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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 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: 000-32259

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 ☒ 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 ☒ 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	☒	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
Emerging growth company	☐		

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 ☒

The number of shares outstanding of the registrant's Common Stock, $0.0001 par value, as of October 25, 2019 was 78,812,958.

ALIGN TECHNOLOGY, INC.

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PART I—FINANCIAL INFORMATION

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Net revenues	$ 607,341	$ 505,289	$ 1,757,009	$ 1,432,472
Cost of net revenues	169,787	133,508	485,070	367,701
Gross profit	437,554	371,781	1,271,939	1,064,771
Operating expenses:				
Selling, general and administrative	277,514	213,873	792,572	625,585
Research and development	39,680	32,700	116,034	93,095
Impairments and other (gains) charges	(6,792)	—	22,990	—
Litigation settlement gain	—	—	(51,000)	—
Total operating expenses	310,402	246,573	880,596	718,680
Income from operations	127,152	125,208	391,343	346,091
Interest income	3,478	2,234	9,576	6,327
Other income (expense), net	(2,211)	(837)	5,935	(7,759)
Net income before provision for income taxes and equity in losses of investee	128,419	126,605	406,854	344,659
Provision for income taxes	25,895	24,601	77,812	35,206
Equity in losses of investee, net of tax	—	1,132	7,528	6,610
Net income	$ 102,524	$ 100,872	$ 321,514	$ 302,843
Net income per share:				
Basic	$ 1.29	$ 1.26	$ 4.03	$ 3.78
Diluted	$ 1.28	$ 1.24	$ 4.00	$ 3.71
Shares used in computing net income per share:				
Basic	79,332	80,111	79,709	80,122
Diluted	79,825	81,359	80,397	81,538

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	**2018**	**2019**	**2018**
Net income	$ 102,524	$ 100,872	$ 321,514	$ 302,843
Net change in foreign currency translation adjustment	(92)	(1,756)	530	(1,473)
Change in unrealized gains (losses) on investments, net of tax	41	117	317	174
Other comprehensive (loss) income	(51)	(1,639)	847	(1,299)
Comprehensive income	$ 102,473	$ 99,233	$ 322,361	$ 301,544

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

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

	September 30, 2019	December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	$ 490,362	$ 636,899
Marketable securities, short-term	292,011	98,460
Accounts receivable, net of allowance for doubtful accounts of $5,572 and $2,378, respectively	531,816	439,009
Inventories	94,795	55,641
Prepaid expenses and other current assets	96,595	72,470
Total current assets	1,505,579	1,302,479
Marketable securities, long-term	—	9,112
Property, plant and equipment, net	606,581	521,329
Operating lease right-of-use assets, net	53,923	—
Equity method investments	—	45,913
Goodwill and intangible assets, net	77,012	81,949
Deferred tax assets	63,150	64,689
Other assets	44,135	26,987
Total assets	$ 2,350,380	$ 2,052,458
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 63,300	$ 64,256
Accrued liabilities	286,132	234,679
Deferred revenues	520,712	393,138
Total current liabilities	870,144	692,073
Income tax payable	101,914	78,008
Operating lease liabilities	43,365	—
Other long-term liabilities	29,408	29,486
Total liabilities	1,044,831	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; 78,809 and 79,778 issued and outstanding, respectively)	8	8
Additional paid-in capital	892,309	877,514
Accumulated other comprehensive income (loss), net	(1,927)	(2,774)
Retained earnings	415,159	378,143
Total stockholders' equity	1,305,549	1,252,891
Total liabilities and stockholders' equity	$ 2,350,380	$ 2,052,458

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

ALIGN TECHNOLOGY, INC.
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(in thousands)
(unaudited)

Three Months Ended September 30, 2019	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss), Net	Retained Earnings	Total
Balance as of June 30, 2019	79,865	$ 8	$ 874,275	$ (1,876)	$ 501,275	$ 1,373,682
Net income	—	—	—	—	102,524	102,524
Net change in unrealized gains (losses) from investments	—	—	—	41	—	41
Net change in foreign currency translation adjustment	—	—	—	(92)	—	(92)
Issuance of common stock relating to employee equity compensation plans	76	—	8,293	—	—	8,293
Tax withholdings related to net share settlements of restricted stock units	—	—	(3,075)	—	—	(3,075)
Common stock repurchased and retired	(1,132)	—	(11,360)	—	(188,640)	(200,000)
Stock-based compensation	—	—	24,176	—	—	24,176
Balance as of September 30, 2019	78,809	$ 8	$ 892,309	$ (1,927)	$ 415,159	$ 1,305,549

Nine Months Ended September 30, 2019	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss), Net	Retained Earnings	Total
Balance as of December 31, 2018	79,778	$ 8	$ 877,514	$ (2,774)	$ 378,143	$ 1,252,891
Net income	—	—	—	—	321,514	321,514
Net change in unrealized gains (losses) from investments	—	—	—	317	—	317
Net change in foreign currency translation adjustment	—	—	—	530	—	530
Issuance of common stock relating to employee equity compensation plans	529	—	17,907	—	—	17,907
Tax withholdings related to net share settlements of restricted stock units	—	—	(55,793)	—	—	(55,793)
Common stock repurchased and retired	(1,498)	—	(15,006)	—	(284,498)	(299,504)
Stock-based compensation	—	—	67,687	—	—	67,687
Balance as of September 30, 2019	78,809	$ 8	$ 892,309	$ (1,927)	$ 415,159	$ 1,305,549

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

ALIGN TECHNOLOGY, INC.
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (CONTINUED)
(in thousands)
(unaudited)

Three Months Ended September 30, 2018	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss), Net	Retained Earnings	Total
Balance as of June 30, 2018	80,313	$ 8	$ 844,599	$ 911	$ 373,441	$ 1,218,959
Net income	—	—	—	—	100,872	100,872
Net change in unrealized gains (losses) from investments	—	—	—	117	—	117
Net change in foreign currency translation adjustment	—	—	—	(1,756)	—	(1,756)
Issuance of common stock relating to employee equity compensation plans	96	—	8,021	—	—	8,021
Tax withholdings related to net share settlements of restricted stock units	—	—	(2,426)	—	—	(2,426)
Common stock repurchased and retired	(426)	—	(4,121)	—	(145,881)	(150,002)
Stock-based compensation	—	—	19,198	—	—	19,198
Balance as of September 30, 2018	79,983	$ 8	$ 865,271	$ (728)	$ 328,432	$ 1,192,983

Nine Months Ended September 30, 2018	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss), Net	Retained Earnings	Total
Balance as of December 31, 2017	80,040	$ 8	$ 886,435	$ 571	$ 267,274	$ 1,154,288
Net income	—	—	—	—	302,843	302,843
Net change in unrealized gains (losses) from investments	—	—	—	174	—	174
Net change in foreign currency translation adjustment	—	—	—	(1,473)	—	(1,473)
Issuance of common stock relating to employee equity compensation plans	765	—	16,607	—	—	16,607
Tax withholdings related to net share settlements of restricted stock units	—	—	(81,756)	—	—	(81,756)
Common stock repurchased and retired	(822)	—	(7,933)	—	(242,069)	(250,002)
Stock-based compensation	—	—	51,918	—	—	51,918
Other	—	—	—	—	384	384
Balance as of September 30, 2018	79,983	$ 8	$ 865,271	$ (728)	$ 328,432	$ 1,192,983

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

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

	Nine Months Ended September 30,	
	2019	**2018**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net income	$ 321,514	$ 302,843
Adjustments to reconcile net income to net cash provided by operating activities:		
Deferred taxes	1,470	2,047
Depreciation and amortization	57,194	38,185
Non-cash operating lease cost	13,600	—
Impairments on long-lived assets	28,498	—
Gain on lease terminations	(6,792)	—
Impairment on equity investment	3,975	—
Gain from sale of equity method investment	(15,769)	—
Stock-based compensation	67,687	51,918
Equity in losses of investee	7,528	6,610
Other non-cash operating activities	17,426	11,363
Changes in assets and liabilities:		
Accounts receivable	(95,566)	(89,843)
Inventories	(40,775)	(17,192)
Prepaid expenses and other assets	(14,826)	(47,775)
Accounts payable	1,343	5,042
Accrued and other long-term liabilities	31,089	(25,436)
Long-term income tax payable	13,425	(18,435)
Deferred revenues	138,072	94,059
Net cash provided by operating activities	529,093	313,386
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property, plant and equipment	(107,157)	(169,033)
Purchase of marketable securities	(588,805)	(150,022)
Proceeds from maturities of marketable securities	211,829	259,870
Proceeds from sales of marketable securities	194,677	9,560
Purchase of investments in privately held companies	—	(5,000)
Note repayment from privately held company	13,185	—
Loan repayment from equity investee	—	30,000
Other investing activities	(14,062)	604
Net cash used in investing activities	(290,333)	(24,021)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock	17,907	16,607
Common stock repurchases	(299,504)	(250,002)
Employees’ taxes paid upon the vesting of restricted stock units	(55,793)	(81,756)
Purchase of finance lease	(45,773)	—
Net cash used in financing activities	(383,163)	(315,151)
Effect of foreign exchange rate changes on cash, cash equivalents, and restricted cash	(2,098)	(2,890)
Net decrease in cash, cash equivalents, and restricted cash	(146,501)	(28,676)
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	$ 491,065	$ 421,449

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

ALIGN TECHNOLOGY, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(unaudited)

Note 1. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying unaudited Condensed Consolidated Financial Statements have been prepared by Align Technology, Inc. ("we", "our", or "Align") in accordance with the rules and regulations of the Securities and Exchange Commission ("SEC") and contains all adjustments, including normal recurring adjustments, necessary to state fairly our results of operations for the three and nine months ended September 30, 2019 and 2018, our comprehensive income for the three and nine months ended September 30, 2019 and 2018, our financial position as of September 30, 2019, our stockholders' equity for the three and nine months ended September 30, 2019 and 2018, and our cash flows for the nine months ended September 30, 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 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 and nine months ended September 30, 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.

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 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) 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; however, we anticipate the adoption of the guidance will not have a material impact to 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 in this update, an entity will recognize an impairment charge for the amount by which the carrying value exceeds the fair value. The updated guidance is 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; however, we anticipate the adoption of the guidance will not have a material impact to 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 updated guidance is 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; however, we anticipate the adoption of the guidance will not have a material impact to our consolidated financial statements and 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 in this update, 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 updated guidance is 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.

Note 2. Investments and Fair Value Measurements

Marketable Securities

As of September 30, 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

September 30, 2019	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Commercial paper	$ 33,259	$ —	$ —	$ 33,259
Corporate bonds	152,452	169	(10)	152,611
U.S. government agency bonds	10,233	6	—	10,239
U.S. government treasury bonds	91,832	48	(5)	91,875
Foreign bonds	4,004	4	—	4,008
Certificates of deposit	19	—	—	19
Total marketable securities, short-term	$ 291,799	$ 227	$ (15)	$ 292,011

As of September 30, 2019, we had no long-term marketable securities.

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 September 30, 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 and nine months ended September 30, 2019 and 2018. For the three and nine months ended September 30, 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 primarily due to changes in interest rates and credit spreads. We expect to realize the full value of all these investments upon maturity or sale. The weighted average remaining duration of these securities was approximately seven months and four months as of September 30, 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 September 30, 2019 and December 31, 2018 (in thousands):

	September 30, 2019	December 31, 2018
One year or less	$ 292,011	$ 98,460
Due in greater than one year	—	9,112
Total available for sale short-term and long-term marketable securities	$ 292,011	$ 107,572

Investments in Privately Held Companies

Our investments in privately held companies as of September 30, 2019 and December 31, 2018 are as follows (in thousands):

	September 30, 2019	December 31, 2018
Equity securities under the equity method investment [1]	$ —	$ 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 nine months ended September 30, 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.

The following tables summarize our financial assets measured at fair value on a recurring basis as of September 30, 2019 and December 31, 2018 (in thousands):

Description	Balance as of September 30, 2019	Level 1	Level 2
Cash equivalents:			
Money market funds	$ 181,401	$ 181,401	$ —
Commercial paper	22,403	—	22,403
Corporate bonds	4,528	—	4,528
U.S. government treasury bonds	5,298	5,298	—
Short-term investments:			
Commercial paper	33,259	—	33,259
Corporate bonds	152,611	—	152,611
U.S. government agency bonds	10,239	—	10,239
U.S. government treasury bonds	91,875	91,875	—
Foreign bonds	4,008	—	4,008
Certificates of deposit	19	—	19
Prepaid expenses and other current assets:			
Israeli funds	3,103	—	3,103
	$ 508,744	$ 278,574	$ 230,170

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
Corporate bonds	3,880	—	3,880
U.S. government treasury bonds	2,195	2,195	—
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:			
Corporate bonds	4,960	—	4,960
U.S. government agency bonds	1,407	—	1,407
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 net gain from the settlement of foreign currency forward contracts during the three months ended September 30, 2019 and September 30, 2018 was $10.1 million and $2.3 million, respectively, and the net gain from the settlement of foreign currency forward contracts during the nine months ended September 30, 2019 and September 30, 2018 was $10.5 million and $7.7 million, respectively. As of September 30, 2019 and December 31, 2018, the fair value of foreign exchange forward contracts outstanding was not material.

The following table presents the gross notional value of all our foreign exchange forward contracts outstanding as of September 30, 2019 and December 31, 2018 (in thousands):

	September 30, 2019	
	Local Currency Amount	Notional Contract Amount (USD)
Euro	€89,000	$ 97,206
Chinese Yuan	¥545,000	76,266
Canadian Dollar	C$44,000	33,250
Israeli Shekel	ILS111,000	32,043
British Pound	£21,000	25,843
Japanese Yen	¥2,700,000	25,021
Brazilian Real	R$89,000	21,318
Mexican Peso	M$140,000	7,078
Australian Dollar	A$3,000	2,030
		$ 320,055

	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

Note 3. Balance Sheet Components

Inventories

Inventories consist of the following (in thousands):

	September 30, 2019	December 31, 2018
Raw materials	$ 43,808	$ 26,119
Work in process	29,172	13,784
Finished goods	21,815	15,738
Total inventories	$ 94,795	$ 55,641

Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following (in thousands):

	September 30, 2019	December 31, 2018
Tax related receivables	$ 35,424	$ 36,794
Current promissory note and related interest receivable [1]	27,101	—
Other current receivables	2,283	6,511
Prepaid software and maintenance	10,735	5,938
Other prepaid expenses and current assets	21,052	23,227
Total prepaid expenses and other current assets	$ 96,595	$ 72,470

[1] Current portion of unsecured promissory note receivable and related interest receivable (*Refer to Note 5"Equity Method Investments" of the Notes to Condensed Consolidated Financial Statements* for more information).

Accrued Liabilities

Accrued liabilities consist of the following (in thousands):

	September 30, 2019	December 31, 2018
Accrued payroll and benefits	$ 131,337	$ 127,109
Accrued expenses	61,858	39,323
Accrued professional fees	15,554	6,752
Current operating lease liabilities	13,706	—
Accrued warranty	10,802	8,551
Accrued property, plant and equipment	10,241	8,193
Accrued sales return reserve	9,390	6,534
Accrued customer credits and deposits	7,181	12,439
Accrued sales tax and value added tax	7,135	6,276
Accrued sales rebate	7,068	5,668
Accrued income taxes	5,885	5,752
Other accrued liabilities	5,975	8,082
Total accrued liabilities	$ 286,132	$ 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.

Warranty accrual consists of the following activity (in thousands):

	Nine Months Ended September 30,	
	2019	2018
Balance at beginning of period	$ 8,551	$ 5,929
Charged to cost of net revenues	9,429	10,874
Actual warranty expenditures	(7,178)	(8,777)
Balance at end of period	$ 10,802	$ 8,026

Deferred Revenues

Deferred revenues consist of the following (in thousands):

	September 30, 2019	December 31, 2018
Deferred revenues - current	$ 520,712	$ 393,138
Deferred revenues - long-term [1]	$ 27,551	$ 17,051

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

During the three months ended September 30, 2019 and 2018, we recognized $607.3 million and $505.3 million of revenue, respectively, of which $70.1 million and $45.5 million was included in the deferred revenues balance at December 31, 2018 and 2017, respectively.

During the nine months ended September 30, 2019 and September 30, 2018, we recognized $1.8 billion and $1.4 billion of revenue, respectively, of which $207.0 million and $145.4 million was included in the deferred revenues balance at December 31, 2018 and 2017, respectively.

Our unfilled performance obligations, including deferred revenues and backlog, as of September 30, 2019 were $558.1 million. These performance obligations are expected to be recognized over the next one to five years.

Align has revised certain previously disclosed amounts within this footnote. These revisions did not impact current or prior period financial statements.

Note 4. Leases

Lessee

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

The supplemental balance sheet information for our operating leases consist of following (in thousands):

Balance Sheet Location	September 30, 2019
Operating lease right-of-use assets, net	$ 53,923
Accrued liabilities	$ 13,706
Operating lease liabilities	43,365
Total operating lease liabilities	$ 57,071

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

Lease Cost	Three Months Ended September 30, 2019	Nine Months Ended September 30, 2019
Operating lease cost [1]	$ 5,957	$ 16,756
Variable lease cost	436	1,543
Total lease cost [2]	$ 6,393	$ 18,299

[1] Includes short-term lease expense which are not material for the periods.
[2] Included in operating expenses within our Condensed Consolidated Statement of Operations.

The following table provides a summary of our operating lease terms and discount rates:

Remaining Lease Term and Discount Rate	September 30, 2019
Weighted average remaining lease term (in years)	5.9
Weighted average discount rate	4.2%

Maturities of operating lease liabilities as of September 30, 2019 are as follows (in thousands):

Fiscal Year Ending December 31,	Operating Leases
Remainder of 2019	$ 3,957
2020	17,934
2021	15,990
2022	10,454
2023	7,014
Thereafter	7,076
Total lease payments	$ 62,425
Less: Interest	(5,354)
Total lease liabilities	$ 57,071

As of September 30, 2019, we had additional operating leases that have not yet commenced of $9.6 million. These operating leases will commence between the remainder of fiscal year 2019 through 2021 with lease terms of 2 years to 4 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 are as follows (in thousands):

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

Lessor

In April 2019, as part of the purchase of a building located in Morrisville, North Carolina, we assumed an existing lease with a third-party for a portion of the building which is classified as an operating lease.

Lease payments due to Align as of September 30, 2019 are as follows (in thousands):

Fiscal Year Ending December 31,	Operating Lease
Remainder of 2019	$ 212
2020	859
2021	1,145
2022	1,199
2023	1,229
Thereafter	7,441
Total minimum lease payments	$ 12,085

For the three and nine months ended September 30, 2019, operating lease income was not material.

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 was accounted for as an equity method investment and recorded in our Condensed Consolidated Balance Sheet. We recorded our proportional share of SDC's losses within equity in losses of investee, net of tax, in our Condensed Consolidated Statement of Operations.

As a result of the arbitrator's decision regarding SDC announced on March 5, 2019, we were ordered to tender our 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 the "capital account" value provided by SDC, we entered into an unsecured promissory note with SDC to receive $54.2 million through February 1, 2021 in exchange for the tender of our membership interests. As a result, we derecognized the equity method investments balance of $38.4 million in exchange for an unsecured promissory note of $54.2 million which we recorded in our Condensed Consolidated Balance Sheet. We recorded the difference of $15.8 million as a gain in the second quarter of 2019 as other income in our Condensed Consolidated Statement of Operation. Although we tendered our membership interests pursuant to the arbitrator's decision, the parties did not agree on the amount of the "capital account" balance as of October 31, 2017 or the appropriate repurchase price for the membership units. On July 3, 2019, we filed a demand for arbitration regarding SDC's calculation of the "capital account" balance. That arbitration proceeding remains pending and currently is scheduled to be heard in June 2020 (*Refer to Note 9 "Legal Proceedings" of the Notes to Condensed Consolidated Financial Statements* for SDC legal proceedings discussion).

Concurrently with the investment on July 25, 2016, we also entered into a supply agreement with SDC to manufacture clear aligners for SDC's program. 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.

Note 6. Goodwill and Intangible Assets

Goodwill

The change in the carrying value of goodwill for the nine months ended September 30, 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]	(274)
Balance as of September 30, 2019	$ 63,755

[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.

Intangible Long-Lived Assets

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

	Weighted Average Amortization Period (in years)	Gross Carrying Amount as of September 30, 2019	Accumulated Amortization	Accumulated Impairment Loss	Net Carrying Value as of September 30, 2019
Trademarks	15	$ 7,100	$ (2,011)	$ (4,179)	$ 910
Existing technology	13	12,600	(5,690)	(4,328)	2,582
Customer relationships	11	33,500	(17,939)	(10,751)	4,810
Reacquired rights	3	7,500	(6,425)	—	1,075
Patents	8	6,796	(2,954)	—	3,842
Other	2	618	(580)	—	38
Total intangible assets		$ 68,114	$ (35,599)	$ (19,258)	$ 13,257

	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 September 30, 2019 is as follows (in thousands):

Fiscal Year Ending December 31,	Amortization
Remainder of 2019	$ 1,493
2020	3,825
2021	3,389
2022	2,116
2023	1,495
Thereafter	939
Total	$ 13,257

Amortization expense for both the three months ended September 30, 2019 and 2018 was $1.5 million and amortization expense for both the nine months ended September 30, 2019 and 2018 was $4.5 million.

Note 7. Credit Facilities

On February 27, 2018, we entered into a 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. 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 September 30, 2019, we had no outstanding borrowings under this credit facility and were in compliance with the conditions and performance requirements.

Note 8. Impairments and Other (Gains) 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, in the first quarter of 2019, we 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. During the third quarter of 2019, we negotiated early termination of our Invisalign store leases and recorded lease termination gains of $6.8 million.

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"). On May 10, 2019, the lead plaintiff filed a consolidated complaint against Align and four of our executive officers alleging similar claims as the initial complaints on behalf of a purported class of purchasers of our common stock between April 25, 2018 and October 24, 2018. On June 24, 2019, defendants filed a motion to dismiss the consolidated complaint. On October 29, 2019, that motion to dismiss was granted with leave to amend. 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 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 Actions, 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 Actions.

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. On May 16, 2019, the court stayed this action pending final disposition of the Securities Actions.

On February 22, 2019, a purported stockholder sent a letter to Align pursuant to 8 Del. C. § 220 demanding certain books and records for the stated purpose of investigating potential breaches of duty, corporate mismanagement, and alleged wrongdoing by fiduciaries of the Company. On April 16, 2019, Align responded and refused the demand on several legal grounds. On June 10, 2019, the purported stockholder petitioned the Superior Court of the State of California, County of Santa Clara, to issue a writ of mandate commanding Align to provide the books and records requested. On August 23, 2019, Align filed a demurrer seeking to dismiss the petition. A hearing on that demurrer was held on October 25, 2019. On October 28, 2019, the Court issued an order sustaining Align's demurrer and dismissing the petition without an opportunity to amend. The Court further ordered Align to submit a proposed judgment of dismissal within 10 days.

Align is currently unable to predict the outcome of this demand or 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 were stayed pending the ITC determinations, and the other two cases are currently active in discovery and pretrial proceedings. Trials have been scheduled to begin on April 20, 2020 in one case and to begin on June 8, 2020 in the other. Certain of Align’s asserted patents in the Delaware actions were found invalid by the District Court Judge. The ITC conducted hearings in the Section 337 investigations 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. 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. Align and 3Shape each petitioned the Commission for review of the Initial Determinations. On July 18 and July 19, 2019, the Commission determined to review each Initial Determination and sought additional briefing by the parties with respect to one of the Section 337 investigations. On August 20, 2019, the Commission vacated one Initial Determination and terminated the investigation, and on October 15, 2019, the Court ordered that the stay be lifted on the corresponding Delaware case. The current target date for completion of the other investigation is November 22, 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 court stayed the case. 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. On August 19, 2019, the Court consolidated the two actions, and 3Shape filed an amended complaint alleging infringement of an additional patent on August 30, 2019. The case is active and in the early discovery phase, with trial scheduled to begin on April 12, 2021.

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 alleged market activities, including Align’s assertion of its patent portfolio, in alleged clear aligner and intraoral scanning markets, and the Court scheduled trial to begin on May 10, 2021. Align filed a motion to dismiss 3Shape’s complaint on October 17, 2018. Align also moved to stay the litigation pending the outcome of its motion to dismiss. The court granted Align’s motion to stay. On August 15, 2019, the Magistrate Judge recommended that Align’s motion to dismiss be granted, and, on September 26, 2019, the District Court Judge adopted the Magistrate Judge’s Report and Recommendation, granted Align’s motion to dismiss, and dismissed 3Shape’s complaint with leave to amend within thirty days of the order. On October 28, 2019, 3Shape filed an amended complaint. Align has until November 18, 2019 to respond.

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. Certain claims of Align’s asserted patents in the Delaware action was found invalid by the District Court Judge. The remaining District Court case is in the very early stages of discovery and pretrial proceedings. The ITC evidentiary hearing was held at the end of October 2019. The deadline for the judge’s initial determination is March 6, 2020.

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.

Simon & Simon

On March 14, 2019, a dental practice named Simon and Simon, PC d/b/a City Smiles brought an antitrust action on behalf of itself and a putative class of similarly situated practices seeking monetary damages and injunctive relief relating to Align's alleged market activities in alleged clear aligner and intraoral scanning markets. Align filed a motion to dismiss the complaint on April 5, 2019, and the court held a hearing on Align's motion. On October 15, 2019, the Magistrate Judge issued a Report and Recommendation on Align's motion to dismiss which recommends that Align's motion be granted and that the plaintiffs' complaint be dismissed without prejudice. On October 29, 2019, Simon and Simon filed objections to the Magistrate Judge's Report and Recommendation. Align has until November 12, 2019 to respond. Align believes the plaintiffs' claims are without merit and intends to vigorously defend itself.

SDC Dispute

In February 2018, Align 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 constituted 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) sought 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 on March 4, 2019. The arbitrator found that Align breached the non-compete provision applicable to the members of SDC Financial LLC and 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 specified aspects 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, to be determined in accordance with the applicable provisions of the SDC Operating Agreements. 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 was granted on April 29, 2019.

As required by the Award, on April 3, 2019, Align had closed its Invisalign stores, returned SDC's alleged confidential information, and tendered its membership interests for a purchase price that SDC claims to be Align's "capital account" balance as of October 31, 2017. Align disputes that the SDC Entities properly determined the value of Align's "capital account" balance as of October 31, 2017 as required by the SDC Operating Agreements and the Award. Consequently, on July 3, 2019, Align filed a confidential demand for arbitration challenging the propriety of the SDC Entities' determination of Align's "capital account" balance as of October 31, 2017. That arbitration proceeding remains pending and currently is scheduled to be heard in June 2020. Relatedly, the SDC Entities filed a contempt petition with the Illinois court which confirmed the Award, asserting that Align had no right to contest the "capital account" determination as made by the SDC Entities. On September 4, 2019, the Illinois court denied in its entirety the contempt petition filed by the SDC Entities.

On August 19, 2019, the SDC Entities filed a separate confidential arbitration proceeding alleging that Align has violated the non-compete provisions applicable to the members of the SDC Entities by virtue of Align's alleged dealings with a third-party claimed to be a competitor of the SDC Entities. Align has denied the claim and intends to vigorously defend itself against the newly asserted allegations. The SDC Entities have yet to identify the range of damages they may seek to recover in the course of this arbitration and no hearing date has yet been set.

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.

Straumann Group Litigation Settlement

In March 2019, Align 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 $35.0 million on March 29, 2019. In addition, Align 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. The agreement provided that if for any reason the companies chose not to enter into the development and distribution agreement by July 2, 2019 or by a mutually agreed extended date, Straumann Group would pay Align an additional $16.0 million in lieu of the development and distribution agreement. In June 2019, the parties terminated the discussions regarding a possible development and distribution agreement and as a result, Straumann paid us the additional $16.0 million in July 2019. During the nine months ended September 30, 2019, we recognized a litigation settlement gain of $51.0 million.

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

Note 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 is payable in six installments according to construction milestones and the delivery of the Property will be throughout 2019 and 2020.

On September 26, 2019, we entered into a Purchase and Sale Agreement to purchase a building located in San Jose, California for $21.3 million. On September 27, 2019, we paid a $0.3 million refundable deposit related to the Purchase and Sale Agreement and an additional $21.0 million will be paid on or before the closing date which is expected to occur in the first quarter of 2020.

Subsequent to the end of third quarter of 2019, on October 3, 2019, we entered into a Promotional Rights Agreement (the "Agreement") for $36.0 million with a third-party which includes certain advertising and media coverage. The expense related to the Agreement will be incurred over the period of April 1, 2020 through March 31, 2023.

Off-Balance Sheet Arrangements

As of September 30, 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.

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

future payments by us could be significant and could have a material adverse effect on our results of operations or cash flows in a particular period. As of September 30, 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 September 30, 2019, the 2005 Incentive Plan (as amended) has a total reserve of 27,783,379 shares of which 5,372,152 shares are available for issuance.

Stock-based compensation is based on the estimated fair value of awards, net of estimated forfeitures, and recognized over the requisite service period. Estimated forfeitures are based on historical experience at the time of grant and may be revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. The stock-based compensation related to all of our stock-based awards and employee stock purchases for the three and nine months ended September 30, 2019 and 2018 is as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Cost of net revenues	$ 1,354	$ 966	$ 3,744	$ 2,747
Selling, general and administrative	19,394	15,403	54,321	41,197
Research and development	3,428	2,829	9,622	7,974
Total stock-based compensation	$ 24,176	$ 19,198	$ 67,687	$ 51,918

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 nine months ended September 30, 2019, 8,187 stock options were exercised at a weighted average exercise price of $8.07 per share. As of September 30, 2019, there were no options outstanding and exercisable.

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 nine months ended September 30, 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	276	256.33		
Vested and released	(422)	103.01		
Forfeited	(61)	181.57		
Nonvested as of September 30, 2019	724	$ 188.86	1.3	$ 131,021

As of September 30, 2019, we expect to recognize $100.6 million of total unamortized compensation cost, net of estimated forfeitures, related to RSUs over a weighted average period of 2.2 years.

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

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 nine months ended September 30, 2019, the maximum number of MSUs which will be eligible to vest are 250% of the MSUs initially granted.

A summary for the nine months ended September 30, 2019 is as follows:

	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	138	240.73		
Vested and released	(191)	77.17		
Forfeited	(12)	258.72		
Nonvested as of September 30, 2019	259	$ 326.15	1.4	$ 46,776

As of September 30, 2019, we expect to recognize $43.7 million of total unamortized compensation cost, net of estimated forfeitures, related to MSUs over a weighted average period of 1.4 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 September 30, 2019, we have 441,293 shares available for future issuance.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Expected term (in years)	1.5	1.2	1.4	1.3
Expected volatility	52.0%	35.7%	50.1%	35.2%
Risk-free interest rate	1.8%	2.5%	2.2%	2.2%
Expected dividends	—	—	—	—
Weighted average fair value at grant date	$ 80.42	$ 109.58	$ 86.02	$ 94.71

As of September 30, 2019, there was $13.4 million of total unamortized compensation costs related to employee stock purchases which we expect to be recognized over a weighted average period of 1.2 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.

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 repurchased on the open market approximately 0.2 million shares of our common stock at an average price of $243.42 per share, including commissions for an aggregate purchase price of $50.0 million. In May 2019, we repurchased on the open market approximately 0.2 million shares of our common stock at an average price of $307.48 per share, including commissions for an aggregate price of $49.5 million. In July 2019, we entered into an accelerated stock repurchase agreement (“2019 ASR”) to repurchase $200.0 million of our common stock which was completed in September 2019. We received a total of approximately 1.1 million shares for an average share price of $176.61. As of September 30, 2019, we have $200.5 million available for repurchase under the May 2018 Repurchase Program.

Note 13. Accounting for Income Taxes

Our provision for income taxes was $25.9 million and $24.6 million for the three months ended September 30, 2019 and 2018, respectively, representing effective tax rates of 20.2% and 19.4%, respectively. Our provision for income taxes was $77.8 million and $35.2 million for the nine months ended September 30, 2019 and 2018, respectively, representing effective tax rates of 19.1% and 10.2%, respectively. Our effective tax rate differs from the statutory federal income tax rate of 21% for the three and nine months ended September 30, 2019 mainly as a result of certain foreign earnings, primarily from the Netherlands and Costa Rica, being taxed at lower tax rates and the recognition of excess tax benefits related to stock-based compensation, partially offset by non-deductible officers’ compensation. Our effective tax rate differs from the statutory federal income tax rate of 21% for the three and nine months ended 2018 mainly as a result of the recognition of excess tax benefits related to stock-based compensation, tax benefits recognized related to a statute of limitations expiration, and certain foreign earnings, primarily from the Netherlands and Costa Rica, being taxed at lower tax rates, partially offset by unfavorable tax impact of the TCJA, including non-deductible officers’ compensation.

The increase in our effective tax rate for the three and nine months ended September 30, 2019 compared to the same periods in 2018 is primarily attributable to reduced excess tax benefits from stock-based compensation mainly due to non-deductible officers’ compensation and tax benefits recorded last year as a result of expiration of statute limitations that did not recur in 2019. For the three and nine months ended September 30, 2019, we recognized excess tax benefits of $0.4 million and $13.5 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 2012.

Our total gross unrecognized tax benefits, excluding interest and penalties, was $46.0 million and $33.3 million as of September 30, 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 September 30, 2019 was $1.6 million. 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, our undistributed earnings of our 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 Global Intangible Low-Taxed Income (“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 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 and nine months ended September 30, 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 and our ESPP.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Numerator:				
Net income	$ 102,524	$ 100,872	$ 321,514	$ 302,843
Denominator:				
Weighted average common shares outstanding, basic	79,332	80,111	79,709	80,122
Dilutive effect of potential common stock	493	1,248	688	1,416
Total shares, diluted	79,825	81,359	80,397	81,538
Net income per share, basic	$ 1.29	$ 1.26	$ 4.03	$ 3.78
Net income per share, diluted	$ 1.28	$ 1.24	$ 4.00	$ 3.71

For the three and nine months ended September 30, 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):

	Nine Months Ended September 30,	
	2019	2018
Non-cash investing and financing activities:		
Fixed assets acquired with accounts payable or accrued liabilities	$ 14,331	$ 24,281
Conversion of convertible notes receivable into equity securities	$ —	$ 4,862
Issuance of promissory note in exchange for sale of equity method investment	$ 54,154	$ —
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	$ 21,186	$ —
Investing cash flows from finance leases [1]	$ 10,896	$ —
Financing cash flows from finance leases	$ 45,773	$ —
Right-of-use assets obtained in exchange for lease obligations:		
Operating leases	$ 26,395	$ —
Finance leases	$ 51,064	$ —

[1] A portion of finance lease purchase payment relates to leasing a part of the building to a third party as a lessor. This amount is included in Other Investing Activities in our Condensed Consolidated Statements of Cash Flows.

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 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, Invisalign First and Invisalign Moderate.
  - 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 September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Net revenues				
Clear Aligner	$ 516,265	$ 427,087	$ 1,482,172	$ 1,245,833
Scanner	91,076	78,202	274,837	186,639
Total net revenues	$ 607,341	$ 505,289	$ 1,757,009	$ 1,432,472
Gross profit				
Clear Aligner	$ 379,202	$ 321,772	$ 1,096,702	$ 950,360
Scanner	58,352	50,009	175,237	114,411
Total gross profit	$ 437,554	$ 371,781	$ 1,271,939	$ 1,064,771
Income from operations				
Clear Aligner	$ 211,952	$ 182,667	$ 614,622	$ 534,408
Scanner	32,760	31,498	100,286	65,250
Unallocated corporate expenses	(117,560)	(88,957)	(323,565)	(253,567)
Total income from operations	$ 127,152	$ 125,208	$ 391,343	$ 346,091
Depreciation and amortization				
Clear Aligner	$ 9,306	$ 7,218	$ 27,851	$ 20,361
Scanner	1,987	1,237	5,349	3,510
Unallocated corporate depreciation and amortization	8,413	5,664	23,994	14,314
Total depreciation and amortization	$ 19,706	$ 14,119	$ 57,194	$ 38,185
Impairments and other (gains) charges				
Clear Aligner	$ (6,792)	$ —	$ 22,990	$ —
Scanner	—	—	—	—
Unallocated corporate impairments and other charges	—	—	—	—
Total impairments and other charges	$ (6,792)	$ —	$ 22,990	$ —

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Total segment income from operations	$ 244,712	$ 214,165	$ 714,908	$ 599,658
Unallocated corporate expenses	(117,560)	(88,957)	(323,565)	(253,567)
Total income from operations	127,152	125,208	391,343	346,091
Interest income	3,478	2,234	9,576	6,327
Other income (expense), net	(2,211)	(837)	5,935	(7,759)
Net income before provision for income taxes and equity in losses of investee	$ 128,419	$ 126,605	$ 406,854	$ 344,659

Geographical Information

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Net revenues [1]:				
United States	$ 286,050	$ 263,349	$ 861,710	$ 754,472
The Netherlands	173,926	141,405	540,858	437,364
China	63,636	52,874	151,075	116,891
Other International	83,729	47,661	203,366	123,745
Total net revenues	$ 607,341	$ 505,289	$ 1,757,009	$ 1,432,472

[1] Net revenues are attributed to countries based on the location of where revenues are recognized by our legal entities.

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

	September 30, 2019	December 31, 2018
Long-lived assets [2]:		
The Netherlands	$ 231,746	$ 206,679
United States	164,732	139,239
Costa Rica	81,574	80,218
China	62,359	36,249
Mexico	38,494	33,240
Other International	81,599	25,704
Total long-lived assets	$ 660,504	$ 521,329

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

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

In addition to historical information, this quarterly report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. These statements include, among other things, our expectations regarding the anticipated impact of our new products and product enhancements will have on doctor utilization and our market share, our expectations regarding product mix and product adoption, our expectations regarding the existence and impact of seasonality, our expectations regarding the 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 expectations regarding the productivity impact additional sales representatives will have 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 than Americas for the foreseeable future, our expectation regarding customer and consumer purchasing behavior, including expectations related to the consumer demand environment in China especially for U.S. based products and services, our expectation to incur additional costs related to the planned corporate structure reorganization, our expectations regarding potential additional litigation with SDC Financial LLC and certain affiliates regarding the “capital account” balance and other matters, 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 which, to date, over 7.5 million people worldwide have been treated with our Invisalign System, 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 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.

    - We launched 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 without the need for elastics typically used to treat teen Class II patients. Invisalign treatment with Mandibular Advancement is commercially available to Invisalign-trained doctors in Canada, select Europe, Middle East and Africa

("EMEA"), Asia Pacific ("APAC") and Latin America ("LATAM") countries and, in the U.S. starting November 2018 as we received 510(k) clearance from the United States ("U.S.") Food and Drug Administration in October 2018.

- 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 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 ("GP") dentists to tailor their treatment plans to the individual needs of each patient.

- In July 2018, we announced Invisalign First clear aligners which are a treatment option designed with features specifically for younger patients with early mixed dentition with a mixture of primary/baby and permanent teeth. 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. 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. Invisalign First clear aligner treatment is commercially available to Invisalign-trained doctors in the U.S., Canada, as well as in select EMEA, APAC and LATAM countries.

- In October 2019, Invisalign Moderate Package launched in the U.S. and Canada. Applicable for mild to moderate malocclusion, the Invisalign Moderate treatment plans each consist of up to 20 aligners. The Invisalign Moderate treatment includes all the features of Invisalign treatment, plus additional features that address the orthodontic needs of teenage patients such as compliance indicators and compensation for tooth eruption. Aligners for Invisalign Moderate Package treatments are delivered to the dental professionals in a single shipment.

- *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 U.S., and a majority of EMEA and 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.

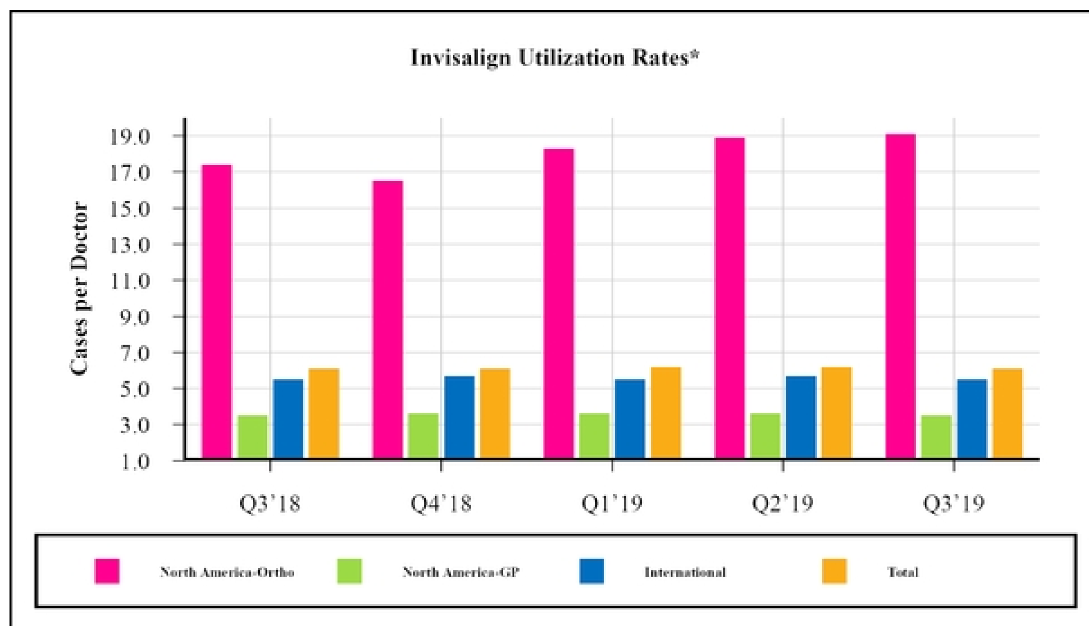
  - In February 2019, we announced the launch of iTero Element 5D Imaging System for comprehensive, preventative and restorative oral care. The iTero Element 5D Imaging System provides a new comprehensive approach to clinical applications, workflows and user experience that expands the suite of existing 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 select APAC countries. The iTero Element 5D Imaging System is not yet available in the U.S. or Latin America.

  - In June 2019, we announced the launch of iTero Element Foundation intraoral scanner with restorative software. The iTero Element Foundation extends Align's portfolio of intraoral scanners with powerful 3D visualization to better meet the needs of doctors, labs and patients. The iTero Element Foundation is available in North America and Japan and will also be available in select APAC and in select EMEA countries in the fourth quarter of 2019.

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 third quarter of 2019, total Invisalign cases submitted with a digital scanner in the Americas increased to 78.7%, up from 77.3% in the second quarter of 2019. International scans increased to 62.5%, up from 60.9% in the second quarter of 2019. 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.

- *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 is calculated by the # of cases shipped divided by the # of doctors cases were shipped to. We report International region to include EMEA and APAC. LATAM is excluded from above chart as it is not material.

  - Total utilization in both the third quarter of 2019 and 2018 was 6.1 cases per doctor.
    - *North America:* Utilization among our North American orthodontist customers reached an all-time high in the third quarter of 2019 at 19.1 cases per doctor, compared to 17.4 cases per doctor utilized in the third quarter of 2018 while utilization among our North American GP was flat or 3.5 cases per doctor in both the third quarter of 2019 and 2018. The increase in North American orthodontist utilization in the third 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 both the third quarter of 2019 and 2018.

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 rates 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 nine months ended September 30, 2019, we trained 16,735 new Invisalign doctors of which 7,670 were trained in the Americas region and 9,065 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 32.1% driven primarily by increased adoption as well as expansion of our customer base in both the EMEA and APAC regions. However, in the second quarter of 2019, we experienced softness in China related to a tougher consumer demand environment. Notwithstanding the current consumer sentiment in China, we continue to see growth from our international orthodontists and 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. 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 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."* and *"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).

- *Increasing Competition.* In the second and third quarters of 2019, we experienced slower adult case growth from North American orthodontists, reflecting a more competitive environment especially for the young adult demographic. Given increased awareness for direct to consumer clear aligners and heavy advertising spend from direct to consumer players, case starts may be shifting away from traditional practices. We also believe that doctors are sampling alternative products and/or taking advantage of wires and brackets bundles that essentially give clear aligners away for free or at very low prices. In the third quarter of 2019, we increased investment in consumer demand with a new advertising campaign for North America and expanding marketing programs such as our Concierge Service, which connects potential patients with Invisalign doctors increasing conversion and loyalty. In addition, we launched new sales tools and professional marketing materials and we also expect to see increased productivity from the approximate 100 sales representatives we added in the first quarter of 2019. If, however, 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 (Refer to *Item 1A Risk Factors "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"* 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. In the third quarter of 2019, we opened our new order acquisition facility in Wroclaw, Poland and new treatment facility in Yokohama, Japan. We continue to 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 and operational efficiencies at our manufacturing and treat facilities"* for information on related risk factors).

- *Corporate Structure Reorganization.* Given our continued growth and expansion internationally, we are reorganizing our corporate structure and intercompany relationships to more closely align with the international nature of our business activities. The new corporate structure may also allow us to obtain financial and operational efficiencies after they are implemented. As part of this corporate structure reorganization, we will relocate our European headquarters from the Netherlands to Switzerland which we expect to be completed in early 2020. As a result, we will continue to 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 $35.0 million on March 29, 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. The agreement provided that if for any reason the companies chose not to enter into the development and distribution agreement by July 2, 2019 or by a mutually agreed extended date, Straumann Group would pay Align an additional $16.0 million in lieu of the development and distribution agreement. In June 2019, the parties terminated the discussions regarding a possible development and distribution agreement and as a result, Straumann paid us the additional $16.0 million in July 2019. During the nine months ended September 30, 2019, we recognized a litigation settlement gain of $51.0 million.

- *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, the "SDC Entities"). 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 specified aspects 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. No financial damages were awarded to the SDC Entities. In the nine months ended September 30, 2019, we recorded net of $23.0 million charges related to the store closures of approximately $29.8 million in the first quarter of 2019, composed of impairments related to the right of use lease assets, leasehold improvements and other fixed assets along with employee severance expenses, and was partially offset by $6.8 million of lease termination gains from our negotiated early termination of our Invisalign store leases recorded in the third quarter of 2019. On April 3, 2019, we had closed all Invisalign stores and returned SDC's confidential information. We also tendered our membership 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. As a result, we recorded a $15.8 million gain in the second quarter of 2019 as other income in our Condensed Consolidated Statement of Operation. Although we tendered our membership interests pursuant to the arbitrator's decision, the parties did not agree on the amount of the "capital account" balance as of October 31, 2017 or the appropriate repurchase price for the membership units. On July 3, 2019, we filed a demand for arbitration regarding SDC's calculation of the "capital account" balance. That arbitration proceeding remains pending and currently is scheduled to be heard in June 2020. Relatedly, the SDC Entities filed a contempt petition with the Illinois court which confirmed the Award, asserting that Align had no right to contest the "capital account" determination as made by the SDC Entities. On September 4, 2019, the Illinois court denied in its entirety the contempt petition filed by the SDC Entities. On August 19, 2019, the SDC Entities filed a separate confidential arbitration proceeding alleging that Align has violated the non-compete provisions applicable to the members of the SDC Entities by virtue of Align's alleged dealings with a third-party claimed to be a competitor of the SDC Entities. Align has denied the claim and intends to vigorously defend itself against the newly asserted allegations. The SDC Entities have yet to identify the range of damages they may seek to recover in the course of this arbitration and no hearing date has yet been set. 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 (Gains) Charges" of the Notes to Consolidated Financial Statements* for details on impairments and other (gains) charges).

- *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 including our new advertising campaign;
    - 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.* During the nine months ended September 30, 2019, we repurchased $99.5 million of our common stock on the open market. In July 2019, we entered into an accelerated share repurchase agreement (“2019 ASR”) to repurchase $200.0 million of our common stock which was completed in September 2019. As of September 30, 2019, we have $200.5 million available for repurchase under the $600.0 million repurchase program authorized by our Board of Directors in May 2018 (*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, Invisalign First and Invisalign Moderate.
  - 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.
  - 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 and nine months ended September 30, 2019 and 2018 are as follows (in millions):

	Three Months Ended September 30,				Nine Months Ended September 30,			
Net Revenues	**2019**	**2018**	**Net Change**	**% Change**	**2019**	**2018**	**Net Change**	**% Change**
Clear Aligner revenues:								
Americas	$ 259.8	$ 228.6	$ 31.1	13.6%	$ 753.6	$ 672.2	$ 81.4	12.1%
International	226.0	172.2	53.9	31.3%	637.4	496.9	140.5	28.3%
Non-case	30.5	26.3	4.2	16.0%	91.2	76.7	14.5	18.9%
Total Clear Aligner net revenues	$ 516.3	$ 427.1	$ 89.2	20.9%	$ 1,482.2	$ 1,245.8	$ 236.3	19.0%
Scanner net revenues	91.1	78.2	12.9	16.5%	274.8	186.6	88.2	47.3%
Total net revenues	$ 607.3	$ 505.3	$ 102.1	20.2%	$ 1,757.0	$ 1,432.5	$ 324.5	22.7%

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

Clear Aligner Case Volume by Region

Case volume data which represents Clear Aligner case shipments by region for the three and nine months ended September 30, 2019 and 2018 is as follows (in thousands):

	Three Months Ended September 30,				Nine Months Ended September 30,			
Region	**2019**	**2018**	**Net Change**	**% Change**	**2019**	**2018**	**Net Change**	**% Change**
Americas	215.4	205.8	9.6	4.7%	641.3	580.3	61.0	10.5%
International	170.0	128.7	41.3	32.1%	482.0	355.6	126.5	35.6%
Total case volume	385.4	334.6	50.9	15.2%	1,123.3	935.9	187.5	20.0%

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

For the three and nine months ended September 30, 2019, total net revenues increased by $102.1 million and $324.5 million, respectively, as compared to the same periods in 2018 primarily as a result of Invisalign case and scanner volume growth across all regions.

Clear Aligner - Americas

For the three months ended September 30, 2019, Americas net revenues increased by $31.1 million as compared to the same period in 2018 primarily due to higher average selling prices (“ASP”) which increased net revenues by $20.5 million. Higher ASP was due to July 2019 price increases across most products which contributed $11.5 million to the revenue growth and a product mix shift towards higher priced products, primarily driven by decreased SDC revenues which carry a lower ASP, increased net revenues $8.3 million. Invisalign case volume growth across all channels and most products increased net revenues by $10.6 million.

For the nine months ended September 30, 2019, Americas net revenues increased by $81.4 million as compared to the same period in 2018 due to Invisalign case volume growth across all channels and products which contributed to the net revenue growth by $70.7 million and higher ASP which increased net revenues by $10.7 million. Higher ASP was mainly the result of higher prices across most products which increased net revenues $22.9 million and a product mix shift towards higher priced products, primarily driven by decreased SDC revenues, increased net revenues $15.2 million. The ASP increases were partially offset by higher deferrals which reduced net revenues by $13.5 million, higher promotional discounts that reduced net revenues by $11.2 million, and unfavorable foreign exchange rates which reduced net revenues by $3.9 million.

Clear Aligner - International

For the three months ended September 30, 2019, International net revenues increased by $53.9 million as compared to the same period in 2018 primarily driven by Invisalign case volume growth across all channels and most products which increased net revenues by $55.2 million. This increase was partially offset by lower ASP that reduced net revenues by $1.3 million. The ASP decline was mainly the result of higher promotional discounts that reduced net revenues by $11.6 million, unfavorable foreign exchange rates that reduced net revenues by $6.8 million, and a product mix shift towards lower priced products that reduced net revenues by $4.3 million. The ASP decreases were partially offset by July 2019 price increases across most products, 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 revenues by $13.5 million and lower net deferrals that increased net revenues by $5.0 million.

For the nine months ended September 30, 2019, International net revenues increased by $140.5 million as compared to the same period in 2018 primarily driven by case volume growth across all channels and most products which increased net revenues by $176.8 million. This increase was partially offset by lower ASP that reduced net revenues by $36.3 million. The ASP decline was mainly the result of unfavorable foreign exchange rates that reduced net revenues by $32.1 million, higher promotional discounts that reduced net revenues by $28.8 million, and a product mix shift towards lower priced products that reduced net revenues by $10.4 million. The ASP decreases were partially offset by higher prices from most products, along with a benefit from going direct in several additional countries, which increased net revenues by $27.3 million and lower net revenue deferrals and sales credits that increased net revenues by $4.8 million.

Clear Aligner - Non-Case

For the three and nine months ended September 30, 2019, non-case net revenues, consisting of Vivera Retainers, training fees and other product revenues, increased by $4.2 million and $14.5 million, respectively, as compared to the same periods in 2018. This was primarily due to increased Vivera volume across all regions, which increased revenues by $4.1 million and $13.3 million, respectively.

Scanner

For the three months ended September 30, 2019, scanner and services net revenues increased by $12.9 million as compared to the same period in 2018. This increase is primarily due to a larger scanner install base which resulted in higher computer-aided design/computer-aided manufacturing (“CAD/CAM”) services which increased net revenues by $8.6 million. Additionally, the increase in the number of scanners recognized increased net revenues by $2.6 million and an increase in scanner ASP contributed $1.7 million to the net revenue growth.

For the nine months ended September 30, 2019, scanner and services net revenues increased by $88.2 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 net revenues by $51.7 million, and higher CAD/CAM services that increased net revenues by $28.6 million. Additionally, net revenues increased by $7.9 million due to an increase in scanner ASP mostly attributable to new higher priced scanners launched in April 2018.

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

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2019	**2018**	**Change**	**2019**	**2018**	**Change**
Clear Aligner						
Cost of net revenues	$ 137.1	$ 105.3	$ 31.7	$ 385.5	$ 295.5	$ 90.0
% of net segment revenues	*26.5%*	*24.7%*		*26.0%*	*23.7%*	
Gross profit	$ 379.2	$ 321.8	$ 57.4	$ 1,096.7	$ 950.4	$ 146.3
Gross margin %	*73.5%*	*75.3%*		*74.0%*	*76.3%*	
Scanner						
Cost of net revenues	$ 32.7	$ 28.2	$ 4.5	$ 99.6	$ 72.2	$ 27.4
% of net segment revenues	*35.9%*	*36.1%*		*36.2%*	*38.7%*	
Gross profit	$ 58.4	$ 50.0	$ 8.3	$ 175.2	$ 114.4	$ 60.8
Gross margin %	*64.1%*	*63.9%*		*63.8%*	*61.3%*	
Total cost of net revenues	$ 169.8	$ 133.5	$ 36.3	$ 485.1	$ 367.7	$ 117.4
% of net revenues	*28.0%*	*26.4%*		*27.6%*	*25.7%*	
Gross profit	$ 437.6	$ 371.8	$ 65.8	$ 1,271.9	$ 1,064.8	$ 207.2
Gross margin %	*72.0%*	*73.6%*		*72.4%*	*74.3%*	

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

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

Clear Aligner

For the three months ended September 30, 2019, our gross margin percentage decreased as compared to the same period in 2018 primarily due to an increase in aligners per case driven by additional aligners offset in part by a higher ASP.

For the nine months ended September 30, 2019, our gross margin percentage decreased as compared to the same period in 2018 primarily due to an increase in aligners per case driven by additional aligners.

Scanner

For the three and nine months ended September 30, 2019, our gross margin increased compared to the same periods in 2018 primarily driven by manufacturing efficiencies and higher ASP.

Selling, general and administrative (in millions):

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2019	2018	Change	2019	2018	Change
Selling, general and administrative	$ 277.5	$ 213.9	$ 63.6	$ 792.6	$ 625.6	$ 167.0
% of net revenues	*45.7%*	*42.3%*		*45.1%*	*43.7%*	

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

Selling, general and administrative expense includes personnel-related costs including payroll, commissions and stock-based compensation for our sales force, marketing and administration in addition to media and advertising expenses, clinical education, trade shows and industry events, product marketing, equipment and maintenance costs, legal and outside service costs, depreciation and amortization expense and allocations of corporate overhead expenses including facilities and Information Technology (“IT”).

For the three months ended September 30, 2019, selling, general and administrative expense increased compared to the same period in 2018 primarily due to higher compensation related costs of $31.0 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 advertising and marketing costs of $13.9 million, legal and outside service costs of $12.0 million and equipment, software and maintenance costs of $5.7 million.

For the nine months ended September 30, 2019, selling, general and administrative expense increased compared to the same period in 2018 primarily due to higher compensation related costs of $94.8 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 $30.4 million, advertising and marketing costs of $22.1 million, equipment, software and maintenance costs of $13.8 million and depreciation and amortization costs of $10.8 million.

Research and development (in millions):

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2019	2018	Change	2019	2018	Change
Research and development	$ 39.7	$ 32.7	$ 7.0	$ 116.0	$ 93.1	$ 22.9
% of net revenues	*6.5%*	*6.5%*		*6.6%*	*6.5%*	

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

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

For the three and nine months ended September 30, 2019, research and development expense increased compared to the same periods 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 (gains) charges (in millions):

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2019	2018	Change	2019	2018	Change
Impairments and other (gains) charges	$ (6.8)	$ —	$ (6.8)	$ 23.0	$ —	$ 23.0
% of net revenues	*(1.1)%*	*—%*		*1.3%*	*—%*	

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

For the three months ended September 30, 2019, we negotiated early termination of our Invisalign store leases and recorded lease termination gains of $6.8 million.

For the nine months ended September 30, 2019, we recorded impairments and other (gains) charges of $23.0 million which are comprised of operating lease right-of-use assets impairments 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, partially offset by the Invisalign store lease termination gains of $6.8 million (Refer to *Note 8"Impairments and Other (Gains) Charges" and Note 9 "Legal Proceedings" of the Notes to Condensed Consolidated Financial Statements* for more information).

Litigation settlement gain (in millions):

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2019	2018	Change	2019	2018	Change
Litigation settlement gain	$ —	$ —	$ —	$ (51.0)	$ —	$ (51.0)
% of net revenues	*—%*	*—%*		*(2.9)%*	*—%*	

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

For the nine months ended September 30, 2019, we recorded a gain of $51.0 million due to the litigation settlement with Straumann (Refer to *Note 9 "Legal Proceedings" of the Notes to Condensed Consolidated Financial Statements* for more information).

Income from operations (in millions):

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2019	2018	Change	2019	2018	Change
Clear Aligner						
Income from operations	$ 212.0	$ 182.7	$ 29.3	$ 614.6	$ 534.4	$ 80.2
Operating margin %	*41.1%*	*42.8%*		*41.5%*	*42.9%*	
Scanner						
Income from operations	$ 32.8	$ 31.5	$ 1.3	$ 100.3	$ 65.3	$ 35.0
Operating margin %	*36.0%*	*40.3%*		*36.5%*	*35.0%*	
Total income from operations [1]	$ 127.2	$ 125.2	$ 1.9	$ 391.3	$ 346.1	$ 45.3
Operating margin %	*20.9%*	*24.8%*		*22.3%*	*24.2%*	

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 September 30, 2019, our operating margin percentage decreased compared to the same period in 2018 primarily due to an increase in aligners per case driven by additional aligners and the increased investments in our geographic expansion and go-to-market activities partially offset by the benefit from the early termination of our Invisalign store leases and higher ASP.

For the nine months ended September 30, 2019, our operating margin percentage decreased compared to the same period in 2018 primarily due to an increase in aligners per case driven by additional aligners partially offset by a gain recognized from the litigation settlement with Straumann.

Scanner

For the three months ended September 30, 2019, our operating margin percentage decreased compared to the same period in 2018 primarily due to higher operating expenses partially offset by manufacturing efficiencies.

For the nine months ended September 30, 2019, our operating margin percentage increased compared to the same period in 2018 primarily due to manufacturing efficiencies and higher ASP partially offset by higher operating expenses.

Interest income (in millions):

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2019	2018	Change	2019	2018	Change
Interest income	$ 3.5	$ 2.2	$ 1.2	$ 9.6	$ 6.3	$ 3.2
% of net revenues	*0.6%*	*0.4%*		*0.5%*	*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 and nine months ended September 30, 2019, interest income increased compared to the same periods in 2018 mainly due to a larger investment portfolio.

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

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2019	2018	Change	2019	2018	Change
Other income (expense), net	$ (2.2)	$ (0.8)	$ (1.4)	$ 5.9	$ (7.8)	$ 13.7
% of net revenues	*(0.4)%*	*(0.2)%*		*0.3%*	*(0.5)%*	

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, gains and losses on equity investments and other miscellaneous charges.

For the three months ended September 30, 2019, other income (expense), net decreased compared to the same period in 2018 primarily due to foreign exchange losses.

For the nine months ended September 30, 2019, other income (expense), net increased compared to the same period in 2018 primarily due to a $15.8 million gain from the sale of our investment in SDC. This increase was partially offset by a $4.0 million impairment of our equity investment in a privately held company along with foreign exchange losses (Refer to *Note 9 "Legal Proceedings" of the Notes to Condensed Consolidated Financial Statements* for details on SDC legal proceedings discussion).

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

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2019	2018	Change	2019	2018	Change
Equity in losses of investee, net of tax	$ —	$ 1.1	$ (1.1)	$ 7.5	$ 6.6	$ 0.9
% of net revenues	*—%*	*0.2%*		*0.4%*	*0.5%*	

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

For the nine months ended September 30, 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 recorded during the first two quarters of 2019. After the second quarter of 2019, we no longer incur equity in losses of investee, net of tax related to SDC as we tendered our SDC equity interest on April 3, 2019. We recognized equity in losses of investee, net of tax on a three-month lag basis (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 September 30,			Nine Months Ended September 30,		
	2019	**2018**	**Change**	**2019**	**2018**	**Change**
Provision for income taxes	$ 25.9	$ 24.6	$ 1.3	$ 77.8	$ 35.2	$ 42.6
Effective tax rates	*20.2%*	*19.4%*		*19.1%*	*10.2%*	

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

The increase in effective tax rate for the three and nine months ended September 30, 2019 compared to the same periods in 2018 is primarily attributable to reduced excess tax benefits from stock-based compensation mainly due to non-deductible officers' compensation and tax benefits recorded last year as a result of expiration of statute limitations that did not recur in 2019.

For the three and nine months ended September 30, 2019, we recognized excess tax benefits of $0.4 million and $13.5 million, respectively, in our provision for income taxes.

Liquidity and Capital Resources

We fund our operations from product sales. As of September 30, 2019 and December 31, 2018, we had the following cash and cash equivalents, and short-term and long-term marketable securities (in thousands):

	September 30, 2019	December 31, 2018
Cash and cash equivalents	$ 490,362	$ 636,899
Marketable securities, short-term	292,011	98,460
Marketable securities, long-term	—	9,112
Total	$ 782,373	$ 744,471

As of September 30, 2019, we had $782.4 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, foreign bonds and certificates of deposit.

As of September 30, 2019, approximately $268.5 million of cash, cash equivalents and short-term and long-term marketable securities was held by our foreign subsidiaries. We repatriated $303.9 million to the U.S. during the nine months ended September 30, 2019 and we may further repatriate funds 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).

Cash flows (in thousands):

	Nine Months Ended September 30,	
	2019	**2018**
Net cash flow provided by (used in):		
Operating activities	$ 529,093	$ 313,386
Investing activities	(290,333)	(24,021)
Financing activities	(383,163)	(315,151)
Effect of exchange rate changes on cash, cash equivalents, and restricted cash	(2,098)	(2,890)
Net decrease in cash, cash equivalents, and restricted cash	$ (146,501)	$ (28,676)

Operating Activities

For the nine months ended September 30, 2019, cash flows from operations of $529.1 million resulted primarily from our net income of approximately $321.5 million as well as the following:

Significant non-cash activities

- Stock-based compensation of $67.7 million related to equity incentive compensation granted to employees and directors;
- Depreciation and amortization of $57.2 million related to our long-lived assets;
- Impairment charges of $28.5 million related to decreases in the fair value of certain assets related to Invisalign stores;
- Gain from sale of equity method investment of $15.8 million; and
- Non-cash operating lease cost of $13.6 million;

Significant changes in working capital

- Increase of $138.1 million in deferred revenues corresponding to the increase in case volume;
- Increase of $95.6 million in accounts receivable which is primarily a result of the increase in net revenues; and
- Increase of $40.8 million in inventories as we expect increased demand of our new and existing products along with increased additional aligner volumes.

Investing Activities

Net cash used in investing activities was $290.3 million for the nine months ended September 30, 2019 which primarily consisted of purchases of marketable securities of $588.8 million, property and plant and equipment purchases of $107.2 million and other investing activities of $14.1 million. These outflows were partially offset by maturities and sales of marketable securities of $406.5 million and payments of $13.2 million received on a note issued to a privately held company.

For the remainder of 2019 we expect to invest an additional $30.0 million to $35.0 million in capital expenditures related to progress payments for building purchases located in Petach Tivka, Israel and San Jose, California 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 Petach Tivka, Israel).

Financing Activities

Net cash used in financing activities was $383.2 million for the nine months ended September 30, 2019 which consisted of common stock repurchases of $299.5 million, payroll taxes paid for vesting of restricted stock units through share withholdings of $55.8 million and the purchase of a building that we previously leased under a finance lease of $45.8 million. These outflows were offset in part by $17.9 million proceeds from the issuance of common stock.

Common Stock Repurchases

In July 2019, we entered into the 2019 ASR to repurchase $200.0 million of our common stock which was completed in September 2019. As of September 30, 2019, we have $200.5 million available for repurchase under the $600.0 million repurchase program authorized by our Board of Directors in May 2018 (Refer to *Note 12 "Common Stock Repurchase Programs" of the Notes to Condensed Consolidated Financial Statements* for details on our stock repurchase programs).

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, including items disclosed in *Note 10 "Commitments and Contingencies" of the Notes to Condensed Consolidated Financial Statements*. 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 September 30, 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.

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.

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 September 30, 2019, we had approximately $292.0 million invested in available-for-sale marketable securities. An immediate 10% change in interest rates would not have a material adverse impact on our future operating results and cash flows.

We do not enter into investments for trading or speculative purposes and have not used any derivative financial instruments to manage our interest rate risk exposure. Based on interest bearing liabilities we have as of September 30, 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 September 30, 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.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of disclosure controls and procedures.

Under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, we have evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of the end of the period covered by this Quarterly Report on Form 10-Q. Based upon that evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that our disclosure controls and procedures are effective as of September 30, 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 September 30, 2019 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

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”). On May 10, 2019, the lead plaintiff filed a consolidated complaint against Align and four of our executive officers alleging similar claims as the initial complaints on behalf of a purported class of purchasers of our common stock between April 25, 2018 and October 24, 2018. On June 24, 2019, defendants filed a motion to dismiss the consolidated complaint. On October 29, 2019, that motion to dismiss was granted with leave to amend. 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 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 Actions, 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 Actions.

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. On May 16, 2019, the court stayed this action pending final disposition of the Securities Actions.

On February 22, 2019, a purported stockholder sent a letter to Align pursuant to 8 Del. C. § 220 demanding certain books and records for the stated purpose of investigating potential breaches of duty, corporate mismanagement, and alleged wrongdoing by fiduciaries of the Company. On April 16, 2019, Align responded and refused the demand on several legal grounds. On June 10, 2019, the purported stockholder petitioned the Superior Court of the State of California, County of Santa Clara, to issue a writ of mandate commanding Align to provide the books and records requested. On August 23, 2019, Align filed a demurrer seeking to dismiss the petition. A hearing on that demurrer was held on October 25, 2019. On October 28, 2019, the Court issued an order sustaining Align’s demurrer and dismissing the petition without an opportunity to amend. The Court further ordered Align to submit a proposed judgment of dismissal within 10 days.

Align is currently unable to predict the outcome of this demand or 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 were stayed pending the ITC determinations, and the other two cases are currently active in discovery and pretrial proceedings. Trials have been scheduled to begin on April 20, 2020 in one case and to begin on June 8, 2020 in the other. Certain of Align’s asserted patents in the Delaware actions were found invalid by the District Court Judge. The ITC conducted hearings in the Section 337 investigations 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. 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. Align and 3Shape each petitioned the Commission for review of the Initial Determinations. On July 18 and July 19, 2019, the Commission determined to review each Initial Determination and sought additional briefing by the parties with respect to one of the Section 337 investigations. On August 20, 2019, the Commission vacated one Initial Determination and terminated the investigation, and on October 15, 2019, the Court ordered that the stay be lifted on the corresponding Delaware case. The current target date for completion of the other investigation is November 22, 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 court stayed the case. 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. On August 19, 2019, the Court consolidated the two actions, and 3Shape filed an amended complaint alleging infringement of an additional patent on August 30, 2019. The case is active and in the early discovery phase, with trial scheduled to begin on April 12, 2021.

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 alleged market activities, including Align's assertion of its patent portfolio, in alleged clear aligner and intraoral scanning markets, and the Court scheduled trial to begin on May 10, 2021. Align filed a motion to dismiss 3Shape's complaint on October 17, 2018. Align also moved to stay the litigation pending the outcome of its motion to dismiss. The court granted Align's motion to stay. On August 15, 2019, the Magistrate Judge recommended that Align's motion to dismiss be granted, and, on September 26, 2019, the District Court Judge adopted the Magistrate Judge's Report and Recommendation, granted Align's motion to dismiss, and dismissed 3Shape's complaint with leave to amend within thirty days of the order. On October 28, 2019, 3Shape filed an amended complaint. Align has until November 18, 2019 to respond.

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. Certain claims of Align's asserted patents in the Delaware action was found invalid by the District Court Judge. The remaining District Court case is in the very early stages of discovery and pretrial proceedings. The ITC evidentiary hearing was held at the end of October 2019. The deadline for the judge's initial determination is March 6, 2020.

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.

Simon & Simon

On March 14, 2019, a dental practice named Simon and Simon, PC d/b/a City Smiles brought an antitrust action on behalf of itself and a putative class of similarly situated practices seeking monetary damages and injunctive relief relating to Align's alleged market activities in alleged clear aligner and intraoral scanning markets. Align filed a motion to dismiss the complaint on April 5, 2019, and the court held a hearing on Align's motion. On October 15, 2019, the Magistrate Judge issued a Report and Recommendation on Align's motion to dismiss which recommends that Align's motion be granted and that the plaintiffs' complaint be dismissed without prejudice. On October 29, 2019, Simon and Simon filed objections to the Magistrate Judge's Report and Recommendation. Align has until November 12, 2019 to respond. Align believes the plaintiffs' claims are without merit and intends to vigorously defend itself.

SDC Dispute

In February 2018, Align 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 constituted 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) sought 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 on March 4, 2019. The arbitrator found that Align breached the non-compete provision applicable to the members of SDC Financial LLC and 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 specified aspects 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, to be determined in accordance with the applicable provisions of the SDC Operating Agreements. 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 was granted on April 29, 2019.

As required by the Award, on April 3, 2019, Align had closed its Invisalign stores, returned SDC’s alleged confidential information, and tendered its membership interests for a purchase price that SDC claims to be Align’s “capital account” balance as of October 31, 2017. Align disputes that the SDC Entities properly determined the value of Align’s “capital account” balance as of October 31, 2017 as required by the SDC Operating Agreements and the Award. Consequently, on July 3, 2019, Align filed a confidential demand for arbitration challenging the propriety of the SDC Entities’ determination of Align’s “capital account” balance as of October 31, 2017. That arbitration proceeding remains pending and currently is scheduled to be heard in June 2020. Relatedly, the SDC Entities filed a contempt petition with the Illinois court which confirmed the Award, asserting that Align had no right to contest the “capital account” determination as made by the SDC Entities. On September 4, 2019, the Illinois court denied in its entirety the contempt petition filed by the SDC Entities.

On August 19, 2019, the SDC Entities filed a separate confidential arbitration proceeding alleging that Align has violated the non-compete provisions applicable to the members of the SDC Entities by virtue of Align’s alleged dealings with a third-party claimed to be a competitor of the SDC Entities. Align has denied the claim and intends to vigorously defend itself against the newly asserted allegations. The SDC Entities have yet to identify the range of damages they may seek to recover in the course of this arbitration and no hearing date has yet been set.

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.

Straumann Group Litigation Settlement

In March 2019, Align 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 $35.0 million on March 29, 2019. In addition, Align 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. The agreement provided that if for any reason the companies chose not to enter into the development and distribution agreement by July 2, 2019 or by a mutually agreed extended date, Straumann Group would pay Align an additional $16.0 million in lieu of the development and distribution agreement. In June 2019, the parties terminated the discussions regarding a possible development and distribution agreement and as a result, Straumann paid us the additional $16.0 million in July 2019. During the nine months ended September 30, 2019, we recognized a litigation settlement gain of $51.0 million.

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.

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. However, given increased awareness for direct to consumer clear aligners and heavy advertising spend from direct to consumer players, case starts may be shifting away from traditional practices. We also believe that doctors are sampling alternative products and/or taking advantage of wires and brackets bundles that essentially give clear aligners away for free or at very low prices. 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;
- 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 these two countries or between the U.S. and Mexico; and
- potential adverse tax consequences.

The United Kingdom’s (“U.K.”) referendum to leave the European Union (“EU”), commonly known as “Brexit,” has exacerbated and may further exacerbate many of the risks and uncertainties described above. The withdrawal of the U.K. from the EU 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 U.K. and the EU and significantly disrupt trade between the U.K. and the EU and other parties. There remains significant risk that the U.K. will exit from the EU without agreement between the EU and U.K. on terms addressing customs and trade matters. Further, uncertainty around these and related issues could lead to adverse effects on the economy of the U.K., EU 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 U.K. 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.

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

- 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

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;

- 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.

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, MyAligntech and Invisalign Doctor Site softwares. 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, 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 or we are unable to comply with data protection laws, 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. We may be or become subject to data localization or data residency laws, which generally require that certain types of data collected within a country be stored and processed only within that country. There is a trend among some non-U.S. countries, including Russia, China and others, in enacting, or considering enacting, data localization or data residency laws. If countries in which we have customers adopt data localization or data residency laws, we could be required to expand our data storage facilities there, build new storage facilities, and/or devote additional resources to comply with the requirements of such laws, any of which could have cost implications for us. We may also be subject to data export restrictions, or international transfer laws which prohibit or impose conditions upon the transfer of such data from one country to another. 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 September 30, 2019, we had 463 active U.S. patents, 489 active foreign patents, and 556 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 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.

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 order to provide more comprehensive sales and service

coverage, we increased 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 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.

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

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

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

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

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

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

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.

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.

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.

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, we are reorganizing our corporate structure and intercompany relationships to more closely align with the international nature of our business activities. The new 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 continue to 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 legal entity structure and/or activities performed within our entities, 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.

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

Following is a summary of stock repurchases for the three months ended September 30, 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]
July 1, 2019 through July 31, 2019	688,807	$ 203.25	688,807	$ 200,500,000
August 1, 2019 through August 31, 2019	—	—	—	$ 200,500,000
September 1, 2019 through September 30, 2019	443,657	$ 135.24	443,657	$ 200,500,000

[1] In July 2019, we entered into an accelerated share repurchase agreement (“2019 ASR”) to repurchase $200.0 million of our common stock which was completed in September 2019. As of September 30, 2019, we have $200.5 million available for repurchase under the $600.0 million repurchase program authorized by our Board of Directors in May 2018 (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

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	Fixed Dollar Accelerated Share Repurchase Transaction dated July 30, 2019				*
101.INS	XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.				*
101.SCH	XBRL Taxonomy Extension Schema Document				*
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document				*
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document				*
101.LAB	XBRL Taxonomy Extension Label Linkbase Document				*
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document				*

SIGNATURES

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

ALIGN TECHNOLOGY, INC.

October 31, 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

Exhibit 10.1

July 30, 2019

Fixed Dollar Accelerated Share Repurchase Transaction

Align Technology, Inc.
2820 Orchard Parkway
San Jose, California 95134

Dear Sir/Madam:

The purpose of this letter agreement (this "Confirmation") is to confirm the terms and conditions of the Transaction entered into between Morgan Stanley & Co LLC ("Dealer") and Align Technology, Inc. ("Issuer") on the Trade Date specified below (the "Transaction"). This confirmation constitutes a "Confirmation" as referred to in the Agreement specified below.

The definitions and provisions contained in the 2002 ISDA Equity Derivatives Definitions (as published by the International Swaps and Derivatives Association, Inc. ("ISDA")) (the "Equity Definitions") are incorporated into this Confirmation. The Transaction is a Share Forward Transaction for purposes of the Equity Definitions. Any reference to a currency shall have the meaning contained in Section 1.7 of the 2006 ISDA Definitions, as published by ISDA.

1. This Confirmation evidences a complete and binding agreement between Dealer and Issuer as to the terms of the Transaction to which this Confirmation relates and shall supersede all prior or contemporaneous written or oral communications with respect thereto. This Confirmation shall be subject to an agreement (the "Agreement") in the form of the 2002 ISDA Master Agreement as if Dealer and Issuer had executed an agreement in such form without any Schedule but with the elections set forth in this Confirmation (and (1) the election of USD as the Termination Currency, (2) the election that subparagraph (ii) of Section 2(c) will not apply to the Transactions and (3) the election that the "Cross Default" provisions of Section 5(a)(vi) shall apply to Dealer, with a "Threshold Amount" of 3% of Dealer shareholders' equity for Dealer (provided that (a) the phrase "or becoming capable at such time of being declared" shall be deleted from clause (1) of such Section 5(a)(vi) of the Agreement and (b) the following sentence shall be added to the end thereof: "Notwithstanding the foregoing, a default hereunder shall not constitute an Event of Default if (i) the default was caused solely by error or omission of an administrative or operational nature; (ii) funds were available to enable the party to make the payment when due; and (iii) the payment is made within two Local Business Days of such party's receipt of written notice of its failure to pay)".

The Transaction shall be the only transaction under the Agreement. If there exists any ISDA Master Agreement between Dealer and Issuer or any confirmation or other agreement between Dealer and Issuer pursuant to which an ISDA Master Agreement is deemed to exist between Dealer and Issuer, then, notwithstanding anything to the contrary in such ISDA Master Agreement, such confirmation or agreement or any other agreement to which Dealer and Issuer are parties, the Transaction shall not be considered a transaction under, or otherwise governed by, such existing or deemed to be existing ISDA Master Agreement.

If there is any inconsistency between the Agreement, this Confirmation and the Equity Definitions, the following will prevail for purposes of the Transaction in the order of precedence indicated: (i) this Master Confirmation; (ii) the Equity Definitions; and (iii) the Agreement.

2. The terms of the particular Transaction to which this Confirmation relates are as follows:

GENERAL TERMS:

Trade Date:	As specified in Schedule I
Buyer:	Issuer
Seller:	Dealer
Shares:	Common Stock, par value USD 0.0001 per share, of Issuer (Ticker: ALGN)
Forward Price:	A price per Share (as determined by the Calculation Agent) equal to the greater of (A) (i) the arithmetic mean (not a weighted average) of the 10b-18 VWAP on each Observation Date that is a Trading Day during the Calculation Period minus (ii) the Discount and (B) $5.00.

Discount:	As specified in Schedule I
10b-18 VWAP:	On any Trading Day, a price per Share equal to the volume-weighted average price of the Rule 10b-18 eligible trades in the Shares for the entirety of such Trading Day as determined by the Calculation Agent by reference to the screen entitled "ALGN <Equity> AQR SEC" or any successor page as reported by Bloomberg L.P. or any successor (excluding (i) trades that do not settle regular way, (ii) opening (regular way) reported trades in the consolidated system on such Scheduled Trading Day, (iii) trades that occur in the last ten minutes before the scheduled close of trading on the Exchange on such Scheduled Trading Day and ten minutes before the scheduled close of the primary trading in the market where the trade is effected, and (iv) trades on such Scheduled Trading Day that do not satisfy the requirements of Rule 10b-18(b)(5) of the Securities Exchange Act of 1934, as amended (the "**Exchange Act**") on such Trading Day) or, if the price displayed on such screen is clearly erroneous, as determined by the Calculation Agent in good faith and in a commercially reasonable manner.
Observation Dates:	As specified in Schedule I
Calculation Period:	The period from, and including, the first Observation Date that is a Trading Day that occurs on or after the Prepayment Date to, but excluding, the relevant Valuation Date; provided, however, that if the Valuation Date is the Scheduled Valuation Date, then the Valuation Date shall be included in the Calculation Period; provided further that in no event shall any Scheduled Valuation Date be postponed to a date later than the Final Termination Date.
Final Termination Date:	As specified in Schedule I; provided that if a Market Disruption Event has occurred pursuant to Section 7 of this Confirmation, such Final Termination Date shall be postponed by one Trading Day for every Trading Day that is a Disrupted Day as a result of such Merger Transaction during the Calculation Period
Trading Day:	Any Exchange Business Day that is not a Disrupted Day in whole
Initial Shares:	As specified in Schedule I; provided that if Dealer is unable to borrow or otherwise acquire a number of Shares equal to the Initial Shares for delivery to Issuer on the Initial Share Delivery Date, the Initial Shares delivered on the Initial Share Delivery Date shall be reduced to such number of Shares that Dealer is able to so borrow or otherwise acquire, and thereafter Dealer shall continue to use commercially reasonable efforts to borrow or otherwise acquire a number of Shares, at a stock borrow cost no greater than the Initial Stock Loan Rate, equal to the shortfall in the Initial Shares and to deliver such additional Shares as soon as reasonably practicable. For the avoidance of doubt, the aggregate of all shares delivered to Dealer in respect of the Transaction pursuant to this paragraph shall be the "Initial Shares" for purposes of determining the "Settlement Amount" below.
Initial Share Delivery Date:	One Exchange Business Day following the Trade Date. On the Initial Share Delivery Date, Seller shall deliver to Buyer a number of Shares equal to the Initial Shares in accordance with Section 9.4 of the Equity Definitions, with the Initial Share Delivery Date being deemed to be a "Settlement Date" for purposes of such Section 9.4.
Prepayment:	Applicable
Prepayment Amount:	As specified in Schedule I
Prepayment Date:	One Exchange Business Day following the Trade Date. On the Prepayment Date, Buyer shall pay to Seller the Prepayment Amount.
Exchange:	NASDAQ
Related Exchange:	All Exchanges; provided that Section 1.26 of the Equity Definitions shall be amended to add the words "United States" before the word "exchange" in the tenth line of such Section.

Market Disruption Event:

The definition of "Market Disruption Event" in Section 6.3(a) of the Equity Definitions is hereby amended by deleting the words "at any time during the one-hour period that ends at the relevant Valuation Time, Latest Exercise Time, Knock-in Valuation Time or Knock-out Valuation Time, as the case may be," starting in the third line thereof.

Section 6.3(d) of the Equity Definitions is hereby amended by deleting the remainder of the provision following the term "Scheduled Closing Time" in the fourth line thereof.

Notwithstanding anything to the contrary in the Equity Definitions, if any Exchange Business Day in the Calculation Period is a Disrupted Day, the Calculation Agent shall have the option, in its reasonable discretion, to take one or more of the following actions in a good faith and commercially reasonable manner: (i) determine that such Exchange Business Day is a Disrupted Day in part, in which case the Calculation Agent shall (x) determine the 10b-18 VWAP on such Exchange Business Day based on Rule 10b-18 eligible trades in the Shares on such day taking into account the nature and duration of the relevant Market Disruption Event and (y) determine the Forward Price using an appropriately weighted average of 10b-18 VWAPs instead of an arithmetic mean, and/or (ii) elect to postpone the Scheduled Valuation Date by up to one Observation Date for every Observation Date that is a Disrupted Day during the Calculation Period; provided that in no event shall any Scheduled Valuation Date be postponed to a date later than the Final Termination Date. For the avoidance of doubt, if the Calculation Agent takes the action described in clause (i) above, then such Disrupted Day shall be a Trading Day for purposes of calculating the Forward Price.

Any Exchange Business Day on which, as of the date hereof, the Exchange is scheduled to close prior to its normal close of trading shall be deemed not to be an Exchange Business Day; if a closure of the Exchange prior to its normal close of trading on any Exchange Business Day is scheduled following the date hereof, then such Exchange Business Day shall be deemed to be a Disrupted Day in full.

If a Disrupted Day occurs during the Calculation Period and each of the nine immediately following Scheduled Trading Days is a Disrupted Day, then the Calculation Agent may, in its good faith and commercially reasonable discretion, deem such ninth Scheduled Trading Day to be an Exchange Business Day that is not a Disrupted Day and determine the VWAP Price for such ninth Scheduled Trading Day using its good faith and commercially reasonable estimate of the value of the Shares on such ninth Scheduled Trading Day based on the volume, historical trading patterns and trading price of the Shares.

VALUATION:

Valuation Date:

The earlier of (i) the Scheduled Valuation Date and (ii) any earlier accelerated Valuation Date as a result of Dealer's election in accordance with the immediately succeeding paragraph.

Dealer shall have the right, in its absolute discretion but subject to the limitation set forth in the immediately succeeding paragraph, to accelerate the Valuation Date, in whole or in part (an "**Acceleration**"), to any Exchange Business Day that is on or after the Lock-Out Date and prior to the Scheduled Valuation Date by notice (each such notice, an "**Acceleration Notice**") to Issuer by 9:00 p.m., New York City time, on the Exchange Business Day immediately following the accelerated Valuation Date; provided that if at any time after the Lock-Out Date Dealer expects the Settlement Amount to be a negative number, then Dealer shall provide Issuer notice of any such expectation.

Dealer shall specify in each Acceleration Notice the portion of the Prepayment Amount that is subject to acceleration (which may be less than the full Prepayment Amount, but only so long as such portion is not less than USD 25,000,000). If the portion of the Prepayment Amount that is subject to acceleration is less than the full Prepayment Amount, then the Calculation Agent shall adjust the terms of the Transaction as appropriate in order to take into account the occurrence of such accelerated Valuation Date (including cumulative adjustments to take into account all prior accelerated Valuation Dates).

On each Valuation Date, the Calculation Agent shall calculate the Settlement Amount.

Scheduled Valuation Date:	As specified in Schedule I, subject to postponement in accordance with “Market Disruption Event” above
Lock-Out Date:	As specified in Schedule I

SETTLEMENT TERMS:

Physical Settlement:	Applicable. On the Settlement Date, Seller shall deliver to Buyer a number of Shares equal to (a) (i) the Prepayment Amount divided by (ii) the Forward Price minus (b) the Initial Shares (such number of Shares, the “**Settlement Amount**”), rounded to the nearest whole number of Shares; provided, however, that if the Settlement Amount is less than zero, then Buyer shall deliver to Seller on the Settlement Date a number of Shares satisfying the conditions set forth in Section 8(a) below (the “**Registered Payment Shares**”), or a number of Shares not satisfying such conditions (the “**Unregistered Payment Shares**”) pursuant to Section 8(b) below, in either case (i) with a value equal to the absolute value of the Forward Cash Settlement Amount, with such Shares’ value determined by the Calculation Agent (which value shall, in the case of Unregistered Payment Shares, take into account a commercially reasonable illiquidity discount), in each case as determined by the Calculation Agent and (ii) as if such Shares were “Early Settlement Shares” or “Make-Whole Shares” under Section 8 below, and references in Section 8 to “Early Settlement Payment” were deemed to be references to the absolute value of the Forward Cash Settlement Amount. Notwithstanding the proviso above, if the Settlement Amount is less than zero, Buyer may elect, in its sole discretion, to cash settle its obligation to deliver Shares by delivering to Seller a notice by no later than the Valuation Date (or, in the event of an Acceleration, the two (2) Business Days after Dealer delivers an Acceleration Notice) electing to cash settle its obligation to deliver Shares, in which case “Cash Settlement” shall be Applicable. Any such Cash Settlement shall be effected in accordance with “Cash Settlement” below.
Settlement Currency:	USD
Settlement Date:	The date that falls one Settlement Cycle after the relevant Valuation Date, or, if the Settlement Amount is less than zero, the date one Settlement Cycle following the last day of the Settlement Valuation Period.
Settlement Valuation Period:	If the Settlement Amount is less than zero, and whether or not Physical Settlement or Cash Settlement is applicable, on the Exchange Business Day immediately following the Valuation Date, Seller may begin purchasing Shares in a commercially reasonable manner in an amount equal to the Settlement Amount (all such Shares purchased, “**Hedge Close-out Shares**”, and the period from and including the Exchange Business Day immediately following the Valuation Date to and including the day on which Seller completes its purchases of Hedge Close-out Shares, the “**Settlement Valuation Period**”). In making any purchases of Hedge Close-out Shares contemplated by this paragraph, Dealer shall use commercially reasonable efforts to purchase such Shares in a manner that would qualify for the safe harbor provided by Rule 10b-18 under the Exchange Act (“**Rule 10b-18**”) if such purchases were made by or on behalf of Issuer. The Settlement Valuation Period shall be considered to be part of the Calculation Period for purposes of the representations, warranties and covenants and other provisions herein as the context requires (but, for the avoidance of doubt, not for purposes of determining the Forward Price).
Forward Cash Settlement Amount:	The aggregate purchase price (including commissions that are reasonable and customary for transactions of this type) of the Hedge Close-out Shares purchased during the Settlement Valuation Period.

Cash Settlement:

If Cash Settlement is applicable, then on the Settlement Date, Buyer shall deliver to Seller an amount in USD equal to (x) 103% of the absolute value of the Settlement Amount multiplied by (y) a price per Share as reasonably determined by the Calculation Agent (such cash amount, the "**Initial Cash Settlement Amount**"). On the Valuation Date (i) a notional Share balance (the "**Settlement Balance**") shall be created with an initial balance equal to the absolute value of the Settlement Amount and (ii) a notional cash balance (the "**Cash Balance**") shall be created with an initial balance equal to the Initial Cash Settlement Amount. At the end of each Exchange Business Day on which Seller purchases Hedge Close-out Shares, Seller shall reduce (i) the Settlement Balance by the number of Hedge Close-out Shares purchased on such Exchange Business Day and (ii) the Cash Balance by the aggregate purchase price (including commissions that are reasonable and customary for transactions of this type) of the Hedge Close-out Shares purchased on such Exchange Business Day. If, on any Exchange Business Day, the Cash Balance is reduced to or below zero but the Settlement Balance is greater than zero, the Buyer shall (i) deliver to Seller or as directed by Seller on the next Currency Business Day after such Exchange Business Day an additional amount in USD (an "**Additional Cash Settlement Amount**") equal to the Settlement Balance as of such Exchange Business Day multiplied by a price per Share as reasonably determined in a good faith manner by the Calculation Agent, and the Cash Balance shall be increased by such amount. This provision shall be applied successively until the Settlement Balance is reduced to zero. On the Currency Business Day immediately following the Exchange Business Day that the Settlement Balance is reduced to zero, Seller shall return to Buyer an amount in USD equal to the remaining Cash Balance, if any, as of such Exchange Business Day.

Other Applicable Provisions: The last sentence of Section 9.2, Sections 9.8, 9.9, 9.10 and 9.11 (except that the Representation and Agreement contained in Section 9.11 of the Equity Definitions shall be modified by excluding any representations therein relating to restrictions, obligations, limitations or requirements under applicable securities laws arising as a result of the fact that Buyer is the issuer of the Shares) and Section 9.12 of the Equity Definitions will be applicable to the Transaction.

SHARE ADJUSTMENTS:

Potential Adjustment Event:

Notwithstanding anything to the contrary in Section 11.2(e) of the Equity Definitions, an Extraordinary Dividend shall not constitute a Potential Adjustment Event.

It shall constitute a Potential Adjustment Event if a Disrupted Day occurs or, pursuant to Section 11 below, is deemed to occur (in whole or in part) on any Trading Day on or prior to the Valuation Date.

Extraordinary Dividend: Any dividend or distribution on the Shares with an ex-dividend date occurring during the period from, and including, the Trade Date to, and including, the last day of the Calculation Period (other than any dividend or distribution of the type described in Section 11.2(e)(i), Section 11.2(e)(ii)(A) or Section 11.2(e)(ii)(B) of the Equity Definitions).

Method of Adjustment:

Calculation Agent Adjustment; provided that the parties hereto agree that any Share repurchases by the Issuer, whether pursuant to Rule 10b-18 of the Exchange Act, Rule 10b5-1 of the Exchange Act on customary terms, at prevailing market prices, or VWAP (subject to any discounts thereto) shall not be considered Potential Adjustment Events; provided further that adjustments for any Potential Adjustment Event (other than pursuant to any Potential Adjustment Event defined in Sections 11.2(e)(i), 11.2(e)(ii)(A) and 11.2(e)(iii) of the Equity Definitions) may be made to account for changes in volatility, stock loan rate or liquidity relevant to the Shares or the Transaction.

Extraordinary Events:

Consequences of Merger Events:

Share-for-Share:	Modified Calculation Agent Adjustment
Share-for-Other:	Cancellation and Payment on that portion of the Other Consideration that consists of cash; Modified Calculation Agent Adjustment on the remainder of the Other Consideration
Share-for-Combined:	Component Adjustment
Tender Offer:	Applicable; provided that the definition of "Tender Offer" in Section 12.1 of the Equity Definitions will be amended by replacing the phrase "greater than 10% and less than 100% of the outstanding voting shares of the Issuer" in the third and fourth line thereof with "(a) greater than 15% and less than 100% of the outstanding Shares of the Issuer in the event that such Tender Offer is being made by any entity or person other than the Issuer or any subsidiary thereof or (b) greater than 20% and less than 100% of the outstanding Shares of the Issuer in the event that such Tender Offer is being made by the Issuer or any subsidiary thereof".

Consequences of Tender Offers:

Share-for-Share:	Modified Calculation Agent Adjustment
Share-for-Other:	Modified Calculation Agent Adjustment
Share-for-Combined:	Modified Calculation Agent Adjustment
New Shares:	In the definition of New Shares in Section 12.1(i) of the Equity Definitions, the text in clause (i) thereof shall be deleted in its entirety (including the word "and" following such clause (i)) and replaced with "publicly quoted, traded or listed on any of the New York Stock Exchange, The NASDAQ Global Select Market or The NASDAQ Global Market (or their respective successors)".

For purposes of the Transaction,

(i) the definition of Merger Date in Section 12.1(c) of the Equity Definitions shall be amended to read, "Merger Date shall mean the Announcement Date.";

(ii) the definition of Tender Offer Date in Section 12.1(e) of the Equity Definitions shall be amended to read, "Tender Offer Date shall mean the Announcement Date.";

(iii) the definition of "Announcement Date" in Section 12.1(l) of the Equity Definitions is hereby amended by (a) replacing the words "a firm" with the word "any bona fide" in the second and fourth lines thereof, (b) replacing the word "leads to the" with the words ", if completed, would lead to a" in the third and the fifth lines thereof, (c) replacing the words "voting shares" with the word "Shares" in the fifth line thereof, (d) inserting the words "by any bona fide entity that is reasonably likely to be a party to the transaction" after the word "announcement" in the second and the fourth lines thereof, (e) inserting the words "or to explore the possibility of engaging in" after the words "engage in" in the second line thereof and (f) inserting the words "or to explore the possibility of purchasing or otherwise obtaining" after the word "obtain" in the fourth line thereof; and

(iv) Section 12.2 of the Equity Definitions is hereby amended by inserting the words "Announcement Date in respect of any Merger Event or any potential" before the words "Merger Event" in the final line thereof.

Composition of Combined Consideration:	Not Applicable
Nationalization, Insolvency or Delisting:	Cancellation and Payment; provided that in addition to the provisions of Section 12.6(a)(iii) of the Equity Definitions, it shall constitute a Delisting if the Exchange is located in the United States and the Shares are not immediately re-listed, re-traded or re-quoted on any of the New York Stock Exchange, The NASDAQ Global Market or The NASDAQ Global Select Market (or their respective successors); if the Shares are immediately re-listed, re-traded or re-quoted on any such exchange or quotation system, such exchange or quotation system shall thereafter be deemed to be the Exchange.
Additional Disruption Events:	

Change in Law:	Applicable; provided that (i) any determination as to whether (A) the adoption of or any change in any applicable law or regulation (including, for the avoidance of doubt and without limitation, (x) any tax law or (y) adoption or promulgation of new regulations authorized or mandated by existing statute) or (B) the promulgation of or any change in the interpretation by any court, tribunal or regulatory authority with competent jurisdiction of any applicable law or regulation (including any action taken by a taxing authority), in each case, constitutes a "Change in Law" shall be made without regard to Section 739 of the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 or any similar legal certainty provision in any legislation enacted, or rule or regulation promulgated, on or after the Trade Date, (ii) Section 12.9(a)(ii) of the Equity Definitions is hereby amended by replacing the parenthetical beginning after the word "regulation" in the second line thereof the words "(including, for the avoidance of doubt and without limitation, (x) any tax law or (y) adoption or promulgation of new regulations authorized or mandated by existing statute)" and (iii) by, immediately following the word "Transaction" in clause (x) thereof, adding the phrase "in the manner contemplated by the Hedging Party on the Trade Date".
Failure to Deliver:	Applicable
Insolvency Filing:	Applicable
Hedging Disruption:	Applicable
Increased Cost of Hedging:	Not Applicable
Loss of Stock Borrow:	Applicable
Maximum Stock Loan Rate:	100 bps
Increased Cost of Stock Borrow:	Applicable
Initial Stock Loan Rate:	25 bps
Determining Party:	For all applicable events, Dealer
Hedging Party:	For all applicable events, Dealer
Non-Reliance:	Applicable
Agreements and Acknowledgements Regarding Hedging Activities:	Applicable
Additional Acknowledgments:	Applicable
3. Calculation Agent:	Dealer; provided that following the occurrence of an Event of Default of the type described in Section 5(a)(vii) of the Agreement with respect to which Dealer is the sole Defaulting Party, if the Calculation Agent fails to timely make any calculation, adjustment or determination required to be made by the Calculation Agent hereunder or to perform any obligation of the Calculation Agent hereunder and such failure continues for five (5) Exchange Business Days following notice to the Calculation Agent by Issuer of such failure the Issuer shall have the right to designate a nationally recognized third-party dealer in over-the-counter corporate equity derivatives to act, during the period commencing on the date such Event of Default occurred and ending on the Early Termination Date with respect to such Event of Default, as the Calculation Agent. All calculations and determinations by the Calculation Agent shall be made in good faith and in a commercially reasonable manner. Following any calculation made by the Calculation Agent hereunder, upon a prior written request by the Issuer, the Calculation Agent will provide to the Issuer by email to the email address provided by the Issuer in such prior written request a report (in a commonly used file format for the storage and manipulation of financial data) displaying in reasonable detail the basis for such calculation and specifying the particular section of the Confirmation pursuant to which such calculation or determination is being made (and in the event that more than one section of the Confirmation would permit the Calculation Agent to make an adjustment upon the occurrence of a specific event, then the Calculation Agent shall specify the particular section number pursuant to which the Calculation Agent is making the adjustment hereunder); provided, however, that in no event will the Calculation Agent be obligated to share with the Issuer any proprietary or confidential data or information or any proprietary models used by it.

4. Account Details and Notices:

(a) Account for delivery of Shares to Issuer:

Shares to be delivered to:
Computershare
250 Royal Street
Canton, MA 02021
ATTN: Client Operations (Align Technology, Inc)

(b) Account for payments to Issuer:

Bank of America
Acct: provided
ABA: provided

(c) Account for payments to Dealer:

Citibank, NY
ABA: provided
Morgan Stanley & Co
Account #: provided, further credit to Align Technology Account # provided

For purposes of this Confirmation:

(i) Address for notices or communications to Issuer:

Align Technology, Inc.
2820 Orchard Parkway
San Jose, CA 95134
Attn: Legal Department

(ii) Address for notices or communications to Dealer:

Usman Khan
1585 Broadway Ave, 4th floor
New York, NY 10036

And email notification to the following address:

Usman.s.khan@morganstanley.com

Amendments to the Equity Definitions and Agreement.

(d) Section 9.2(a)(iii) of the Equity Definitions is hereby amended by deleting the words “the Excess Dividend Amount, if any, and”.

(e) Section 11.2(a) of the Equity Definitions is hereby amended by deleting the words “a diluting or concentrative effect on the theoretical value of the relevant Shares” and replacing them with the words “a material economic effect on the relevant Transaction”.

(f) The first sentence of Section 11.2(c) of the Equity Definitions, prior to clause (A) thereof, is hereby amended to read as follows: ‘(c) If “Calculation Agent Adjustment” is specified as the Method of Adjustment in the related Confirmation of a Share Option Transaction or Share Forward Transaction, then, following the announcement or occurrence of any Potential Adjustment Event, the Calculation Agent will determine whether such Potential Adjustment Event has a material economic effect on the Transaction and, if so, will (i) make appropriate adjustment(s), if any, to any one or more of:’.

(g) Section 11.2(e)(vii) of the Equity Definitions is hereby amended by deleting the words “diluting or concentrative effect on the theoretical value of the relevant Shares” and replacing them with the words “a material economic effect on the relevant Transaction”.

(h) Section 12.6(c)(ii) of the Equity Definitions is hereby amended by replacing the words “the Transaction will be cancelled,” in the first line with the words “Dealer will have the right to cancel the Transaction,”.

(i) Section 12.9(b)(iv) of the Equity Definitions is hereby amended by (A) deleting (1) subsection (A) in its entirety, (2) the phrase “or (B)” following subsection (A) and (3) the phrase “in each case” in subsection (B); and (B) deleting the phrase “neither the Non-Hedging Party nor the Lending Party lends Shares in the amount of the Hedging Shares or” in the penultimate sentence.

(j) Section 12.9(b)(v) of the Equity Definitions is hereby amended by (A) adding the word “or” immediately before subsection “(B)” and deleting the comma at the end of subsection (A); and (B)(1) deleting subsection (C) in its entirety, (2) deleting the word “or” immediately preceding subsection (C) and (3) replacing in the penultimate sentence the words “either party” with “the Hedging Party” and (4) deleting clause (X) in the final sentence.

(k) Section 2(a)(iii) of the Agreement is hereby amended by deleting the words “or Potential Event of Default” in clause (1) of such Section and deleting the word “and” immediately before subsection (3) and deleting clause “(3)” in its entirety.

5. Certain Payments and Deliveries by Dealer.

Notwithstanding anything to the contrary herein, or in the Equity Definitions, if at any time (i) an Early Termination Date occurs and Dealer would be required to make a payment pursuant to Section 6 of the Agreement or (ii) an Extraordinary Event occurs and Dealer would be required to make a payment pursuant to Article 12 of the Equity Definitions (the amount of any such payment obligation described in Section 6(i) or (ii) above, an “**Dealer Payment Amount**”), then Issuer shall have the right, by prior written notice to Dealer, to require Dealer to settle such payment obligation in Shares in lieu of cash; provided, however, that Issuer shall not have the right to so elect in the event of (i) an Insolvency, a Nationalization, a Merger Event or a Tender Offer, in each case, in which the consideration or proceeds to be paid to holders of Shares consists solely of cash or (ii) an Event of Default in which Issuer is the Defaulting Party or a Termination Event in which Issuer is an Affected Party, which Event of Default or Termination Event resulted from an event or events within Issuer’s control. If Issuer does not so elect for Dealer to settle an Dealer Payment Amount in Shares, then Dealer shall have the right, in its sole discretion, to elect to settle such Dealer Payment Amount in Shares. If either Issuer or Dealer so elects, then Dealer shall deliver to Issuer, on or within a commercially reasonable time following the date on which such Dealer Payment Amount would have been due, a number of Shares with a market value, as determined by the Calculation Agent, equal to all or a portion (which portion may be zero) of the Dealer Payment Amount. If the market value of such Shares equals a portion, but not all, of the Dealer Payment Amount, then, on the date such Dealer Payment Amount is due, a notional balance (the “**Settlement Balance**”) shall be established equal to the remaining portion of the Dealer Payment Amount, and Dealer shall commence purchasing Shares for delivery to Issuer. At the end of each Trading Day on which Dealer purchases Shares pursuant to this Section 6, Dealer shall reduce the Settlement Balance by the amount paid by Dealer to purchase the Shares purchased on such Trading Day. Dealer shall deliver any Shares purchased on a Trading Day pursuant to this Section 6 to Issuer on the third Exchange Business Day following such Trading Day. Dealer shall continue so purchasing and delivering Shares until the Settlement Balance has been reduced to zero. In making any purchases of Shares contemplated by this Section 6, Dealer shall use commercially reasonable efforts to purchase such Shares in a manner that would qualify for the safe harbor provided by Rule 10b-18 if such purchases were made by or on behalf of Issuer. The period until the Settlement Balance is reduced to zero shall be considered to be part of the Calculation Period for purposes of the representations, warranties and covenants and other provisions herein as the context requires.

6. Certain Payments and Deliveries by Issuer.

Notwithstanding anything to the contrary herein, or in the Equity Definitions, if at any time (i) an Early Termination Date occurs and Issuer would be required to make a payment pursuant to Section 6 of the Agreement or (ii) an Extraordinary Event occurs and Issuer would be required to make a payment pursuant to Article 12 of the Equity Definitions (any such payment described in Section 7(i) or (ii) above, an “**Early Settlement Payment**”), then Issuer shall have the right, by prior written notice to Dealer, in lieu of making such cash payment, to settle such payment obligation in Shares (such Shares, “**Early Settlement Shares**”); provided, however, that Issuer shall not have the right to so elect in the event of (i) an Insolvency, a Nationalization, a Merger Event or a Tender Offer, in each case, in which the consideration or proceeds to be paid to holders of Shares consists solely of cash or (ii) an Event of Default in which Issuer is the Defaulting Party or a Termination Event in which Issuer is an Affected Party, which Event of Default or Termination Event resulted from an event or events within Issuer’s control. In order to elect to deliver Early Settlement Shares, (i) Issuer must notify Dealer of its election by no later than 4:00 p.m., New York City time, on the date that is three Exchange Business Days before the date that the Early Settlement Payment is due, (ii) Issuer must specify whether such Early Settlement Shares are to be sold by means of a registered offering or by means of a private placement and (iii) Issuer must comply with Section 8 below.

7. Provisions Relating to Delivery of Early Settlement Shares.

(a) Issuer may deliver Early Settlement Shares and Make-Whole Shares (as defined below) by means of a registered offering only if the following conditions are satisfied:

(i) On the later of (A) the second Trading Day following Issuer's election to deliver Early Settlement Shares and any Make-Whole Shares by means of a registered offering (the "**Registration Notice Date**"), and (B) the date on which the Registration Statement is declared effective by the SEC or becomes effective, but in no event later than the date the Early Settlement Payment is due, Issuer shall deliver to Dealer a number of Early Settlement Shares equal to the quotient of (I) the relevant Early Settlement Payment divided by (II) a price per Share as reasonably determined by the Calculation Agent (the date of such delivery, the "**Registered Share Delivery Date**").

(ii) Promptly following the Registration Notice Date, Issuer shall file with the SEC a registration statement ("**Registration Statement**") covering the public sale by Dealer of the Early Settlement Shares and any Make-Whole Shares (collectively, the "**Registered Securities**") on a continuous or delayed basis pursuant to Rule 415 (or any similar or successor rule), if available, under the Securities Act of 1933, as amended (the "**Securities Act**"); provided that no such filing shall be required pursuant to this paragraph (ii) if Issuer shall have filed a similar registration statement with unused capacity at least equal to the relevant Early Settlement Payment and such registration statement has become effective or been declared effective by the SEC on or prior to the Registration Notice Date and no stop order is in effect with respect to such registration statement as of the Registration Notice Date, in which case such registration statement shall be the Registration Statement. Issuer shall use its commercially reasonable efforts to file the Registration Statement as an automatic shelf registration statement or have the Registration Statement declared effective by the SEC as promptly as possible. The Registration Statement shall be effective and subject to no stop order as of the Registered Share Delivery Date.

(iii) Promptly following the Registration Notice Date, Issuer shall afford Dealer a reasonable opportunity to conduct a due diligence investigation with respect to Issuer customary in scope for underwritten offerings of equity securities for companies of comparable size, maturity and line of business (including, without limitation, the availability of senior management to respond to questions regarding the business and financial condition of Issuer and the right to have made available to Dealer for inspection at times reasonably acceptable to Issuer any financial and other records, pertinent corporate documents and other information reasonably requested in connection with underwritten offerings of this type by Dealer), and Dealer shall be satisfied in its good faith discretion with the results of such due diligence investigation of Issuer. For the avoidance of doubt, Issuer shall not have the right to deliver Shares pursuant to this Section 8(a) (and the conditions to delivery of Early Settlement Shares specified in this Section 8(a) shall not be satisfied) unless and until Dealer is satisfied in its good faith discretion with the results of such due diligence investigation of Issuer.

(iv) From the effectiveness of the Registration Statement until the earlier of (1) when all Registered Securities have been sold by Dealer or (2) thirty (30) days after effectiveness, Issuer shall, at the request of Dealer, make available to Dealer a printed prospectus relating to the Registered Securities in form and substance (including, without limitation, any sections describing the plan of distribution) reasonably satisfactory to Dealer (a "**Prospectus**", which term shall include any prospectus supplement thereto), in such quantities as Dealer shall reasonably request.

(v) Issuer shall use its commercially reasonable efforts to avoid or prevent the issuance of any stop order suspending the effectiveness of the Registration Statement or of any order preventing or suspending the use of any Prospectus and, if any such order is issued, to obtain the lifting thereof as promptly as practicable. If the Registration Statement, the Prospectus or any document incorporated therein by reference contains a misstatement of a material fact or omits to state a material fact required to be stated therein or necessary to make any statement therein not misleading, Issuer shall use its commercially reasonable efforts to as promptly as practicable file any required document and prepare and furnish to Dealer a reasonable number of copies of such supplement or amendment thereto as may be necessary so that the Prospectus, as thereafter delivered to the purchasers of the Registered Securities, will not contain a misstatement of a material fact or omit to state a material fact required to be stated therein or necessary to make any statement therein not misleading.

(vi) On or prior to the Registered Share Delivery Date, Issuer shall enter into an agreement (a "**Transfer Agreement**") with Dealer (or any affiliate of Dealer designated by Dealer) relating to the public sale of the Registered Securities and substantially similar to underwriting agreements customary for underwritten offerings of equity securities for companies of comparable size, maturity and line of business, in form and substance reasonably satisfactory to Dealer (or such affiliate), which Transfer Agreement shall (without limiting the foregoing) contain provisions substantially similar to those contained in such underwriting agreements relating to:

(A) the indemnification of, and contribution in connection with the liability of, Dealer and its affiliates,

(B) the delivery to Dealer (or such affiliate) of customary letters and customary opinions (including, without limitation, accountants' comfort letters, opinions relating to the due authorization, valid issuance and fully paid and non-assessable nature of the Registered Securities and letters of counsel relating to the lack of material misstatements and omissions in the Registration Statement, and the Prospectus); and

(C) the payment by Issuer of all fees and expenses in connection with such resale of the Registered Securities, including all registration costs and all reasonable fees and expenses of counsel for Dealer documented in writing (or such affiliate).

(vii) On the Registered Share Delivery Date, a notional balance (the "**Early Settlement Balance**") shall be established with an initial balance equal to the amount of the Early Settlement Payment. Following the delivery of Early Settlement Shares or any Make-Whole Shares, Dealer shall sell all such Early Settlement Shares or Make-Whole Shares in a commercially reasonable manner.

(viii) At the end of each day on which sales have been made pursuant to paragraph 8(a)(vii) above, the Early Settlement Balance shall be (A) reduced by an amount equal to the net proceeds to be received by Dealer upon settlement of such sales, and (B) increased by an amount (as reasonably determined by the Calculation Agent) equal to Dealer's funding cost with respect to the Early Settlement Balance as of the close of business on the day one Settlement Cycle prior to such day.

(ix) If, on any date, the Settlement Balance has been reduced to zero but not all of the Early Settlement Shares have been sold, no additional Early Settlement Shares shall be sold and Dealer shall promptly deliver to Issuer (A) any remaining Early Settlement Shares and (B) if the Early Settlement Balance has been reduced to an amount less than zero, an amount in cash equal to the absolute value of the then-current Early Settlement Balance.

(x) If, on any date, all of the Early Settlement Shares have been sold and the Settlement Balance has not been reduced to zero, Issuer shall, at its election, either pay the remaining Early Settlement Balance to Dealer in cash or promptly deliver to Dealer an additional number of Shares ("**Make-Whole Shares**") equal to (A) the Settlement Balance as of such date divided by (B) a price per Share as reasonably determined by the Calculation Agent. This clause (x) shall be applied successively until the Settlement Balance is reduced to zero.

(xi) If at any time the number of Shares covered by the Registration Statement is less than the number of Registered Securities required to be delivered pursuant to this Section 8(a), Issuer shall, at the request of Dealer, file additional registration statement(s) to register the sale of all Registered Securities required to be delivered to Dealer.

(xii) The provisions of Section 8(b) shall apply to any then-current Early Settlement Balance if (i) on any given day, Issuer cannot satisfy any of the conditions set forth in this Section 8(a) or (ii) for a period of at least 10 consecutive Exchange Business Days, Dealer has determined that it is inadvisable to effect sales of Registered Securities, unless in either case Issuer pays such then-current Early Settlement Balance to Dealer in cash pursuant to the Registration Statement.

(b) If Issuer timely elects to deliver Early Settlement Shares and Make-Whole Shares by means of a private placement, the following provisions shall apply:

(i) All Early Settlement Shares and Make-Whole Shares shall be delivered to Dealer (or any affiliate of Dealer designated by Dealer) pursuant to the exemption from the registration requirements of the Securities Act provided by Section 4(2) thereof.

(ii) Issuer shall afford Dealer and any potential purchaser of any such Shares from Dealer (or any affiliate of Dealer designated by Dealer) identified by Dealer a commercially reasonable opportunity to conduct a due diligence investigation with respect to Issuer customary in scope for private placements of equity securities for companies of comparable size, maturity and line of business (including, without limitation, the right to have made available to them for inspection at times reasonably acceptable to Issuer any financial and other records, pertinent corporate documents and other information reasonably requested by them in connection with underwritten offerings of this type), subject to any such potential purchasers entering into a non-disclosure agreement with Issuer in connection with such due diligence.

(iii) Issuer shall enter into an agreement (a "Private Placement Agreement") with Dealer (or any affiliate of Dealer designated by Dealer) in connection with the private placement of such Shares by Issuer to Dealer (or any such affiliate) and the private resale of such Shares by Dealer (or any such affiliate), substantially similar to private placement purchase

agreements customary for private placements of equity securities for companies of comparable size, maturity and line of business, in form and substance commercially reasonably satisfactory to Dealer and Issuer, which Private Placement Agreement shall include, without limitation, provisions substantially similar to those contained in such private placement purchase agreements relating to the indemnification of, and contribution in connection with the liability of, Dealer and its affiliates, and shall provide for the payment by Issuer of all fees and expenses in connection with such resale (which fees and expenses shall be payable in cash or unregistered Shares), including all reasonable fees and expenses of one counsel for Dealer but not including any underwriter or broker discounts and commissions, and shall contain representations, warranties and agreements of Issuer and Dealer reasonably necessary or advisable to establish and maintain the availability of an exemption from the registration requirements of the Securities Act for such resales.

(iv) Issuer shall not take or cause to be taken any action that would make unavailable either (A) the exemption set forth in Section 4(2) of the Securities Act for the sale of any Early Settlement Shares or Make-Whole Shares by Issuer to Dealer or (B) an exemption from the registration requirements of the Securities Act reasonably acceptable to Dealer for resales of Early Settlement Shares and Make-Whole Shares by Dealer.

(v) On the date requested by Dealer, Issuer shall deliver a number of Early Settlement Shares equal to the quotient of (A) the amount of the Early Settlement Payment divided by (B) a per Share value, determined by Dealer in a commercially reasonable manner, which value shall take into account transfer restrictions applicable to such Shares and may be based on indicative bids from institutional "accredited investors" (as defined in Rule 501 under the Securities Act), and the provisions of Section 8(a)(vii) through (x) shall apply to the Early Settlement Shares delivered pursuant to this Section 8(b)(v). For purposes of applying the foregoing, the Registered Share Delivery Date referred to in Section 8(a)(vii) shall be the date on which Issuer delivers the Early Settlement Shares.

(c) If Issuer elects to deliver Early Settlement Shares to settle its obligation to make an Early Settlement Payment, then, if necessary, Issuer shall use its commercially reasonable efforts to cause the number of authorized but unissued Shares of Common Stock to be increased to an amount sufficient to permit Issuer to fulfill its obligations under Sections 8(a) and/or 8(b) above.

8. Special Provisions for Merger Transactions.

Notwithstanding anything to the contrary herein or in the Equity Definitions:

(a) Issuer agrees that:

(i) Issuer will use its commercially reasonable efforts such that Issuer will not during the term of the Transaction make, or, to the extent within its control, permit to be made, any public announcement (as defined in Rule 165(f) under the Securities Act) of any Merger Transaction or potential Merger Transaction unless such public announcement is made prior to the open or after the close of the regular trading session on the Exchange for the Shares.

(ii) To the extent that an announcement of a potential Merger Transaction occurs during the term of the Transaction and Dealer has not provided notice to Issuer as promptly as reasonably practicable following such announcement that Dealer will cause the Transaction to be cancelled or terminated in whole pursuant to "Extraordinary Events" in Section 2 above, then as soon as practicable following such notice from Dealer (but in any event prior to the next opening of the regular trading session on the Exchange), Issuer shall provide Dealer with written notice specifying (x) Issuer's average daily "Rule 10b-18 purchases" (as defined in Rule 10b-18) during the three full calendar months immediately preceding the Announcement Date that were not effected through Dealer or its affiliates and (y) the number of Shares purchased pursuant to the block purchase proviso in Rule 10b-18(b)(4) under the Exchange Act for the three full calendar months preceding the Announcement Date. Such written notice shall be deemed to be a certification by Issuer to Dealer that such information is true and correct. Issuer understands that Dealer will use this information in calculating the trading volume for purposes of Rule 10b-18. In addition, Issuer shall promptly notify Dealer of the earlier to occur of the completion of such transaction and the completion of the vote by target shareholders. Issuer acknowledges that any such public announcement may trigger the provision set forth in Section 11 below. Accordingly, Issuer acknowledges that its actions in relation to any such announcement or transaction must comply with the standards set forth in Section 13(b) below.

(b) Upon the occurrence of any public announcement of a Merger Transaction, Dealer may in a good faith and commercially reasonable manner elect either to (i) apply the provisions of Section 11 below or (ii) treat the occurrence of such announcement as an Additional Termination Event with respect to which the Transaction shall be the sole Affected Transaction, Issuer shall be the sole Affected Party and Dealer shall be the party entitled to designate an Early Termination Date pursuant to Section 6(b) of the Agreement (a "**Merger Termination Event**"). In the event that the Dealer elects to treat the Merger

Transaction as a Merger Termination Event under this Section 9(b), then neither the provisions of "Extraordinary Events: Consequences of Merger Events" set forth above in this Confirmation nor the provisions of Section 10 below shall apply.

"**Merger Transaction**" means any merger, acquisition or similar transaction involving a recapitalization of Issuer as contemplated by Rule 10b-18(a)(13)(iv) under the Exchange Act.

9. Special Provisions for Acquisition Transaction Announcements.

(a) If an Acquisition Transaction Announcement occurs on or prior to the final Valuation Date, then the Forward Price shall be determined as if the words "minus (ii) the Discount" were deleted from the definition thereof. If an Acquisition Transaction Announcement occurs after the Trade Date but prior to the Lock-Out Date, the Lock-Out Date shall be deemed to be the date of such Acquisition Transaction Announcement.

(b) "**Acquisition Transaction Announcement**" means (i) the announcement of an Acquisition Transaction, (ii) an announcement that Issuer or any of its subsidiaries has entered into an agreement, a letter of intent or an understanding designed to result in an Acquisition Transaction, (iii) the announcement of the intention to solicit or enter into, or to explore strategic alternatives or other similar undertaking that may include, an Acquisition Transaction, or (iv) any announcement subsequent to an Acquisition Transaction Announcement relating to a material amendment, a material extension, withdrawal or other material change to the subject matter of the previous Acquisition Transaction Announcement. For the avoidance of doubt, the term "announcement" as used in the definition of Acquisition Transaction Announcement refers to any public announcement whether made by Issuer or by a bona fide third party that is reasonably likely to be a party to the Acquisition Transaction.

(c)"**Acquisition Transaction**" means (i) any Merger Event (for purposes of this definition, the definition of Merger Event shall be read with the references therein to "100%" being replaced by "25%" and to "50%" by "75%" and without reference to the clause beginning immediately following the definition of Reverse Merger therein to the end of such definition), Tender Offer or Merger Transaction or any other transaction involving the merger of Issuer with or into any third party, (ii) the sale or transfer of all or substantially all of the assets or liabilities of Issuer, (iii) a recapitalization, reclassification, binding share exchange or other similar transaction or (iv) any acquisition, lease, exchange, transfer, disposition (including by way of spin-off or distribution) of assets or liabilities (including any capital stock or other ownership interests in subsidiaries) or other similar event by Issuer or any of its subsidiaries where the aggregate consideration transferable or receivable by or to Issuer or its subsidiaries exceeds 25% of the market capitalization of Issuer.

10. Dealer Adjustments.

In the event that Dealer determines, in a good faith and commercially reasonable manner that, based on advice of legal counsel, it is appropriate with regard to any legal, regulatory or self-regulatory requirements or related policies and procedures (whether or not such requirements, policies or procedures are imposed by law or have been voluntarily adopted by Dealer, and including, without limitation, Rule 10b-18, Rule 10b-5, Regulations 13D-G and Regulations 14 D-E under the Exchange Act; provided that such requirements, policies and procedures relate to legal and regulatory issues and are generally applicable in similar situations and applied in a consistent manner in similar transactions), for Dealer to refrain from purchasing Shares or engaging in other market activity or to purchase fewer than the number of Shares or to engage in fewer or smaller other market transactions Dealer would otherwise purchase or engage in on any Trading Day on or prior to the last day of the Calculation Period, then Dealer may, in its reasonable discretion, elect that a Market Disruption shall be deemed to have occurred on such Trading Day. Dealer shall notify Issuer upon the exercise of Dealer's rights pursuant to this Section 11 and the Trading Days affected by it and shall subsequently notify Issuer on the day Dealer believes that the circumstances giving rise to such exercise have changed.

11. Covenants.

(a) Issuer covenants and agrees that:

Until the end of the Potential Purchase Period (as defined below), neither it nor any of its affiliated purchasers (as defined in Rule 10b-18 under the Exchange Act) shall directly or indirectly (which shall be deemed to include the writing or purchase of any cash-settled or other derivative or structured Share repurchase transaction with a hedging period, calculation period or settlement valuation period or similar period that overlaps with the Transaction) purchase, offer to purchase, place any bid or limit order relating to a purchase of or commence any tender offer relating to Shares (or any security convertible into or exchangeable for Shares) without the prior written approval of Dealer or take any other action that would cause the purchase by Dealer of any Shares in connection with this Agreement not to qualify for the safe harbor provided in Rule 10b-18 under the

Exchange Act (assuming for the purposes of this paragraph that such safe harbor were otherwise available for such purchases); provided that this Section 12(a)(i) shall not (i) limit the Issuer's ability, pursuant to its employee incentive plan or dividend reinvestment program to re-acquire Shares in connection with the related equity transactions, (ii) limit the Issuer's ability to withhold shares to cover tax liabilities associated with such equity transactions, (iii) limit the Issuer's ability to grant stock and options to "affiliated partners" (as defined in Rule 10b-18) or the ability of such affiliated purchasers to acquire such stock or options, provided that in connection with any such purchase Issuer will be deemed to represent to Dealer that such purchase does not constitute a "Rule 10b-18 Purchase" (as defined in Rule 10b-18) (any such incentive or compensatory plan, program or policy of Counterparty, a "Compensatory Plan") or (iv) limit any purchases by affiliated purchasers (as defined in Rule 10b-18) of the Issuer in an amount, in aggregate, not to exceed [3]% of ADTV (as defined in Rule 10b-18) for such Exchange Business Day, which purchases shall be executed by Dealer (or its affiliate) and made pursuant to documentation and terms reasonably acceptable to Dealer and Issuer. "**Potential Purchase Period**" means the period from, and including, the Trade Date to, and including, the latest of (i) the last day of the Calculation Period, (ii) the earlier of (A) the date ten Exchange Business Days immediately following the last day of the Calculation Period and (B) the Scheduled Valuation Date and (iii) if an Early Termination Date occurs or the Transaction is cancelled pursuant to Article 12 of the Equity Definitions, a date determined by Dealer in its commercially reasonable discretion and communicated to Issuer no later than the Exchange Business Day immediately following such date.

(i) Without limiting the generality of Section 13.1 of the Equity Definitions, it is not relying, and has not relied, upon Dealer or any of its representatives or advisors with respect to the legal, accounting, tax or other implications of this Agreement and that it has conducted its own analyses of the legal, accounting, tax and other implications of this Agreement, and that Dealer and its affiliates may from time to time effect transactions for their own account or the account of customers and hold positions in securities or options on securities of Issuer and that Dealer and its affiliates may continue to conduct such transactions during the term of this Agreement. Without limiting the generality of the foregoing, Issuer acknowledges that Dealer is not making any representations or warranties or taking any position or expressing any view with respect to the treatment of the Transaction under any accounting standards including ASC Topic 260, *Earnings Per Share*, ASC Topic 815, *Derivatives and Hedging*, or ASC Topic 480, *Distinguishing Liabilities from Equity* and ASC 815-40, *Derivatives and Hedging - Contracts in Entity's Own Equity* (or any successor issue statements) or under FASB's Liabilities & Equity Project.

(ii) Neither it nor any affiliates shall take any action that would cause a restricted period (as defined in Regulation M under the Exchange Act ("**Regulation M**")) to be applicable to any purchases of Shares, or of any security for which Shares is a reference security (as defined in Regulation M), by Issuer or any affiliated purchasers (as defined in Regulation M) of Issuer during the Potential Purchase Period.

(iii) It will not make any election or take any other action in connection with the Transaction while aware of any material nonpublic information regarding Issuer or the Shares.

(iv) It shall not declare or pay any Extraordinary Dividend until the earlier of (i) the Scheduled Valuation Date or (ii) the date ten Exchange Business Days immediately following the Valuation Date.

(b) [Reserved]

12. Representations, Warranties and Acknowledgments.

(a) Issuer hereby represents and warrants to Dealer on the date hereof and on and as of the Initial Share Delivery Date that:

(i) (A) None of Issuer and its officers and directors is aware of any material nonpublic information regarding Issuer or the Shares, and is entering into the Transaction in good faith and not as part of a plan or scheme to evade the prohibitions of federal securities laws, including, without limitation, Rule 10b-5 under the Exchange Act and (B) Issuer agrees not to alter or deviate from the terms of the Agreement or enter into or alter a corresponding or hedging transaction or position with respect to the Shares (including, without limitation, with respect to any securities convertible or exchangeable into the Shares) during the term of the Agreement. Without limiting the generality of the foregoing, all reports and other documents filed by Issuer with the Securities and Exchange Commission pursuant to the Exchange Act when considered as a whole (with the more recent such reports and documents deemed to amend inconsistent statements contained in any earlier such reports and documents) do not contain any untrue statement of a material fact or any omission of a material fact required to be stated therein or necessary to make the statements therein, in the light of the circumstances in which they were made, not misleading.

(ii) The transactions contemplated by this Confirmation have been authorized under Issuer's publicly announced program to repurchase Shares.

(iii) Issuer is not entering into this Agreement to facilitate a distribution of the Shares (or any security convertible into or exchangeable for Shares) or in connection with a future issuance of securities.

(iv) Issuer is not entering into this Agreement to create actual or apparent trading activity in the Shares (or any security convertible into or exchangeable for Shares) or to manipulate the price of the Shares (or any security convertible into or exchangeable for Shares) in violation of the federal securities laws.

(v) There have been no purchases of Shares in Rule 10b-18 purchases of blocks pursuant to the once-a-week block exception contained in Rule 10b-18(b)(4) by or for Issuer or any of its affiliated purchasers during each of the four calendar weeks preceding the Trade Date and during the calendar week in which the Trade Date occurs ("Rule 10b-18 purchase", "blocks" and "affiliated purchaser" each being used as defined in Rule 10b-18).

(vi) Issuer is as of the date hereof, and after giving effect to the transactions contemplated hereby will be, Solvent. As used in this paragraph, the term "Solvent" means, with respect to a particular date, that on such date (A) the present fair market value (or present fair saleable value) of the assets of Issuer is not less than the total amount required to pay the liabilities of Issuer on its total existing debts and liabilities (including contingent liabilities) as they become absolute and matured, (B) Issuer is able to realize upon its assets and pay its debts and other liabilities, contingent obligations and commitments as they mature and become due in the normal course of business, (C) assuming consummation of the transactions as contemplated by this Agreement, Issuer is not incurring debts or liabilities beyond its ability to pay as such debts and liabilities mature, (D) Issuer is not engaged in any business or transaction, and does not propose to engage in any business or transaction, for which its property would constitute unreasonably small capital after giving due consideration to the prevailing practice in the industry in which Issuer is engaged, (E) Issuer is not a defendant in any civil action that could reasonably be expected to result in a judgment that Issuer is or would become unable to satisfy, (F) Issuer is not "insolvent" (as such term is defined under Section 101(32) of the U.S. Bankruptcy Code (Title 11 of the United States Code) (the "Bankruptcy Code")) and (G) Issuer would be able to purchase Shares with an aggregate purchase price equal to the Prepayment Amount in compliance with the corporate laws of the jurisdiction of its incorporation.

(vii) Issuer is not, and after giving effect to the transactions contemplated hereby will not be, required to register as an "investment company" as such term is defined in the Investment Company Act of 1940, as amended.

(viii) No state or local (including non-U.S. jurisdictions) law, rule, regulation or regulatory order applicable to the Shares would give rise to any reporting, consent, registration or other requirement (including without limitation a requirement to obtain prior approval from any person or entity) as a result of Dealer or its affiliates owning or holding (however defined) Shares other than any such law, rule, regulation or regulatory order that applies (A) to the beneficial ownership of Shares under the Exchange Act or (B) solely as a result of the business, identity, place of business or jurisdiction of organization of Dealer or any such affiliate.

(b) Issuer acknowledges and agrees that the Initial Shares may be sold short to Issuer. Issuer further acknowledges and agrees that Dealer may purchase Shares in connection with the Transaction, which Shares may be used to cover all or a portion of such short sale or may be delivered to Issuer. Such purchases and any other market activity by Dealer will be conducted independently of Issuer by Dealer as principal for its own account. All of the actions to be taken by Dealer in connection with the Transaction shall be taken by Dealer independently and without any advance or subsequent consultation with Issuer. It is the intent of the parties that the Transaction comply with the requirements of Rule 10b5-1(c)(1)(i)(B) of the Exchange Act, and the parties agree that this Confirmation shall be interpreted to comply with the requirements of such Rule, and Issuer shall not take any action that results in the Transaction not so complying with such requirements. Without limiting the generality of the preceding sentence, Issuer acknowledges and agrees that (A) Issuer does not have, and shall not attempt to exercise, any influence over how, when or whether Dealer effects any market transactions in connection with the Transaction and (B) neither Issuer nor its officers or employees shall, directly or indirectly, communicate any information regarding Issuer or the Shares to any employee of Dealer or its Affiliates that have been identified by Dealer to Issuer in writing as employees responsible for executing market transactions in connection with the Transaction. Issuer also acknowledges and agrees that any amendment, modification, waiver or termination of this Confirmation must be effected in accordance with the requirements for the amendment or termination of a "plan" as defined in Rule 10b5-1(c) under the Exchange Act. Without limiting the generality of the foregoing, any such amendment, modification, waiver or termination shall be made in good faith and not as part of a plan or scheme to evade the prohibitions of Rule 10b-5 under the Exchange Act, and no such amendment, modification or waiver shall be made at any time at which Issuer or any officer or director of Issuer is aware of any material nonpublic information regarding Issuer or the Shares.

(c) Each of Issuer and Dealer represents and warrants to the other that it is an "eligible contract participant" as defined in Section 1a(12) of the U.S. Commodity Exchange Act, as amended.

(d) Each of Issuer and Dealer acknowledges that the offer and sale of the Transaction to it is intended to be exempt from registration under the Securities Act by virtue of Section 4(2) thereof. Accordingly, it represents and warrants to the other party that (i) it has the financial ability to bear the economic risk of its investment in the Transaction and is able to bear a total loss of its investment, (ii) it is an "accredited investor" as that term is defined in Regulation D as promulgated under the Securities Act, (iii) it is entering into the Transaction for its own account and without a view to the distribution or resale thereof and (iv) the assignment, transfer or other disposition of the Transaction has not been and will not be registered under the Securities Act and is restricted under this Confirmation, the Securities Act and state securities laws.

13. Acknowledgements of Issuer.

(a) Issuer agrees, understands and acknowledges that:

(i) during the period from (and including) the Trade Date to (and including) the Settlement Date, Dealer and its Affiliates may buy or sell Shares or other securities or buy or sell options or futures contracts or enter into swaps or other derivative transactions in order to adjust its Hedge Position with respect to the Transaction;

(ii) Dealer and its Affiliates also may be active in the market for the Shares or options, futures contracts, swaps or other derivative transactions relating to the Shares other than in connection with hedging activities in relation to the Transaction;

(iii) Dealer shall make its own determination as to whether, when and in what manner any hedging or market activities in Issuer's securities or other securities or transactions shall be conducted and shall do so in a manner that it deems appropriate to hedge its price and market risk with respect to the Transaction; and

(iv) any such market activities of Dealer and its Affiliates may affect the market price and volatility of the Shares, including the 10b-18 VWAP and the Forward Price, each in a manner that may be adverse to Issuer.

(b) Issuer:

(i) is an "institutional account" as defined in FINRA Rule 4512(c);

(ii) is capable of evaluating investment risks independently, both in general and with regard to all transactions and investment strategies involving a security or securities, and will exercise independent judgment in evaluating the recommendations of Dealer or its associated persons, unless it has otherwise notified Dealer in writing; and

(iii) will notify Dealer if any of the statements contained in clause (i) or (ii) of this Section 14(b) ceases to be true.

14. Reserved.

15. Other Provisions.

(a) Issuer agrees and acknowledges that Dealer is a "financial institution" and "financial participant" within the meaning of Sections 101(22) and 101(22A) of the Bankruptcy Code. The parties hereto further agree and acknowledge that it is the intent of the parties that (A) this Confirmation is a "securities contract," as such term is defined in Section 741(7) of the Bankruptcy Code, with respect to which each payment and delivery hereunder or in connection herewith is a "termination value," "payment amount" or "other transfer obligation" within the meaning of Section 362 of the Bankruptcy Code and a "settlement payment," within the meaning of Section 546 of the Bankruptcy Code, and (B) Dealer is entitled to the protections afforded by, among other sections, Sections 362(b)(6), 362(b)(17), 362(o), 546(e), 555 and 561 of the Bankruptcy Code.

(b) Dealer and Issuer hereby agree and acknowledge that Dealer has authorized Issuer to disclose the Transaction to any and all persons, and there are no express or implied agreements, arrangements or understandings to the contrary, and authorizes Issuer to use any information that Issuer receives or has received with respect to the Transaction in any manner.

(c) In the event Issuer becomes the subject of proceedings ("**Bankruptcy Proceedings**") under the Bankruptcy Code or any other applicable bankruptcy or insolvency statute, any rights or claims of Dealer hereunder in respect of the Transaction shall rank for all purposes no higher than, but on a parity with, the rights or claims of holders of Shares, and Dealer hereby agrees that its rights and claims hereunder shall be subordinated to those of all parties with claims or rights against Issuer (other than common stockholders) to the extent necessary to assure such ranking. Without limiting the generality of the foregoing, after the commencement of Bankruptcy Proceedings, the claims of Dealer hereunder shall for all purposes have rights equivalent to the rights of a holder of a percentage of the Shares equal to the aggregate amount of such claims (the "**Claim Amount**") taken as a percentage of the sum of (i) the Claim Amount and (ii) the aggregate fair market value of all outstanding Shares on the record date for distributions made to the holders of such Shares in the related Bankruptcy Proceedings. Notwithstanding any right it might otherwise have to assert a higher priority claim in any such Bankruptcy Proceedings, Dealer shall be entitled to receive a distribution solely to the extent and only in the form that a holder of such percentage of the Shares would be entitled to receive in such Bankruptcy Proceedings, and, from and after the commencement of such Bankruptcy Proceedings, Dealer expressly waives (i) any other rights or distributions to which it might otherwise be entitled in such Bankruptcy Proceedings in respect of its rights and claims hereunder and (ii) any rights of setoff it might otherwise be entitled to assert in respect of such rights and claims.

(d) Notwithstanding any provision of this Confirmation or any other agreement between the parties to the contrary, neither the obligations of Issuer nor the obligations of Dealer hereunder are secured by any collateral, security interest, pledge or lien.

(e) Each party waives any and all rights it may have to set off obligations arising under the Agreement and the Transaction against other obligations between the parties, whether arising under any other agreement, applicable law or otherwise.

(f) Notwithstanding anything to the contrary herein, Dealer may, by prior notice to Issuer, satisfy its obligation to deliver any Shares or other securities on any date due (an "**Original Delivery Date**") by making separate deliveries of Shares or such securities, as the case may be, at more than one time on or prior to such Original Delivery Date, so long as the aggregate number of Shares and other securities so delivered on or prior to such Original Delivery Date is equal to the number required to be delivered on such Original Delivery Date.

(g) It shall constitute an Additional Termination Event with respect to which the Transaction is the sole Affected Transaction and Issuer is the sole Affected Party and Dealer shall be the party entitled to designate an Early Termination Date pursuant to Section 6(b) of the Agreement if, at any time on or prior to the Valuation Date, the price per Share on the Exchange, as determined by the Calculation Agent, is at or below the Threshold Price (as specified in Schedule I).

16. Share Cap.

Notwithstanding any other provision of this Confirmation or the Agreement to the contrary, in no event shall Issuer be required to deliver to Dealer in the aggregate a number of Shares that exceeds the Share Cap as of the date of delivery (as specified in Schedule I).

17. Transfer and Assignment.

Dealer may transfer or assign its rights and obligations hereunder and under the Agreement ("**Transfer**"), in whole or in part, to any of its Affiliates that have a credit rating that is not lower than the credit rating of Dealer immediately prior to the proposed time of such Transfer (or whose obligations are guaranteed by an entity of equivalent credit quality) without the consent of Issuer. Dealer will provide prompt written notice of any such transfer to Issuer.

18. Principal Version of Incorporation by Reference Rider.

The parties agree that (i) to the extent that prior to the date hereof both parties have adhered to the 2018 ISDA U.S. Resolution Stay Protocol (the "Protocol"), the terms of the Protocol are incorporated into and form a part of this Agreement, and for such purposes this Agreement shall be deemed a Protocol Covered Agreement and each party shall be deemed to have the same status as Regulated Entity and/or Adhering Party as applicable to it under the Protocol; (ii) to the extent that prior to the date hereof the parties have executed a separate agreement the effect of which is to amend the qualified financial contracts between them to conform with the requirements of the QFC Stay Rules (the "Bilateral Agreement"), the terms of the Bilateral Agreement are incorporated into and form a part of this Agreement and each party shall be deemed to have the status of "Covered Entity" or "Counterparty Entity" (or other similar term) as applicable to it under the Bilateral Agreement; or (iii) if clause (i) and clause (ii) do not apply, the terms of Section 1 and Section 2 and the related defined terms (together, the

“Bilateral Terms”) of the form of bilateral template entitled “Full-Length Omnibus (for use between U.S. G-SIBs and Corporate Groups)” published by ISDA on November 2, 2018 (currently available on the 2018 ISDA U.S. Resolution Stay Protocol page at www.isda.org and, a copy of which is available upon request), the effect of which is to amend the qualified financial contracts between the parties thereto to conform with the requirements of the QFC Stay Rules, are hereby incorporated into and form a part of this Agreement, and for such purposes this Agreement shall be deemed a “Covered Agreement,” MSCO shall be deemed a “Covered Entity” and Issuer shall be deemed a “Counterparty Entity.” In the event that, after the date of this Agreement, both parties hereto become adhering parties to the Protocol, the terms of the Protocol will replace the terms of this paragraph . In the event of any inconsistencies between this Agreement and the terms of the Protocol, the Bilateral Agreement or the Bilateral Terms (each, the “QFC Stay Terms”), as applicable, the QFC Stay Terms will govern. Terms used in this paragraph without definition shall have the meanings assigned to them under the QFC Stay Rules. For purposes of this paragraph, references to “this Agreement” include any related credit enhancements entered into between the parties or provided by one to the other. In addition, the parties agree that the terms of this paragraph shall be incorporated into any related covered affiliate credit enhancements, with all references to Morgan Stanley replaced by references to the covered affiliate support provider.

“QFC Stay Rules” means the regulations codified at 12 C.F.R. 252.2, 252.81-8, 12 C.F.R. 382.1-7 and 12 C.F.R. 47.1-8, which, subject to limited exceptions, require an express recognition of the stay-and-transfer powers of the FDIC under the Federal Deposit Insurance Act and the Orderly Liquidation Authority under Title II of the Dodd Frank Wall Street Reform and Consumer Protection Act and the override of default rights related directly or indirectly to the entry of an affiliate into certain insolvency proceedings and any restrictions on the transfer of any covered affiliate credit enhancements.

19. Governing Law; Jurisdiction; Waiver.

THIS CONFIRMATION AND ANY CLAIM, CONTROVERSY OR DISPUTE ARISING UNDER OR RELATED TO THIS CONFIRMATION SHALL BE GOVERNED BY THE LAWS OF THE STATE OF NEW YORK. THE PARTIES HERETO IRREVOCABLY SUBMIT TO THE EXCLUSIVE JURISDICTION OF THE COURTS OF THE STATE OF NEW YORK AND THE UNITED STATES COURT FOR THE SOUTHERN DISTRICT OF NEW YORK IN CONNECTION WITH ALL MATTERS RELATING HERETO AND WAIVE ANY OBJECTION TO THE LAYING OF VENUE IN, AND ANY CLAIM OF INCONVENIENT FORUM WITH RESPECT TO, THESE COURTS.

Each PARTY hereby irrevocably waives (on its own behalf and, to the extent permitted by applicable law, on behalf of its stockholders) all right to trial by jury in any action, proceeding or counterclaim (whether based on contract, tort or otherwise) arising out of or relating to the Transaction or the actions of ISSUER or its affiliates in the negotiation, performance or enforcement hereof.

Remainder of Page Intentionally Blank

Please confirm that the foregoing correctly sets forth the terms of our agreement by executing this Confirmation and returning it to us by facsimile to the number provided on the attached facsimile cover page.

Confirmed as of the date first written above:

ALIGN TECHNOLOGY, INC.	Morgan Stanley & Co LLC
By: /s/ John F. Morici	By: /s/ Darren McCarley
Name: John F. Morici	Name: Darren McCarley
Title: Sr. V.P. & C.F.O.	Title: Managing Director

Exhibit 31.1

CERTIFICATION

I, Joseph M. Hogan, certify that:

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

Date: October 31, 2019

/s/ JOSEPH M. HOGAN

Joseph M. Hogan

President and Chief Executive Officer

Exhibit 31.2

CERTIFICATION

I, John F. Morici, certify that:

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

Date: October 31, 2019

/s/ JOHN F. MORICI

John F. Morici

Chief Financial Officer and Senior Vice President, Global Finance

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Align Technology, Inc. (the “Company”) on Form 10-Q for the period ending September 30, 2019 as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

By:	/s/ JOSEPH M. HOGAN
Name:	**Joseph M. Hogan**
Title:	**President and Chief Executive Officer**

Date: October 31, 2019

In connection with the Quarterly Report of Align Technology, Inc. (the “Company”) on Form 10-Q for the period ending September 30, 2019 as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

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

Date: October 31, 2019