarily due to increased Vivera volume across all regions, which increased revenue by $4.5 million across all regions.

Scanner

For the three months ended March 31, 2019, scanner and services net revenues increased by $28.3 million as compared to the same period in 2018. This increase is primarily due to an increase in the number of scanners recognized which increased revenues by $11.0 million, and a larger scanner install base which resulted in higher computer-aided design/computer-aided manufacturing (“CAD/CAM”) services, which increased net revenues by $10.1 million. Additionally, net revenues increased by $7.2 million due to an increase in scanner ASP, mostly attributable to higher prices from new scanner products introduced in May 2018 and price increases in North America and APAC.

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

	Three Months Ended March 31,		
	2019	**2018**	**Change**
Clear Aligner			
Cost of net revenues	$117.8	$88.5	$29.3
% of net segment revenues	*25.1 %*	*23.0 %*	
Gross profit	$351.4	$297.0	$54.4
Gross margin %	*74.9 %*	*77.0 %*	
Scanner			
Cost of net revenues	$29.0	$21.0	$8.0
% of net segment revenues	*36.4 %*	*40.8 %*	
Gross profit	$50.7	$30.4	$20.3
Gross margin %	*63.6 %*	*59.2 %*	
Total cost of net revenues	$146.9	$109.5	$37.4
% of net revenues	*26.8 %*	*25.1 %*	
Gross profit	$402.1	$327.4	$74.7
Gross margin %	*73.2 %*	*74.9 %*	

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

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

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Clear Aligner

For the three months ended March 31, 2019, our gross margin percentage decreased as compared to the same period in 2018 primarily due to increase in aligners per case driven by additional aligners and lower ASP.

Scanner

For the three months ended March 31, 2019, our gross margin increased compared to the same period in 2018 primarily driven by higher ASP and lower freight costs.

Selling, general and administrative (in millions):

	Three Months Ended March 31,		
	2019	2018	Change
Selling, general and administrative	$247.1	$199.6	$47.5
% of net revenues	*45.0 %*	*45.7 %*	

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, equipment and maintenance costs, outside service costs, legal costs, depreciation and amortization expense and allocations of corporate overhead expenses including facilities and Information Technology ("IT").

For the three months ended March 31, 2019, selling, general and administrative expense increased compared to the same period in 2018 primarily due to higher compensation related costs of $32.0 million mainly from increased headcount resulting in higher salaries expense, incentive bonuses and fringe benefits partially due to investments in sales coverage and international expansion. We also incurred higher expenses from legal and outside service costs of $9.6 million, depreciation and amortization costs of $4.5 million and equipment, software and maintenance costs of $4.0 million.

Research and development (in millions):

	Three Months Ended March 31,		
	2019	2018	Change
Research and development	$37.5	$29.6	$ 7.9
% of net revenues	*6.8 %*	*6.8 %*	

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

Research and development expense includes the personnel-related costs including payroll and stock-based compensation and outside consulting expenses associated with the research and development of new products and enhancements to existing products and allocations of corporate overhead expenses including facilities and IT.

For the three months ended March 31, 2019, research and development expense increased compared to the same period in 2018 primarily due to higher compensation costs mainly from increased headcount resulting in higher salaries expense, incentive bonuses and fringe benefits.

Impairments and other charges (in millions):

	Three Months Ended March 31,

	2019	2018	Change
Impairments and other charges	$29.8	$—	$29.8
% of net revenues	*5.4 %*	*—%*	

For the three months ended March 31, 2019, we recorded impairments and other charges of $29.8 million due to costs related to the Invisalign store closures. The impairments and other charges are comprised of operating lease right-of-use assets impairments

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of $14.2 million, store leasehold improvement and other fixed asset impairments of $14.3 million, and employee severance and other expenses of $1.3 million (*Refer to Note 8"Impairments and Other Charges" and Note 9 "Legal Proceedings" of the Notes to Condensed Consolidated Financial Statements* for more information).

Income from operations (in millions):

	Three Months Ended March 31,		
	2019	**2018**	**Change**
Clear Aligner			
Income from operations	$158.6	$161.5	$(2.8)
Operating margin %	*33.8 %*	*41.9 %*	
Scanner			
Income from operations	$28.3	$16.1	$12.2
Operating margin %	*35.4 %*	*31.3 %*	
Total income from operations [1]	$87.7	$98.2	$(10.5)
Operating margin %	*16.0 %*	*22.5 %*	

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

[1] *Refer to Note 16 "Segments and Geographical Information" of the Notes to Condensed Consolidated Financial Statements* for details on unallocated corporate expenses and the reconciliation to Consolidated Income from Operations.

Clear Aligner

For the three months ended March 31, 2019, our operating margin percentage decreased compared to the same period in 2018 primarily due to higher operating expenses, costs related to the Invisalign store closures, an increase in aligners per case driven by additional aligners and lower ASP.

Scanner

For the three months ended March 31, 2019, our operating margin percentage increased compared to the same period in 2018 primarily driven by higher ASP and lower freight costs.

Interest income (in millions):

	Three Months Ended March 31,		
	2019	**2018**	**Change**
Interest income	$2.6	$2.2	$ 0.4

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

Interest includes interest income earned on cash, cash equivalents and investment balances.

For the three months ended March 31, 2019, interest income increased slightly compared to the same period in 2017 mainly due to higher interest rates.

Other income (expense), net (in millions):

	Three Months Ended March 31,		
	2019	**2018**	**Change**
Other income (expense), net	$(5.7)	$0.2	$(5.9)

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

Other income (expense), net, includes foreign exchange gains and losses, gains and losses on foreign currency forward contracts, interest expense and other miscellaneous charges.

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For the three months ended March 31, 2019, other income (expense), net decreased compared to the same period in 2018 primarily due to a $4.0 million impairment of our equity investment in a privately held company.

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

	Three Months Ended March 31,		
	2019	2018	Change
Equity in losses of investee, net of tax	$3.9	$1.8	$ 2.2

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

For the three months ended March 31, 2019, equity in losses of investee, net of tax increased compared to the same period in 2018 due to higher losses attributable from our equity method investments (*Refer to Note 5 "Equity Method Investments" of the Notes to Condensed Consolidated Financial Statements* for details on equity method investments).

Provision for income taxes (in millions):

	Three Months Ended March 31,		
	2019	2018	Change
Provision for income taxes	$8.8	$2.9	$ 5.9
Effective tax rates	*10.4 %*	*2.9 %*	

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

For the three months ended March 31, 2019 and 2018, provision for income taxes was $8.8 million and $2.9 million, respectively, representing effective tax rates of 10.4% and 2.9%, respectively.

The increase in effective tax rate for the three months ended March 31, 2019 compared to the same period in 2018 is primarily attributable to the reduction in excess tax benefits related to stock-based compensation resulting from the unfavorable tax impact of IRS Notice 2018-68 issued in August 2018, which limited our officers' stock compensation deductions.

For the three months ended March 31, 2019 and 2018, we recognized excess tax benefits of $11.9 million and $23.3 million, respectively, in our provision for income taxes.

Liquidity and Capital Resources

We fund our operations from product sales. As of March 31, 2019 and December 31, 2018, we had the following cash and cash equivalents, and short-term and long-term marketable securities (in thousands):

	March 31, 2019	December 31, 2018
Cash and cash equivalents	$588,001	$636,899
Marketable securities, short-term	144,540	98,460
Marketable securities, long-term	—	9,112
Total	$732,541	$744,471

As of March 31, 2019, we had $732.5 million in cash, cash equivalents and short-term marketable securities. Cash equivalents and marketable securities are comprised of money market funds and highly liquid debt instruments which primarily include commercial paper, corporate bonds, U.S. government agency bonds, U.S. government treasury

bonds, U.S. government treasury bonds, foreign bonds and certificates of deposit.

As of March 31, 2019, approximately $359.9 million of cash, cash equivalents and short-term and long-term marketable securities was held by our foreign subsidiaries. We did not repatriate funds to the U.S. during the three months ended March 31, 2019; however, we may do so in the future to invest in market expansion opportunities, provide additional working capital, and have greater flexibility to fund our stock repurchase programs (*Refer to Note 13 "Accounting for Income Taxes" of the Notes to Condensed Consolidated Financial Statements* for details).

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Cash flows (in thousands):

	Three Months Ended March 31,	
	2019	2018
Net cash flow provided by (used in):		
Operating activities	$ 117,207	$ 77,332
Investing activities	(74,418)	109,269
Financing activities	(92,762)	(139,822)
Effect of exchange rate changes on cash, cash equivalents, and restricted cash	1,089	1,715
Net (decrease) increase in cash, cash equivalents, and restricted cash	$ (48,884)	$ 48,494

Operating Activities

For the three months ended March 31, 2019, cash flows from operations of $117.2 million resulted primarily from our net income of approximately $71.8 million as well as the following:

Significant non-cash activities

- Impairment charges of $28.5 million related to decreases in fair values of certain assets related to Invisalign stores;
- Depreciation and amortization of $22.7 million related to our property, plant and equipment and intangible assets;
- Stock-based compensation of $21.0 million related to equity incentive compensation granted to employees and directors; and
- Net change in deferred tax assets of $7.6 million.

Significant changes in working capital

- Increase of $42.7 million in accounts receivable which is primarily a result of the increase in net revenues;
- Increase of $42.5 million in deferred revenues corresponding to the increase in case volume;
- Increase of $35.0 million in prepaid expenses and other assets due to timing of payments and activities; and
- Decrease of $5.2 million in accrued and other long-term liabilities due to timing of payments and activities partially offset by $35.0 million deferred settlement gain from Straumann litigation due to a refundable provision.

Investing Activities

Net cash used in investing activities was $74.4 million for the three months ended March 31, 2019 which primarily consisted of purchases of marketable securities of $125.8 million and property and plant and equipment purchases of $35.3 million. These outflows were partially offset by maturities and sales of marketable securities of $89.0 million.

For the remainder of 2019, we expect to invest an additional $200.0 million to $220.0 million in capital expenditures primarily related to purchases of buildings located in Morrisville, North Carolina and Petach Tivka, Israel as well as

additional manufacturing capacity to support our international expansion. Although we believe our current investment portfolio has little risk of impairment, we cannot predict future market conditions or market liquidity and can provide no assurance that our investment portfolio will remain unimpaired (*Refer to Note 10 "Commitments and Contingencies" of the Notes to Condensed Consolidated Financial Statements* for details on purchase of building in Morrisville, North Carolina).

Financing Activities

Net cash used in financing activities was $92.8 million for the three months ended March 31, 2019 which primarily consisted of payroll taxes paid for vesting of restricted stock units through share withholdings of $50.2 million and common stock repurchases of $50.0 million. These outflows were offset in part by $9.6 million proceeds from the issuance of common stock.

Common Stock Repurchases

In February 2019, we purchased $50.0 million of our common stock on the open market. As of March 31, 2019, we have $450.0 million remaining under the May 2018 Repurchase Program (*Refer to Note 12 "Common Stock Repurchase Programs" of the Notes to Condensed Consolidated Financial Statements* for details on our stock repurchase programs).

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Contractual Obligations

Our contractual obligations have not significantly changed since December 31, 2018 as disclosed in our Annual Report on Form 10-K, other than obligations described in the Form 10-Q herein. We believe that our current cash, cash equivalents and short-term marketable securities combined with our existing borrowing capacity will be sufficient to fund our operations for at least the next 12 months. If we are unable to generate adequate operating cash flows and need more funds beyond our available liquid investments and those available under our credit facility, we may need to suspend our stock repurchase programs 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 March 31, 2019, 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 other than certain items disclosed in Note 9 “Commitments and Contingencies” of the Notes to Consolidated Financial Statements included in our Annual Report on Form 10-K.

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 U.S. The preparation of condensed consolidated financial statements requires management to make estimates and judgments that affect the reported amounts of assets and liabilities, revenues and expenses and disclosures at the date of the financial statements. We evaluate our estimates on an on-going basis, including those related to revenue recognition, stock-based compensation, goodwill and finite-lived assets and related impairment, and income taxes. We use authoritative pronouncements, historical experience and other assumptions as the basis for making estimates. Actual results could differ from those estimates.

Other than the adoption of the new lease accounting standard (“ASC 842”) during the quarter ended March 31, 2019, there have been no material changes to our critical accounting policies and estimates from the information provided in the “Critical Accounting Policies and Estimates” section of our Management’s Discussion and Analysis of Financial Condition and Results of Operations included in our Annual Report on Form 10-K for the year ended December 31, 2018. Significant changes to the lease accounting policy is discussed in Note 1 “Summary of Significant Accounting Policies” of the Notes to Condensed Consolidated Financial Statements.

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 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 March 31, 2019, we had approximately $144.5 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.

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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. Based on interest bearing liabilities we have as of March 31, 2019, we are not subject to risks from immediate interest rate increases.

Currency Rate Risk

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

We enter into foreign currency forward contracts to minimize the short-term impact of foreign currency exchange rate fluctuations on cash and certain trade and intercompany receivables and payables. These forward contracts are not designated as hedging instruments and do not subject us to material balance sheet risk due to fluctuations in foreign currency exchange rates. The gains and losses on these forward contracts are intended to offset the gains and losses in the underlying foreign currency denominated monetary assets and liabilities being economically hedged. These instruments are marked to market through earnings every period and generally are one month in original maturity. We do not enter into foreign currency forward contracts for trading or speculative purposes. As our international operations grow, we will continue to reassess our approach to managing the risks relating to fluctuations in currency rates. It is difficult to predict the impact forward contracts could have on our results of operations. The fair value of foreign exchange forward contracts outstanding as of March 31, 2019 was not material.

Although we will continue to monitor our exposure to currency fluctuations, and, where appropriate, may use forward contracts 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.

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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 March 31, 2019, to provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our Chief Executive Officer and our Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure, and that such information is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission rules and forms.

Changes in internal control over financial reporting.

There were no changes in our internal control over financial reporting during the quarter ended March 31, 2019 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 5, 2018, a class action lawsuit against Align, and three of our executive officers, was filed in the U.S. District Court for the Northern District of California on behalf of a purported class of purchasers of our common stock between July 25, 2018 and October 24, 2018. The complaint generally alleges claims under the federal securities laws and seeks monetary damages in an unspecified amount and costs and expenses incurred in the litigation. On December 12, 2018, a similar lawsuit was filed in the same court on behalf of a purported class of purchasers of our common stock between April 25, 2018 and October 24, 2018 (together with the first lawsuit, the "Securities Actions"). The Court appointed a lead plaintiff on March 22, 2019 and that lead plaintiff is expected to file a consolidated complaint on May 10, 2019. Align believes these claims are without merit and intends to vigorously defend itself. Align is currently unable to predict the outcome of these lawsuits and therefore cannot determine the likelihood of loss nor estimate a range of possible loss.

Shareholder Derivative Lawsuit

In January 2019, three derivative lawsuits were also filed in the U.S. District Court for the Northern District of California, purportedly on behalf of Align, naming as defendants the members of our Board of Directors along with certain of our executive officers. The allegations in the complaints are similar to those presented in the Securities Action, but the complaints assert various state law causes of action, including for breaches of fiduciary duty, insider trading, and unjust enrichment, among others. The complaints seek unspecified monetary damages on behalf of Align, which is named solely as a nominal defendant against whom no recovery is sought, as well as disgorgement and the costs and expenses associated with the litigation, including attorneys' fees. On February 26, 2019, the three lawsuits were consolidated. On April 10, 2019, the Court stayed the consolidated action pending final disposition of the Securities Action.

On April 12, 2019, a derivative lawsuit was also filed in California Superior Court for Santa Clara County, purportedly on behalf of Align, naming as defendants the members of our Board of Directors along with certain of our executive officers. The allegations in this complaint are similar to those in the derivative suits described above.

Align is currently unable to predict the outcome of these lawsuits and therefore cannot determine the likelihood of loss nor estimate a range of possible loss.

3Shape Litigation

On November 14, 2017, Align filed six patent infringement lawsuits asserting 26 patents against 3Shape, a Danish corporation, and a related U.S. corporate entity, asserting that 3Shape's Trios intraoral scanning system and Dental System software infringe Align patents. Align filed two Section 337 complaints with the U.S. International Trade Commission ("ITC") alleging that 3Shape violates U.S. trade laws by selling for importation and importing its infringing Trios intraoral scanning system and Dental System software. Align's ITC complaints seek cease and desist orders and exclusion orders prohibiting the importation of 3Shape's Trios scanning system and Dental System software products into the U.S. Align also filed four separate complaints in the U.S. District Court for the District of Delaware alleging patent infringement by 3Shape's Trios intraoral scanning system and Dental System software. Two of those cases are stayed pending the ITC determinations, and the other two cases are currently active in discovery. The ITC conducted hearings in September and November 2018. On March 1, 2019, the Administrative Law Judge

issued an Initial Determination in one of the Section 337 investigations, finding no violation of Section 337 by 3Shape. Align and 3Shape each petitioned the Commission for review of the Initial Determination, and the Commission has not yet ruled on those petitions. On April 26, 2019, the Administrative Law Judge issued an Initial Determination in the second Section 337 investigations, finding no violation of Section 337 by 3Shape. Petitions for review by the Commission, if any, are due May 10, 2019. The target dates for completion of the investigations is July 1 and August 26, 2019.

On May 9, 2018, 3Shape filed a complaint in the U.S. District Court for the District of Delaware alleging patent infringement by Align's iTero Element scanner of a single 3Shape patent; the case was subsequently stayed. On June 14, 2018, 3Shape filed another complaint in the U.S. District Court for the District of Delaware alleging patent infringement by Align's iTero Element scanner of a single 3Shape patent, which remains an active case.

On August 28, 2018, 3Shape filed a complaint against Align in the U.S. District Court for the District of Delaware alleging antitrust violations and seeking monetary damages and injunctive relief relating to Align's market activities, including Align's

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assertion of its patent portfolio, in the clear aligner and intraoral scanning markets. Align filed a motion to dismiss 3Shape's complaint on October 17, 2018, which the Court has yet to rule on. Align has also moved to stay the litigation pending the outcome of its motion to dismiss and/or the patent litigations involving 3Shape.

On December 10, 2018, Align filed three additional patent infringement lawsuits asserting 10 additional patents against 3Shape. Align filed one Section 337 complaint with the ITC alleging that 3Shape violates U.S. trade laws through unfair competition by selling for importation and importing the infringing TRIOS intraoral scanning system, Trios Lab Scanners and TRIOS software, TRIOS Module software, Dental System software, and Ortho System Software. On December 11, 2018, Align filed two separate complaints in the U.S. District Court for the District of Delaware alleging patent infringement by 3Shape's Trios intraoral scanning system, Lab Scanners and Dental and Ortho System Software. The ITC instituted the investigation, and one of the District Court cases was stayed pending the ITC determination.

3Shape has sought to invalidate certain of Align's patents through petitions for inter partes review proceedings. Align disputes 3Shape's positions and intends to vigorously defend the validity of its patent rights.

Each of the District Court patent infringement complaints seek monetary damages and injunctive relief against further infringement. We are currently unable to predict the outcome of this dispute and therefore cannot determine the likelihood of loss, if any, nor estimate a range of possible loss.

SDC Dispute

In February 2018, we received a communication on behalf of SDC Financial LLC, SmileDirectClub LLC, and the Members of SDC Financial LLC other than the Company (collectively, the SDC Entities) alleging that the launch and operation of the Invisalign locations pilot program constitutes a breach of non-compete provisions applicable to the members of SDC Financial LLC, including Align. As a result of this alleged breach, SDC Financial LLC notified us that its members (other than Align) seek to exercise a right to repurchase all of Align's SDC Financial LLC membership interests for a purchase price equal to the current "capital account" balance of Align. The SDC Entities' communication also alleged that we breached confidentiality provisions applicable to the SDC Financial LLC members and demanded that we cease all activities related to the Invisalign store pilot project, close existing Invisalign stores and cease using SDC's confidential information. In April 2018, the SDC Entities instigated confidential arbitration proceedings and filed a complaint in the Chancery Court of Davidson County, State of Tennessee that sought, among other forms of relief, to preliminarily and permanently enjoin all activities related to the Invisalign store pilot project, require us to close existing Invisalign stores, prohibit us from opening any additional stores, and allow the SDC Entities to exercise a right to repurchase all of our SDC Financial LLC membership interests for a purchase price equal to the current "capital account" balance of Align.

On June 29, 2018, the Chancery Court of Davidson County, State of Tennessee denied the SDC Entities' request for a temporary injunction to prevent us from opening additional Invisalign stores. During December 2018, the parties participated in binding arbitration proceedings and presented closing arguments on January 23, 2019. The arbitrator issued his decision (the Award) on March 4, 2019. The arbitrator found that we breached the non-compete provision applicable to the members of SDC Financial LLC, including that we misused the SDC Entities' confidential information and violated fiduciary duties to SDC Financial LLC. The arbitrator ordered us to close our Invisalign stores by April 3, 2019, and enjoined us from opening new Invisalign stores or providing certain services in physical retail establishments in connection with the marketing and sale of clear aligners, and enjoined us from using the SDC Entities' confidential information. The arbitrator extended the expiration date of the non-compete provision to August 18, 2022. The arbitrator also ordered us to tender our SDC Financial LLC membership interests to the SDC Entities for a purchase price equal to the "capital account" balance of Align as of October 31, 2017, a price which is significantly below the current fair market value of such investment. No financial damages were awarded to the SDC Entities. The SDC Entities filed a motion to confirm the Award, which we did not oppose, in the Circuit Court for Cook County, Illinois. The motion to confirm the Award is under submission.

As required by the Award, on April 3, 2019, we closed our Invisalign stores, returned SDC's alleged confidential information, and tendered our memberships interests to certain SDC Entities for a purchase price that SDC claims to be "capital account" balance of Align as of October 31, 2017. Align disputes the "capital account" balance as of October 31, 2017 as provided by the SDC Entities and anticipate that there may be additional litigation with the SDC Entities regarding the "capital account" balance and other issues relating to the Award and the parties' relationship.

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

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complex legal proceedings are difficult to predict and Align's view of these matters may change in the future as litigation and events related thereto unfold; Align currently does not believe that these matters, individually or in the aggregate, will materially affect Align's financial position, results of operations or cash flows (*Refer to Note 9 "Legal Proceedings" of the Notes to the Consolidated Financial Statement*s for details on legal proceedings).

Straumann Group Litigation Settlement

In March 2019, we entered into an agreement with Straumann Group to settle all outstanding patent disputes in the U.S., the U.K., and Brazil, including those involving ClearCorrect, a subsidiary of Straumann Group. Under the terms of the settlement, Straumann Group paid Align $35 million on March 29, 2019 and it was recorded as a deferred litigation settlement gain in accrued liabilities in our Condensed Consolidated Balance Sheet due to certain contingencies which made the payment refundable as of March 31, 2019. We expect to recognize most of this gain in operating income in our Condensed Consolidated Statement of Operation in the second quarter of 2019. In addition, we also signed a non-binding letter of intent with Straumann Group for a 5-year global development and distribution agreement whereby Straumann would distribute 5,000 iTero Element scanners which would be fully integrated into the Straumann/Dental Wings CARES®/DWOS® workflow. This device would offer users access to the Straumann CARES digital workflow, Straumann's CoDiagnostix guided implant surgery and ClearCorrect, in addition to the Invisalign workflow. If for any reason the companies choose not to enter into the development and distribution agreement by July 2, 2019 or by a mutually agreed extended date, Straumann Group will pay Align an additional $16 million in lieu of the development and distribution agreement.

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ITEM 1A.RISK FACTORS

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

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

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

Currently, our products compete directly against products manufactured and distributed by various companies, both within and outside the U.S. Although the number of competitors varies by segment, geography and customer, we encounter a wide variety of competitors, including well-established regional competitors in certain foreign markets, as well as larger companies or divisions of larger companies with substantial sales, marketing, research and financial capabilities. Due in part to the expiration of certain key patents owned by us beginning in 2017, we are facing increased competition in the clear aligner market as a result of the entry of new, large companies into certain markets who have the ability to leverage their existing channels in the dental market to compete directly with us. In addition, corresponding foreign patents started to expire in 2018 and will likely result in increased competition in some of the markets outside the U.S. Large consumer product companies may also enter the orthodontic supply market. Furthermore, we also face competition from companies that now offer clear aligners directly to the consumer and do not require the consumer to see a doctor before or during orthodontic treatment. Unlike these direct to consumer competitors, we are committed to a doctor in the core of everything we do, and Invisalign Treatment requires a doctor's prescription and an in person physical examination of the patients dentition before treatment can begin. In addition, we may also face competition in the future from new companies that may introduce new technologies. We may be unable to compete with these competitors and one or more of these competitors may render our technology obsolete or economically unattractive. If we are unable to compete effectively with existing products or respond effectively to any products developed by new or existing competitors, our business could be harmed. Increased competition has resulted in the past and may in the future result in volume discounting and price reductions, reduced gross margins, reduced profitability and loss of market share, and reduce dental professionals’ efforts and commitment to expand their use of our products, any of which could have a material adverse effect on our net revenues, volume growth, net income and stock price. We cannot assure that we will be able to compete successfully against our current or future competitors or that competitive pressures will not have a material adverse effect on our business, results of operations and financial condition.

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

Our key production steps are performed in operations located outside of the U.S. Technicians use a sophisticated, internally developed computer-modeling program to prepare digital treatment plans, which are then transmitted electronically to our aligner fabrication facilities. These digital files form the basis of the ClinCheck treatment plan and are used to manufacture aligner molds and aligners. Our digital treatment planning and aligner fabrication are

performed in multiple international locations. We will continue to establish treatment planning and aligner fabrication facilities closer to our international customers in order to improve our operational efficiency. In addition to the research and development efforts conducted in our North America facilities, we also carry out research and development in Moscow, Russia. We also have operations in Israel where we design and assemble wands, and our intraoral scanner is manufactured. Our reliance on international operations exposes us to risks and uncertainties that may affect our business or results of operation, including:

- difficulties in hiring and retaining employees generally, as well as difficulties in hiring and retaining employees with the necessary skills to perform the more technical aspects of our operations;
- difficulties in managing international operations, including any travel restrictions to or from our facilities;
- fluctuations in currency exchange rates;
- import and export controls, license requirements and restrictions;

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

The United Kingdom's referendum to leave the European Union, commonly known as "Brexit," has exacerbated and may further exacerbate many of the risks and uncertainties described above. The withdrawal of the United Kingdom from the European Union could, among other potential outcomes, adversely affect the tax, tax treaty, currency, operational, legal and regulatory regimes to which our businesses in the region are subject. The withdrawal could also, among other potential outcomes, disrupt the free movement of goods, services and people between the United Kingdom and the European Union and significantly disrupt trade between the United Kingdom and the European Union and other parties. There remains significant risk that the United Kingdom will exit from the European Union without agreement between the European Union and United Kingdom on terms addressing customs and trade matters. Further, uncertainty around these and related issues could lead to adverse effects on the economy of the United Kingdom, European Union and the other economies in which we operate.

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

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

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

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

with these laws;
- fluctuations in currency exchange rates; and
- increased expense of developing, testing and making localized versions of our products.

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

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

We currently sell our products outside of North America. As a result, we are subject to foreign regulatory requirements that vary widely from country to country. The time required to obtain clearances or approvals required by other countries may be longer than that required for U.S. Food and Drug Administration ("FDA") clearance or approval, and requirements for such approvals may differ from FDA requirements. We may be unable to obtain regulatory approvals in one or more of the other countries in which we do business or in which we may do business in the future. We may also incur significant costs in attempting to obtain and maintain foreign regulatory approvals. If we experience delays in receipt of approvals to market our products outside of the U.S., or if we fail to receive these approvals, we may be unable to market our products or enhancements in international markets in a timely manner, if at all, which could materially impact our international operations and adversely affect our business as a whole.

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

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

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

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

- correctly identify customer needs and preferences and predict future needs and preferences;
- include functionality and features that address customer requirements;
- ensure compatibility of our computer operating systems and hardware configurations with those of our customers;
- allocate our research and development funding to products with higher growth prospects;

- anticipate and respond to our competitors' development of new products. product offerings and technological innovations;
- differentiate our products and product offerings from our competitors;
- innovate and develop new technologies and applications;
- the availability of third-party reimbursement of procedures using our products;
- obtain adequate intellectual property rights; and

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- encourage customers to adopt new technologies.

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

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

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

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

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

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

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

Although the U.S. dollar is our reporting currency, a portion of our net revenues and net income are generated in foreign currencies. Net revenues and net income generated by subsidiaries operating outside of the U.S. are translated into U.S. dollars using exchange rates effective during the respective period and are affected by changes in exchange rates. As a result, negative movements in currency exchange rates against the U.S. dollar will adversely affect our net revenues and net income in our consolidated financial statements. The exchange rate between the U.S. dollar and foreign currencies has fluctuated substantially in recent years and may continue to fluctuate substantially in the future. As a result, we enter into currency forward contract 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 and operational efficiencies at our manufacturing and treat facilities.

We are subject to growth related risks, including excess or constrained capacity and pressure on our internal systems and personnel. In order to manage current operations and future growth effectively, we will need to continue to implement and improve our operational, financial and management information systems and to hire, train, motivate, manage and retain employees. We may be unable to manage such growth effectively. Any such failure could have a material adverse impact on our business, operations and prospects. We are establishing additional order acquisition, treatment planning and manufacturing facilities closer to our international customers in order to improve our operational efficiency and provide doctors with a better experience to further improve their confidence in using Invisalign to treat more patients, more often. Our ability to plan, construct and equip additional order acquisition, treatment planning and manufacturing facilities is subject to significant risk and uncertainty, including risks inherent in the establishment of a facility, such as hiring and retaining employees and delays and cost overruns as a result of a number of factors, any of which may be out of our control and may negatively impact our gross margin. In addition, these new facilities are located in higher cost regions compared to Mexico and Costa Rica, which may negatively impact our gross margin. If the transition into these additional facilities is significantly delayed or demand for our product exceeds our current expectations, we may not be able to fulfill orders timely, which may negatively impact our financial results and overall business. In addition, because we cannot immediately adapt our production capacity and related cost structures to changing market conditions, our facility

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capacity may at times exceed or fall short of our production requirements. In addition, if product demand decreases or we fail to forecast demand accurately, we could be required to write off inventory or record excess capacity charges, which would lower our gross margin. Production of our intraoral scanners may also be limited by capacity constraints due to a variety of factors, including our dependency on third party vendors for key components in addition to limited production yields. Any or all of these problems could result in the loss of customers, provide an opportunity for competing products to gain market acceptance and otherwise harm our business and financial results.

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

If we are to sustain or increase profitability in future periods, we will need to continue to increase our net revenues, while controlling our expenses. Because our business is evolving, it is difficult to predict our future operating results or levels of growth, and we have not in the past and may not in the future be able to sustain our historical growth rates. If we do not increase profitability, Invisalign volume and 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 from quarter to quarter, the level of activity in our customers' practices;
- weakness in consumer spending as a result of a slowdown in the global, U.S. or other economies;
- changes in product mix;
- higher manufacturing costs driven by an increase in the numbers of aligners per case;
- changes in relationships with our dental support organizations, including timing of orders;
- 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 revenues can be recognized;
- fluctuations in currency exchange rates against the U.S. dollar;
- our inability to scale production of our iTero Element scanner to meet customer demand;
- if participation in our customer rebate or discount programs increases, our average selling price will be adversely affected;
- seasonal fluctuations in the number of doctors in their offices and their availability to take appointments;
- success of or changes to our marketing programs from quarter to quarter;
- our reliance on our contract manufacturers for the production of sub-assemblies for our intraoral scanners;
- timing of industry tradeshows;
- changes in the timing of when revenues are recognized, including as a result of the introduction of new products, product offerings 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;
- underutilization of manufacturing and treat facilities;
- the development and marketing of directly competitive products by existing and new competitors;

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- changes in relationships with our distributors;
- impairments in the value of our privately held companies could be material;
- major changes in available technology or the preferences of customers may cause our current product offerings to become less competitive or obsolete;
- aggressive price competition from competitors;
- costs and expenditures in connection with litigation;
- costs and expenditures in connection with establishment of treatment planning and Aligner fabrication in international locations;
- costs and expenditures in connection with hiring and deployment of direct sales force personnel;
- the timing of new product introductions by us and our competitors, as well as customer order deferrals in anticipation of enhancements or new products;
- unanticipated delays in our receipt of patient records made through an intraoral scanner for any reason;
- disruptions to our business due to political, economic or other social instability, including the impact of an epidemic any of which results in changes in consumer spending habits, consumers unable or unwilling to visit the orthodontist or general practitioners office, as well as any impact on workforce absenteeism;
- inaccurate forecasting of net revenues, production and other operating costs,
- investments in research and development to develop new products and enhancements;
- changes in accounting standards, policies and estimates; and
- our ability to successfully hedge against a portion of our foreign currency-denominated assets and liabilities.

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

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

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

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

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

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

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

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

We rely on the efficient and uninterrupted operation of complex information technology systems. All information technology systems are vulnerable to damage or interruption from a variety of sources. As our business has grown in size and complexity, the growth has placed, and will continue to place, significant demands on our information technology systems. To effectively manage this growth, our information systems and applications require an ongoing commitment of significant resources to maintain, protect and enhance existing systems and develop new systems to keep pace with continuing changes in information processing technology, evolving industry and regulatory standards and changing customer preferences. We are continuing to transform certain business processes, extend established processes to new subsidiaries and/or implement additional functionality in our enterprise resource planning (“ERP”) software system which entails certain risks, including difficulties with changes in business processes that could disrupt our operations, such as our ability to track orders and timely ship products, manage our supply chain and aggregate financial and operational data.

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

Additionally, we continuously upgrade our customer facing software applications, specifically the ClinCheck and MyAligntech software. Software applications frequently contain errors or defects, especially when they are first introduced or when new versions are released. The discovery of a defect or error or the incompatibility with the

computer operating system and hardware configurations of customers in a new upgraded version or the failure of our primary information systems may result in the following consequences, among others: loss of revenues or delay in market acceptance, damage to our reputation or increased service costs, any of which could have a material adverse effect on our business, financial condition or results of operations.

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

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viruses and bugs could be significant, and the efforts to address these problems could result in interruptions that may have a material adverse impact on our operations, net revenues and operating results.

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

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

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

We retain confidential customer and patient information in our processing centers. Therefore, it is critical that our facilities and infrastructure remain secure and are also perceived by the marketplace and our customers to be secure. Despite the implementation of security measures, we have experienced breaches in the past and our infrastructure may be vulnerable to physical break-ins, computer viruses, programming errors or other technical malfunctions, hacking or phishing attacks by third parties, employee error or malfeasance or similar disruptive problems. If we fail to meet our customer and patient's expectations regarding the security of healthcare information, we could be liable for damages and our reputation and competitive position could be impaired. Affected parties could initiate legal or regulatory action against us, which could cause us to incur significant expense and liability or result in orders forcing us to modify our business practices. Concerns over our privacy practices could adversely affect others' perception of us and deter customers, advertisers and partners from using our products. In addition, patient care could suffer, and we could be liable if our systems fail to deliver correct information in a timely manner. We have cybersecurity insurance related to a breach event covering expenses for notification, credit monitoring, investigation, crisis management, public relations and legal advice. The policy also provides coverage for regulatory action defense including fines and penalties, potential payment card industry fines and penalties and costs related to cyber extortion; however, damage and claims arising from such incidents may not be covered or may exceed the amount of any insurance available.

We are also subject to several federal, state and foreign laws and regulations, including ones relating to privacy, data protection, content regulation, and consumer protection. These laws and regulations are constantly evolving and may be interpreted, applied, created or amended in a manner that could adversely affect our business.

In addition, we must comply with numerous data protection requirements that span from individual state and national laws in the U.S. to multinational requirements in the EU. In the EU, Align must comply with the General Data Protection Regulation ("GDPR"), which became effective on May 25, 2018 and serves as a harmonization of European data-privacy laws. We believe we have designed our product and service offerings to be compliant with the requirements of applicable data protection laws and regulations. Maintaining systems that are compliant with these laws and regulations is costly and could require complex changes in the way we do business or provide services to our customers and their patients. Additionally, our success may be dependent on the success of healthcare providers in managing data protection requirements.

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

Our success will depend in part on our ability to maintain existing intellectual property and to obtain and maintain further intellectual property protection for our products, both in the U.S. and in other countries. Our inability to do so could harm our competitive position. As of March 31, 2019, we had 452 active U.S. patents, 442 active foreign patents, and 502 pending global patent applications.

We intend to rely on our portfolio of issued and pending patent applications in the U.S. and in other countries to protect a large part of our intellectual property and our competitive position; however, our currently pending or future patent filings may not result in the issuance of patents. Additionally, any patents issued to us may be challenged, invalidated, held unenforceable, circumvented, or may not be sufficiently broad to prevent third parties from producing competing products similar in design to our products. In addition, any protection afforded by foreign patents may be more limited than that provided under U.S. patents and intellectual property laws. Certain of our key patents began to expire in 2017, which may result in increased competition or

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less expensive alternatives to our products. We also rely on protection of our copyrights, trade secrets, know-how and proprietary information. We generally enter into confidentiality agreements with our employees, consultants and our collaborative partners upon commencement of a relationship with us; however, these agreements may not provide meaningful protection against the unauthorized use or disclosure of our trade secrets or other confidential information, and adequate remedies may not exist if unauthorized use or disclosure were to occur. Our inability to maintain the proprietary nature of our technology through patents, copyrights or trade secrets would impair our competitive advantages and could have a material adverse effect on our operating results, financial condition and future growth prospects. In particular, a failure to protect our proprietary rights might allow competitors to copy our technology, which could adversely affect our pricing and market share. In addition, in an effort to protect our intellectual property we have in the past been and may in the future be involved in litigation. The potential effects on our business operations resulting from litigation that we may participate in the future, whether or not ultimately determined in our favor or settled by us, are costly and divert the efforts and attention of our management and technical personnel from normal business operations.

Litigation, interferences, oppositions, re-exams, inter partes reviews, post grant reviews or other proceedings are, have been and may in the future be necessary in some instances to determine the validity and scope of certain of our proprietary rights, and in other instances to determine the validity, scope or non-infringement of certain patent rights claimed by third parties to be pertinent to the manufacture, use or sale of our products. Litigation, interference, oppositions, re-exams, inter partes reviews, post grant reviews, administrative challenges or other similar types of proceedings are unpredictable and may be protracted, expensive and distracting to management. The outcome of such proceedings could adversely affect the validity and scope of our patent or other proprietary rights, hinder our ability to manufacture and market our products, require us to seek a license for the infringed product or technology or result in the assessment of significant monetary damages. An unfavorable ruling could include monetary damages or, in cases where injunctive relief is sought, an injunction prohibiting us from selling our products. Any of these results from our litigation could adversely affect our results of operations and stock price.

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

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

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

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

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

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

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

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

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

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

results in delays in our fulfillment of customer orders may cause us to lose revenues and suffer damage to our customer relationships.

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

Our ability to sell our products and generate revenues primarily depends upon our direct sales force within our Americas and International markets. We do not have any long-term employment contracts with the members of our direct sales force. The loss of the services provided by these key personnel may harm our business. In the fourth quarter of 2018, we hired approximately 100 sales personnel in the Americas. In order to provide more comprehensive sales and service coverage, in the fourth quarter of 2018, we increased our sales force in the Americas by adding approximately 100 sales team members. We intend to continue to invest in expanding our sales force to allow us to pursue the growth opportunities within and outside of our existing geographic markets. To adequately train and successfully deploy new representatives into these regions and to establish strong customer relationships takes approximately six to twelve months. As a result, if we are unable to retain our direct sales force personnel or replace them with individuals of equivalent technical expertise and qualifications, or if we are unable to successfully instill such technical

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expertise in recently hired sales representatives or if we fail to establish and maintain strong relationships with our customers within a relatively short period of time, our net revenues and our ability to maintain market share could be materially harmed. In addition, due to our large and fragmented customer base, we may not be able to provide all of our customers with product support immediately upon the launch of a new product. As a result, adoption of new products by our customers may be slower than anticipated and our ability to grow market share and increase our net revenues may be harmed.

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

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

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

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

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

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

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

In addition, as part of the Dodd-Frank Wall Street Reform and Consumer Protection Act, the SEC adopted disclosure requirements regarding the use of certain minerals, known as conflict minerals, which are mined from the Democratic Republic of Congo and adjoining countries, as well as procedures regarding a manufacturer’s efforts to identify and discourage the sourcing of such minerals and metals produced from those minerals. Additional reporting obligations are being proposed by the European Union. The U.S. requirements and any additional requirements in Europe could

affect the sourcing and availability of metals used in the manufacture of a limited number of parts (if any) contained in our products. For example, these disclosure requirements

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may decrease the number of suppliers capable of supplying our needs for certain metals, thereby negatively affecting our ability to obtain products in sufficient quantities or at competitive prices. Our material sourcing is broad based and multi-tiered, and we may be unable to conclusively verify the origins for all metals used in our products. We may suffer financial and reputational harm if customers require, and we are unable to deliver, certification that our products are conflict free. Regardless, we will incur additional costs associated with compliance with these disclosure requirements, including time-consuming and costly efforts to determine the source of any conflict minerals used in our products.

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

Participants in the healthcare industry are subject to extensive and frequently changing regulations under numerous laws administered by governmental entities at the federal, state and local levels, some of which are, and others of which may be, applicable to our business.

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

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

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

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

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

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

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

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

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

- quarterly variations in our results of operations and liquidity;
- changes in recommendations by the investment community or in their estimates of our net revenues or operating results;
- speculation in the press or investment community concerning our business and results of operations;

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- strategic actions by our competitors, such as product announcements or acquisitions;
- announcements of technological innovations or new products or product offerings by us, our customers or competitors;
- key decisions in pending litigation; and
- general economic market conditions.

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

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

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

We are subject to risks associated with our strategic investments. Impairments in the value of our investments and receivables in privately held companies could negatively impact our financial results.

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

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

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

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

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

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

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

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We may experience unexpected issues and expenses associated with the corporate structure reorganization, including the relocation of our European headquarters to Switzerland.

Given our continued growth and expansion internationally, during the year we intend to reorganize our corporate structure and intercompany relationships to more closely align with the international nature of our business activities. The proposed corporate structure may also allow us to obtain financial and operational efficiencies after they are implemented. As part of this corporate structure reorganization, we intend to move our European headquarters from the Netherlands to Switzerland. As a result, we will incur expenses in the near term and expect to realize the related benefits in subsequent years. The implementation of this reorganization plan may be disruptive to our business, and, following completion of the reorganization plan, our business may not be more efficient or effective than prior to implementation of the plan. We expect the relocation of our European headquarters to Switzerland to be completed in early 2020. This relocation is accompanied by a number of risks and uncertainties that may affect our results of operations and statement of cash flows, including:

- the relocation may absorb significant management and key employee attention and resources that would otherwise be available for the ongoing business operations;
- failure to retain key employees who possess specific knowledge or expertise and upon whom we are depending upon for the timely and successful transition to Switzerland;
- difficulties in hiring employees in Switzerland with the necessary skills and expertise; and
- increased costs as we transition the operations to Switzerland along with higher costs of doing business in Switzerland.

If any of these risks materialize in the future, our operating results, statement of operations and cash flows may be adversely affected.

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

Various internal and external factors may have favorable or unfavorable effects on our future effective tax rate. These factors include, but are not limited to, changes in tax laws such as the TCJA enacted into law on December 22, 2017, regulations and/or rates, new or changes to accounting pronouncements, non-deductible goodwill impairments, changing interpretations of existing tax laws or regulations, changes in the relative proportions of revenues and income before taxes in the various jurisdictions in which we operate that have differing statutory tax rates, the future levels of tax benefits of stock-based compensation, settlement of income tax audits, and changes in overall levels of pretax earnings. As a result of the adoption of ASU 2016-09 in 2017, we anticipate our effective tax rate to vary significantly in our first quarter due to the timing of when the majority of our equity compensation vests each year. Other quarters can also be impacted depending on the timing of equity vests.

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

As a U.S. multinational corporation, we are subject to changing tax laws both within and outside of the U.S. Changes in tax laws or tax rulings, or changes in interpretations of existing tax laws, could affect our income tax provision and net income or require us to change the manner in which we operate our business. In addition, governmental tax authorities are increasingly scrutinizing the tax positions of companies. Many countries in Europe, as well as a number of other countries and organizations, have recently proposed or recommended changes to existing tax laws or have enacted new laws. For example, the Organization for Economic Cooperation and Development (“OECD”) has been working on a “Base Erosion and Profit Shifting Project,” which is focused on a number of issues, including the shifting

of profits between affiliated entities in different tax jurisdictions. In 2015, the OECD issued and is expected to continue to issue, guidelines and proposals that may change various aspects of the existing framework under which our tax obligations are determined in many of the countries in which we do business.

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

Following is a summary of stock repurchases for the three months ended March 31, 2019:

Period	Total Number of Shares Repurchased	Average Price Paid per Share	Total Number of Shares Repurchased as Part of Publicly Announced Program	Approximate Dollar Value of Shares that May Yet Be Repurchased Under the Program [1]
January 1, 2019 through January 31, 2019	—	$—	—	$500,000,000
February 1, 2019 through February 28, 2019	205,408	$243.42	205,408	$450,000,000
March 1, 2019 through March 31, 2019	—	$—	—	$450,000,000

[1] In February 2019, we purchased $50.0 million of our common stock on the open market. As of March 31, 2019, we have $450.0 million remaining under the $600.0 million May 2018 Repurchase Program (*Refer to Note 12 "Common Stock Repurchase Programs" of the Notes to Condensed Consolidated Financial Statements* for details on our stock repurchase programs).

ITEM 3.DEFAULTS UPON SENIOR SECURITIES

Not applicable.

ITEM 4.MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5.OTHER INFORMATION

None

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ITEM 6. EXHIBITS

(a) Exhibits:

Exhibit Number	Description	Filing	Date	Exhibit Number	Filed here with
31.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				*
31.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				*
32.1	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				*
10.1	Purchase Agreement between Align Technology Ltd., a subsidiary of Align Technology, Inc., and Ganei Ben Zvi Ltd and Ramat HaChayal Equities LLC. dated January 15, 2019	Form 8-K	1/23/2019		*
10.26	Purchase and Sale Agreement Between Align Technology, Inc and Slater Road I, LLC dated January 29, 2019	Form 8-K	1/30/2019	10.4	
101.INS	XBRL Instance Document				*
101.SCH	XBRL Taxonomy Extension Schema Document				*
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document				*
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document				*
101.LAB	XBRL Taxonomy Extension Label Linkbase Document				*
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document				*

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SIGNATURES

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

ALIGN TECHNOLOGY, INC.

May 2, 2019 By: /s/ JOSEPH M. HOGAN
Joseph M. Hogan
President and Chief Executive Officer

By: /s/ JOHN F. MORICI
John F. Morici
Chief Financial Officer and Senior Vice President, Global Finance