
**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 June 30, 2020
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
(State or other jurisdiction of
incorporation or organization)

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

2820 Orchard Parkway
San Jose, California 95134
(Address of principal executive offices)
(408) 470-1000
(Registrant's telephone number, including area code)

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	<input checked="" type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input type="checkbox"/>
Emerging growth company	<input type="checkbox"/>		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 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 July 24, 2020 was 78,786,683.

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 June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Net revenues	\$ 352,314	\$ 600,697	\$ 903,277	\$ 1,149,668
Cost of net revenues	127,986	168,408	284,593	315,283
Gross profit	224,328	432,289	618,684	834,385
Operating expenses:				
Selling, general and administrative	256,967	267,948	539,873	515,058
Research and development	40,361	38,851	81,893	76,354
Impairments and other charges	—	—	—	29,782
Litigation settlement gain	—	(51,000)	—	(51,000)
Total operating expenses	297,328	255,799	621,766	570,194
Income (loss) from operations	(73,000)	176,490	(3,082)	264,191
Interest income and other income (expense), net:				
Interest income	473	3,465	2,459	6,098
Other income (expense), net	(966)	13,892	(19,515)	8,146
Total interest income and other income (expense), net	(493)	17,357	(17,056)	14,244
Net income (loss) before provision for (benefit from) income taxes and equity in losses of investee	(73,493)	193,847	(20,138)	278,435
Provision for (benefit from) income taxes	(32,891)	43,121	(1,497,667)	51,917
Equity in losses of investee, net of tax	—	3,584	—	7,528
Net income (loss)	\$ (40,602)	\$ 147,142	\$ 1,477,529	\$ 218,990
Net income (loss) per share:				
Basic	\$ (0.52)	\$ 1.84	\$ 18.78	\$ 2.74
Diluted	\$ (0.52)	\$ 1.83	\$ 18.70	\$ 2.71
Shares used in computing net income (loss) per share:				
Basic	78,769	79,943	78,681	79,901
Diluted	78,769	80,590	79,016	80,665

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 June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Net income (loss)	\$ (40,602)	\$ 147,142	\$ 1,477,529	\$ 218,990
Change in foreign currency translation adjustment, net of tax	9,294	213	9,983	622
Change in unrealized gains (losses) on investments, net of tax	—	192	(194)	276
Other comprehensive income	9,294	405	9,789	898
Comprehensive income (loss)	\$ (31,308)	\$ 147,547	\$ 1,487,318	\$ 219,888

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)

	June 30, 2020	December 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 404,359	\$ 550,425
Marketable securities, short-term	—	318,202
Accounts receivable, net of allowance for doubtful accounts of \$17,099 and \$6,756, respectively	473,314	550,291
Inventories	131,276	112,051
Prepaid expenses and other current assets	140,295	102,450
Total current assets	1,149,244	1,633,419
Property, plant and equipment, net	668,951	631,730
Operating lease right-of-use assets, net	68,578	56,244
Goodwill and intangible assets, net	543,211	75,692
Deferred tax assets	1,568,293	64,007
Other assets	27,580	39,610
Total assets	<u>\$ 4,025,857</u>	<u>\$ 2,500,702</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 94,987	\$ 87,250
Accrued liabilities	244,774	319,958
Deferred revenues	601,831	563,762
Total current liabilities	941,592	970,970
Income tax payable	115,257	102,794
Operating lease liabilities	50,619	43,463
Other long-term liabilities	73,344	37,306
Total liabilities	1,180,812	1,154,533
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; 78,781 and 78,433 issued and outstanding, respectively)	8	8
Additional paid-in capital	918,495	906,937
Accumulated other comprehensive income (loss), net	9,101	(688)
Retained earnings	1,917,441	439,912
Total stockholders' equity	2,845,045	1,346,169
Total liabilities and stockholders' equity	<u>\$ 4,025,857</u>	<u>\$ 2,500,702</u>

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 June 30, 2020	<u>Common Stock</u>		<u>Additional Paid-In Capital</u>	<u>Accumulated Other Comprehensive Income (Loss), Net</u>	<u>Retained Earnings</u>	<u>Total</u>
	<u>Shares</u>	<u>Amount</u>				
Balance as of March 31, 2020	78,759	\$ 8	\$ 895,131	\$ (193)	\$ 1,958,043	\$ 2,852,989
Net loss	—	—	—	—	(40,602)	(40,602)
Net change in foreign currency translation adjustment	—	—	—	9,294	—	9,294
Issuance of common stock relating to employee equity compensation plans	22	—	—	—	—	—
Tax withholdings related to net share settlements of equity awards	—	—	(1,643)	—	—	(1,643)
Stock-based compensation	—	—	25,007	—	—	25,007
Balance as of June 30, 2020	<u>78,781</u>	<u>\$ 8</u>	<u>\$ 918,495</u>	<u>\$ 9,101</u>	<u>\$ 1,917,441</u>	<u>\$ 2,845,045</u>

Six Months Ended June 30, 2020	<u>Common Stock</u>		<u>Additional Paid-In Capital</u>	<u>Accumulated Other Comprehensive Income (Loss), Net</u>	<u>Retained Earnings</u>	<u>Total</u>
	<u>Shares</u>	<u>Amount</u>				
Balance as of December 31, 2019	78,433	\$ 8	\$ 906,937	\$ (688)	\$ 439,912	\$ 1,346,169
Net income	—	—	—	—	1,477,529	1,477,529
Net change in unrealized gains (losses) from investments	—	—	—	(194)	—	(194)
Net change in foreign currency translation adjustment	—	—	—	9,983	—	9,983
Issuance of common stock relating to employee equity compensation plans	348	—	10,662	—	—	10,662
Tax withholdings related to net share settlements of equity awards	—	—	(47,038)	—	—	(47,038)
Stock-based compensation	—	—	47,934	—	—	47,934
Balance as of June 30, 2020	<u>78,781</u>	<u>\$ 8</u>	<u>\$ 918,495</u>	<u>\$ 9,101</u>	<u>\$ 1,917,441</u>	<u>\$ 2,845,045</u>

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 June 30, 2019	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss), Net	Retained Earnings	Total
	Shares	Amount				
Balance as of March 31, 2019	80,000	\$ 8	\$ 855,956	\$ (2,281)	\$ 402,021	\$ 1,255,704
Net income	—	—	—	—	147,142	147,142
Net change in unrealized gains (losses) from investments	—	—	—	192	—	192
Net change in foreign currency translation adjustment	—	—	—	213	—	213
Issuance of common stock relating to employee equity compensation plans	26	—	5	—	—	5
Tax withholdings related to net share settlements of equity awards	—	—	(2,537)	—	—	(2,537)
Common stock repurchased and retired	(161)	—	(1,616)	—	(47,888)	(49,504)
Stock-based compensation	—	—	22,467	—	—	22,467
Balance as of June 30, 2019	79,865	\$ 8	\$ 874,275	\$ (1,876)	\$ 501,275	\$ 1,373,682

Six Months Ended June 30, 2019	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss), Net	Retained Earnings	Total
	Shares	Amount				
Balance as of December 31, 2018	79,778	\$ 8	\$ 877,514	\$ (2,774)	\$ 378,143	\$ 1,252,891
Net income	—	—	—	—	218,990	218,990
Net change in unrealized gains (losses) from investments	—	—	—	276	—	276
Net change in foreign currency translation adjustment	—	—	—	622	—	622
Issuance of common stock relating to employee equity compensation plans	453	—	9,614	—	—	9,614
Tax withholdings related to net share settlements of equity awards	—	—	(52,718)	—	—	(52,718)
Common stock repurchased and retired	(366)	—	(3,646)	—	(95,858)	(99,504)
Stock-based compensation	—	—	43,511	—	—	43,511
Balance as of June 30, 2019	79,865	\$ 8	\$ 874,275	\$ (1,876)	\$ 501,275	\$ 1,373,682

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)

	Six Months Ended June 30,	
	2020	2019
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net income	\$ 1,477,529	\$ 218,990
Adjustments to reconcile net income to net cash provided by operating activities:		
Deferred taxes	(1,504,251)	5,606
Depreciation and amortization	44,283	37,488
Stock-based compensation	47,934	43,511
Non-cash operating lease cost	11,148	8,681
Allowance for doubtful accounts	12,578	3,240
Impairments on equity investments	3,787	3,975
Impairments on long-lived assets	—	28,498
Gain from sale of equity method investment	—	(15,769)
Equity in losses of investee	—	7,528
Other non-cash operating activities	11,542	9,548
Changes in assets and liabilities, net of effects of acquisition:		
Accounts receivable	64,645	(89,055)
Inventories	(21,398)	(26,681)
Prepaid expenses and other assets	(31,058)	(48,949)
Accounts payable	11,918	1,847
Accrued and other long-term liabilities	(106,572)	1,321
Long-term income tax payable	6,707	9,608
Deferred revenues	40,892	95,174
Net cash provided by operating activities	69,684	294,561
CASH FLOWS FROM INVESTING ACTIVITIES:		
Acquisition, net of cash acquired	(420,788)	—
Purchase of property, plant and equipment	(80,502)	(80,598)
Purchase of marketable securities	(5,341)	(353,995)
Proceeds from maturities of marketable securities	42,641	107,021
Proceeds from sales of marketable securities	278,817	14,456
Repayment on unsecured promissory note	11,087	6,598
Other investing activities	1,760	(14,502)
Net cash used in investing activities	(172,326)	(321,020)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock	10,662	9,614
Common stock repurchases	—	(99,504)
Payroll taxes paid upon the vesting of equity awards	(47,038)	(52,718)
Purchase of finance lease	—	(45,773)
Net cash used in financing activities	(36,376)	(188,381)
Effect of foreign exchange rate changes on cash, cash equivalents, and restricted cash	(7,172)	1,467
Net decrease in cash, cash equivalents, and restricted cash	(146,190)	(213,373)
Cash, cash equivalents, and restricted cash at beginning of the period	551,134	637,566
Cash, cash equivalents, and restricted cash at end of the period	\$ 404,944	\$ 424,193

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 six months ended June 30, 2020 and 2019, our comprehensive income for the three and six months ended June 30, 2020 and 2019, our financial position as of June 30, 2020, our stockholders’ equity for the three and six months ended June 30, 2020 and 2019, and our cash flows for the six months ended June 30, 2020 and 2019. The Condensed Consolidated Balance Sheet as of December 31, 2019 was derived from the December 31, 2019 audited financial statements. It does not include all disclosures required by accounting principles generally accepted in the United States of America (“U.S.”).

The results of operations for the three and six months ended June 30, 2020 are not necessarily indicative of the results that may be expected for the year ending December 31, 2020 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 the Consolidated Financial Statements and notes thereto included in Item 8 of our Annual Report on Form 10-K for the year ended December 31, 2019.

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 revenue recognition, useful lives of intangible assets and property and equipment, long-lived assets and goodwill, income taxes and contingent liabilities, the fair values of financial instruments, stock-based compensation, unsecured promissory note receivable, and valuation of investments in privately held companies 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. As a result of our exocad Global Holdings GmbH (“exocad”) acquisition, we have added or amended relevant significant accounting policies as described below. Refer to *Note 4 “Business Combination” of the Notes to Consolidated Financial Statements* for additional details on the exocad acquisition which is included in our Imaging Systems and CAD/CAM Services (“Systems and Services”) reportable segment.

Business Combinations

We allocate the fair value of the purchase consideration to the assets acquired and liabilities assumed based on their estimated fair values at the acquisition date. When determining the fair value of assets acquired and liabilities assumed, management is required to make certain estimates and assumptions, especially with respect to intangible assets. The estimates and assumptions used in valuing intangible assets include, but are not limited to, the amount and timing of projected future cash flows, the discount rate used to determine the present value of these cash flows, and the determination of the assets’ life cycle. These estimates are inherently uncertain and, therefore, actual results may differ from the estimates made.

Revenue Recognition - Systems and Services

We sell intraoral scanners and computer-aided design/computer-aided manufacturing (“CAD/CAM”) services through both our direct sales force and distribution partners. The intraoral scanner sales price includes one year of warranty and unlimited scanning services. The customer may also select, for additional fees, extended warranty and unlimited scanning services for periods beyond the initial year. When intraoral scanners are sold with an unlimited scanning service agreement and/or extended warranty, we allocate revenues based on the respective standalone selling price (“SSP”) of the scanner and the subscription service. We estimate the SSP of each element, taking into consideration historical prices as well as our discounting

strategies. Revenues are then recognized over time as the monthly services are rendered and upon shipment of the scanner, as that is when we deem the customer to have obtained control. CAD/CAM services, where sold separately, include the initial software license and maintenance and support. We allocate revenues based upon the respective SSPs of the software license and the maintenance and support. We estimate the SSP of each element using historical prices. Revenues related to the software license are recognized upfront and revenues related to the maintenance and support are recognized over time. For both scanner and service sales, most consideration is collected upfront and in cases where there are payment plans, consideration is collected within one year and, therefore, there are no significant financing components.

Certain Risks and Uncertainties

Due to the COVID-19 pandemic, we are subject to a greater degree of uncertainty than normal in making the judgments and estimates needed to apply our significant accounting policies. As the COVID-19 pandemic continues to be a global issue, we may make changes to these estimates and judgments, which could result in meaningful impacts to our financial statements in future periods. The extent and duration of the impact of the COVID-19 pandemic on our business is highly uncertain and difficult to predict and the response to the pandemic is rapidly evolving. The severity of the impact of the COVID-19 pandemic on our business will depend on a number of factors, including, but not limited to, the duration and severity of the pandemic and the extent and severity of the impact on our customers, all of which are uncertain and cannot be predicted. Our future results of operations and liquidity could be adversely impacted by delays in payments of outstanding receivable amounts beyond normal payment terms, supply chain disruptions and uncertain demand, and the impact of any initiatives or programs that we may undertake to address financial and operations challenges faced by us or our customers. Additionally, the uncertainty of future results and cash flows may impact our significant assumptions and estimates including the collectability of accounts and other receivables and realization of our deferred tax assets. As of the date of issuance of these condensed consolidated financial statements, the extent to which the COVID-19 pandemic may materially impact our financial condition, liquidity, or results of operations is uncertain.

Recent Accounting Pronouncements

(i) New Accounting Updates Recently Adopted

In June 2016, the Financial Accounting Standards Board ("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. We adopted this standard in the first quarter of fiscal year 2020 which did not have a material impact on our condensed 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. We adopted this standard in the first quarter of fiscal year 2020 which did not have any impact on our condensed 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. We adopted this standard in the first quarter of fiscal year 2020 which did not have any impact on our condensed 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. We adopted this standard in the first quarter of fiscal year 2020 on a prospective basis which did not have any impact on our condensed consolidated financial statements and related disclosures.

(ii) *Recent Accounting Updates Not Yet Effective*

In December 2019, the FASB issued ASU 2019-12, "Income Taxes (Topic 740) Simplifying the Accounting for Income Taxes," to enhance and simplify various aspects of the income tax accounting guidance. The amendment removes certain exceptions to the general principles in Topic 740 and also clarifies and amends existing guidance to improve consistent application. The amendments are effective for fiscal years and interim periods within those fiscal years beginning after December 15, 2020. 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.

Note 2. Investments and Fair Value Measurements

Marketable Securities

We have no short-term or long-term marketable securities as of June 30, 2020.

As of December 31, 2019, the estimated fair value of our short-term marketable securities, classified as available for sale, are as follows (in thousands):

December 31, 2019	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Corporate bonds	\$ 210,891	\$ 142	\$ (27)	\$ 211,006
U.S. government treasury bonds	70,587	65	(2)	70,650
U.S. government agency bonds	22,085	17	(1)	22,101
Commercial paper	14,426	—	—	14,426
Certificates of deposit	19	—	—	19
Total marketable securities, short-term	<u>\$ 318,008</u>	<u>\$ 224</u>	<u>\$ (30)</u>	<u>\$ 318,202</u>

We had no long-term marketable securities as of December 31, 2019.

Cash equivalents are not included in the table above as the gross unrealized gains and losses are not material. We had no short-term marketable securities that have been in a continuous material unrealized loss position for greater than twelve months as of December 31, 2019. Amounts reclassified to earnings from accumulated other comprehensive income (loss), net related to unrealized gains or losses were not material for the three and six months ended June 30, 2020 and 2019. For the three and six months ended June 30, 2020 and 2019, realized gains or losses were not material.

Our fixed-income securities investment portfolio allows for investments with 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 which 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 as of December 31, 2019.

As the carrying value approximates the fair value for our short-term marketable securities shown in the table above, the fair value of our short-term marketable securities as of December 31, 2019 had a contractual maturity one year or less.

Fair Value Measurements

The following tables summarize our financial assets measured at fair value on a recurring basis as of June 30, 2020 and December 31, 2019 (in thousands):

Description	Balance as of June 30, 2020	Level 1	Level 2	Level 3
Cash equivalents:				
Money market funds	\$ 149,230	\$ 149,230	\$ —	\$ —
Prepaid expenses and other current assets:				
Israeli funds	3,291	—	3,291	—
Current unsecured promissory note	21,246	—	—	21,246
	<u>\$ 173,767</u>	<u>\$ 149,230</u>	<u>\$ 3,291</u>	<u>\$ 21,246</u>

Description	Balance as of December 31, 2019	Level 1	Level 2	Level 3
Cash equivalents:				
Money market funds	\$ 236,923	\$ 236,923	\$ —	\$ —
Short-term investments:				
Corporate bonds	211,006	—	211,006	—
Commercial paper	14,426	—	14,426	—
U.S. government treasury bonds	70,650	70,650	—	—
U.S. government agency bonds	22,101	—	22,101	—
Certificates of deposit	19	—	19	—
Prepaid expenses and other current assets:				
Israeli funds	3,226	—	3,226	—
Current unsecured promissory note	25,005	—	—	25,005
Other assets:				
Long-term unsecured promissory note	7,328	—	—	7,328
	<u>\$ 590,684</u>	<u>\$ 307,573</u>	<u>\$ 250,778</u>	<u>\$ 32,333</u>

The unsecured promissory note that was entered into in 2019 is classified as Level 3 in our fair value hierarchy as financial information of third parties may not be timely available and consequently we estimate the fair value based on the best available information at the measurement date. The original amount of the note was \$54.2 million which has decreased due to payments received. Refer to Note 6 "Equity Method Investments" of the Notes to Condensed Consolidated Financial Statements for more information.

Investments in Privately Held Companies

Our investments in equity securities of privately held companies without readily determinable fair values were \$2.1 million and \$5.9 million as of June 30, 2020 and December 31, 2019, respectively, and are reported as nonrecurring investments within other assets in our Condensed Consolidated Balance Sheet. Our investments in equity securities are considered Level 3 in the fair value hierarchy since the investments are in private companies without quoted market prices and we adjust the carrying value based on observable price changes. During the six months ended June 30, 2020 and June 30, 2019, we recorded impairment losses of \$3.8 million and \$4.0 million, respectively, resulting from observable price changes.

Derivatives Not Designated as Hedging Instruments

Recurring foreign currency forward contracts

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 loss from the settlement of foreign currency forward contracts during the three months ended June 30, 2020 was \$3.0 million and the net gain from the settlement of foreign currency forward contracts during the six months ended June 30, 2020 was \$12.7 million. The net gain (loss) from the settlement of foreign currency forward contracts during the three and six months ended June 30, 2019 was not material. As of June 30, 2020 and December 31, 2019, 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 June 30, 2020 and December 31, 2019 (in thousands):

	June 30, 2020	
	Local Currency Amount	Notional Contract Amount (USD)
Chinese Yuan	¥997,000	\$ 140,618
Euro	€81,000	90,879
Canadian Dollar	C\$46,000	33,623
Brazilian Real	R\$153,000	27,859
British Pound	£20,000	24,584
Japanese Yen	¥2,385,000	22,154
Israeli Shekel	IL\$33,400	9,647
Mexican Peso	M\$140,000	6,038
Swiss Franc	CHF3,000	3,161
Australian Dollar	A\$2,800	1,924
		<u>\$ 360,487</u>

	December 31, 2019	
	Local Currency Amount	Notional Contract Amount (USD)
Euro	€97,000	\$ 108,870
Chinese Yuan	¥431,000	60,702
Canadian Dollar	C\$52,000	39,802
British Pound	£28,000	36,770
Brazilian Real	R\$130,000	32,185
Japanese Yen	¥3,000,000	27,604
Israeli Shekel	IL\$63,700	18,439
Mexican Peso	M\$140,000	7,398
Australian Dollar	A\$3,000	2,101
		<u>\$ 333,871</u>

Other foreign currency forward contract

Prior to the closing of the exocad Global Holdings GmbH ("exocad") acquisition on April 1, 2020, we entered into a Euro foreign currency forward contract with a notional contract amount of €376.0 million. During the three and six months ended June 30, 2020, we recognized losses of \$1.0 million and \$10.2 million, respectively, within other income (expense), net in our Condensed Consolidated Statement of Operations.

Note 3. Balance Sheet Components

Inventories consist of the following (in thousands):

	June 30, 2020	December 31, 2019
Raw materials	\$ 73,183	\$ 54,947
Work in process	32,232	30,974
Finished goods	25,861	26,130
Total inventories	<u>\$ 131,276</u>	<u>\$ 112,051</u>

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

	June 30, 2020	December 31, 2019
Tax related receivables	\$ 72,481	\$ 41,252
Prepaid software and maintenance	21,543	7,128
Current promissory note ¹	21,314	25,005
Others	24,957	29,065
Total prepaid expenses and other current assets	\$ 140,295	\$ 102,450

¹Refer to Note 6 “Equity Method Investments” of the Notes to Condensed Consolidated Financial Statements for more information.

Accrued liabilities consist of the following (in thousands):

	June 30, 2020	December 31, 2019
Accrued payroll and benefits	\$ 82,256	\$ 162,486
Accrued expenses	55,844	55,529
Current operating lease liabilities	20,860	15,737
Accrued professional fees	19,506	10,410
Accrued sales tax and value added tax	11,733	9,089
Accrued warranty	11,629	11,205
Others	42,946	55,502
Total accrued liabilities	\$ 244,774	\$ 319,958

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. We also warrant our CAD/CAM software for a one year period to perform in accordance with agreed product specifications. As we have not historically incurred any material warranty costs, we do not accrue for these software warranties. Warranty accrual consists of the following activity (in thousands):

	Six Months Ended June 30,	
	2020	2019
Balance at beginning of period	\$ 11,205	\$ 8,551
Charged to cost of net revenues	5,820	6,000
Actual warranty expenditures	(5,396)	(4,052)
Balance at end of period	\$ 11,629	\$ 10,499

Deferred revenues consist of the following (in thousands):

	June 30, 2020	December 31, 2019
Deferred revenues - current	\$ 601,831	\$ 563,762
Deferred revenues - long-term ¹	\$ 36,142	\$ 35,503

¹ Included in Other long-term liabilities within our Condensed Consolidated Balance Sheet

During the three months ended June 30, 2020 and 2019, we recognized \$352.3 million and \$600.7 million of revenue, respectively, of which \$72.4 million and \$68.6 million was included in the deferred revenues balance at December 31, 2019 and 2018, respectively.

During the six months ended June 30, 2020 and 2019, we recognized \$903.3 million and \$1.1 billion of revenue, respectively, of which \$167.9 million and \$137.0 million was included in the deferred revenues balance at December 31, 2019 and 2018, respectively.

Our unfilled performance obligations, including deferred revenues and backlog, as of June 30, 2020 were \$651.9 million. These performance obligations are expected to be recognized over the next one to five years.

Note 4. Business Combination

On April 1, 2020 (the "acquisition date"), we completed the acquisition of privately-held exocad for a total purchase consideration of \$430.0 million and exocad became a wholly-owned subsidiary. exocad is a German dental CAD/CAM software company that offers fully integrated workflows to dental labs and dental practices. We believe the synergies from the acquisition will strengthen our digital platform by adding exocad's expertise in restorative dentistry, implantology, guided surgery, and smile design to extend our digital solutions and pave the way for new, seamless cross-discipline dentistry in lab and at chairside.

The total purchase consideration consisted of the following (in thousands):

Cash paid to exocad stockholders	\$	412,287
Cash paid to settle exocad's bank debt		17,691
Total purchase consideration paid	\$	429,978

The following table summarizes the allocation of purchase price to assets acquired and liabilities assumed as of April 1, 2020 which are considered preliminary and therefore subject to change (in thousands):

Goodwill	\$	344,238
Identified intangible assets		118,700
Cash and cash equivalents		9,190
Deferred tax liabilities		(35,419)
Other assets (liabilities), net		(6,731)
Total	\$	429,978

Goodwill represents the excess of the purchase price over the fair value of the underlying net tangible and identifiable intangible assets, and represents the expected synergies of the transaction and the knowledge and experience of the workforce in place. None of this goodwill is deductible for tax purposes. Under the applicable accounting guidance, goodwill will not be amortized but will be tested for impairment on an annual basis or more frequently if certain indicators are present. We allocated approximately \$300.7 million of goodwill to our Systems and Services reporting unit (formerly the "Scanner and Services" reporting unit prior to its renaming during the second quarter of 2020) and approximately \$43.5 million of the goodwill to our Clear Aligner reporting unit (Refer to Note 5 "Goodwill and Intangible Assets" of the Notes to Condensed Consolidated Financial Statements for additional details). Our reporting units are the same as our operating segments. Acquisition related costs are recognized separately from the business combination and expensed as incurred.

The following table presents details of the identified intangible assets acquired (in thousands, except years):

	Weighted Average Amortization Period (in years)	Fair Value
Intangible assets subject to amortization:		
Existing technology	10	\$ 87,000
Customer relationships	10	21,500
Tradenames	7	9,800
Intangible assets not subject to amortization:		
In-process Research and Development ("IPR&D")		400
Total intangible assets		\$ 118,700

We believe the amount of purchased intangible assets recorded above represent the fair values and approximate the amount a market participant would pay for these intangible assets as of the acquisition date.

Existing technology represents the estimated fair value of exocad's core technology that has reached technological feasibility. We valued the existing technology using the multi-period excess earnings method under the income approach. The economic useful life of existing technology was determined by considering the life cycle of the technology and related cash flows.

Customer relationships represent the fair value of future projected revenue that will be derived from sales of products to existing customers. Customer relationships were valued using the with-and-without method under the income approach. The economic useful life for customer relationships was based on historical customer attrition rates.

Tradenames relates to the exocad tradenames that are recognized within the industry. The fair value was determined using the relief-from-royalty method under the income approach. The economic useful life of tradenames was determined by benchmarking against similar transactions entered into by peer companies.

IPR&D refers to the fair value of projects that are not yet completed but have potential value to the company.

Deferred tax liabilities were recorded for significant basis differences primarily to reflect the tax effect of fair value adjustments made to the beginning balance of the intangible assets and deferred revenue as of the acquisition date (Refer to *Note 13 "Accounting for Income Taxes" of the Notes to Condensed Consolidated Financial Statements* for additional details).

Our condensed consolidated financial statements include the operating results of exocad from the acquisition date. Separate post-acquisition operating results and pro forma results of operations for this acquisition have not been presented as the effect is not material to our financial results.

Note 5. Goodwill and Intangible Assets

Goodwill

The change in the carrying value of goodwill for the six months ended June 30, 2020, categorized by reportable segments, is as follows (in thousands):

	Clear Aligner	Systems and Services	Total
Balance as of December 31, 2019	\$ 63,924	\$ —	\$ 63,924
Additions from exocad acquisition ¹	43,500	300,738	344,238
Adjustments ²	574	6,800	7,374
Balance as of June 30, 2020	\$ 107,998	\$ 307,538	\$ 415,536

¹ Refer to *Note 4 "Business Combination" of the Notes to Condensed Consolidated Financial Statements* for additional details

² Adjustments were related to foreign currency translation within the measurement period

During the fourth quarter of fiscal 2019, we performed our 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 June 30, 2020	Accumulated Amortization	Accumulated Impairment Loss	Net Carrying Value as of June 30, 2020
Trademarks and tradenames	10	\$ 16,900	\$ (2,514)	\$ (4,179)	\$ 10,207
Existing technology	10	99,600	(5,936)	(4,328)	89,336
Customer relationships	11	55,000	(19,348)	(10,751)	24,901
Other ¹	5	15,314	(12,083)	—	3,231
Total intangible assets ²		\$ 186,814	\$ (39,881)	\$ (19,258)	\$ 127,675

¹ Includes reacquired rights, patents, IPR&D and other intangible assets

² Refer to *Note 4 "Business Combination" of the Notes to Condensed Consolidated Financial Statements* for additional details on intangible assets from our exocad acquisition.

	Weighted Average Amortization Period (in years)	Gross Carrying Amount as of December 31, 2019	Accumulated Amortization	Accumulated Impairment Loss	Net Carrying Value as of December 31, 2019
Trademarks	15	\$ 7,100	\$ (2,045)	\$ (4,179)	\$ 876
Existing technology	13	12,600	(5,831)	(4,328)	2,441
Customer relationships	11	33,500	(18,405)	(10,751)	4,344
Reacquired rights	3	7,500	(7,059)	—	441
Patents	8	6,796	(3,165)	—	3,631
Other	2	618	(583)	—	35
Total intangible assets		\$ 68,114	\$ (37,088)	\$ (19,258)	\$ 11,768

The total estimated annual future amortization expense for these acquired intangible assets as of June 30, 2020 is as follows (in thousands):

Fiscal Year Ending December 31,

	Amortization
Remainder of 2020	\$ 8,178
2021	15,899
2022	14,642
2023	14,022
2024	13,081
Thereafter	61,853
Total	\$ 127,675

Amortization expense for the three months ended June 30, 2020 and 2019 was \$4.1 million and \$1.5 million, respectively, and amortization expense for the six months ended June 30, 2020 and 2019 was \$5.4 million and \$3.0 million, respectively.

Note 6. 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. Concurrently with the investment, we also entered into a supply agreement to manufacture clear aligners for SDC, which expired 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. 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 investment balance of \$38.4 million in exchange for an unsecured promissory note of \$54.2 million and we recorded the difference of \$15.8 million as a gain in the second quarter of 2019 in other income in our Condensed Consolidated Statement of Operations. 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. The arbitration proceeding remains pending (Refer to Note 9 “Legal Proceedings” of the Notes to Condensed Consolidated Financial Statements for SDC legal proceedings discussion).

Note 7. Credit Facility

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 (“2018 Credit Facility”). The 2018 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 June 30, 2020, we had no outstanding borrowings under the 2018 Credit Facility and were in compliance with the conditions and performance requirements.

On July 21, 2020 we entered into a new credit facility for a \$300.0 million unsecured revolving line of credit, with a \$50.0 million letter of credit sublimit, and a maturity date of July 21, 2023 ("2020 Credit Facility"). Upon entry into the 2020 Credit Facility, the 2018 Credit Facility was terminated. The 2020 Credit Facility requires us to comply with specific financial conditions and performance requirements. Loans under the 2020 Credit Facility 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 1.50% to 2.25% for LIBOR loans and 0.50% to 1.25% 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. The outstanding principal, together with accrued and unpaid interest, is due on the maturity date.

Note 8. Impairments and Other Charges

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

Note 9. Legal Proceedings

2018 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. On November 29, 2019, the lead plaintiff filed an amended consolidated complaint against Align and two of our executive officers alleging similar claims as the initial complaints on behalf of a purported class of purchasers of our common stock from May 23, 2018 and October 24, 2018. A motion to dismiss the amended consolidated complaint was filed on January 17, 2020 and a ruling on the motion is pending. 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.

2019 Shareholder Derivative Lawsuit

In January 2019, three derivative lawsuits were filed in the U.S. District Court for the Northern District of California which were later consolidated, 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 2018 Securities Class Action Lawsuit, but the complaints assert various state law causes of action, including for breaches of fiduciary duty, insider trading, and unjust enrichment. 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. The consolidated action has been stayed pending final disposition of the 2018 Securities Class Action Lawsuit.

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. The matter has been similarly stayed pending final disposition of the 2018 Securities Class Action Lawsuit.

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.

2020 Securities Class Action Lawsuit

On March 2, 2020, a class action lawsuit against Align and two of our executive officers was filed in the U.S. District Court for the Southern District of New York on behalf of a purported class of purchasers of our common stock between April 24, 2019 and July 24, 2019. The complaint filed in the Southern District of New York alleges claims under the federal securities laws and seeks monetary damages in an unspecified amount and costs and expenses incurred in the litigation. On April 16, 2020, the Court approved the parties' stipulation to transfer the case to the U.S. District Court for the Northern District of California. The lead plaintiff in this matter is expected to file an amended complaint by August 4, 2020. Align believes these claims are without merit and intends to vigorously defend itself. Align is currently unable to predict the outcome of this lawsuit and therefore cannot determine the likelihood of loss nor estimate a range of possible loss.

2020 Shareholder Derivative Lawsuit

On May 4, 2020, a derivative lawsuit was 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 complaint are similar to those presented in the 2020 Securities Class Action Lawsuit, but this complaint asserts state law claims for breach of fiduciary duty and insider trading. The complaint seeks 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. This action has been stayed pending final disposition of the 2020 Securities Class Action Lawsuit. Align is currently unable to predict the outcome of this lawsuit and therefore cannot determine the likelihood of loss nor estimate a range of possible loss.

3Shape Litigation

On November 14, 2017, Align filed several patent infringement lawsuits asserting 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.

These lawsuits included 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. Three of the cases are active, and one is stayed. Trials have been scheduled to begin on November 30, 2020, and November 8, 2021, in two of the three active cases, with an additional trial to be scheduled in the third. Certain of Align's asserted patents in the Delaware actions were found invalid by the District Court judge.

On May 9, 2018, and June 14, 2018, 3Shape filed separate complaints in the U.S. District Court for the District of Delaware alleging patent infringement by Align's iTero Element scanner of two 3Shape patents. On August 19, 2019, the Court consolidated the two actions, and on August 30, 2019, 3Shape filed an amended complaint alleging infringement of a third patent. Trial is scheduled to begin on April 12, 2021.

In December 2018, Align filed three additional patent infringement lawsuits asserting 10 additional patents against 3Shape as follows: On December 10, 2018, Align filed one Section 337 complaint with the ITC alleging that 3Shape violates U.S. trade laws 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 April 30, 2020, an Administrative Law Judge ("ALJ") issued an initial determination that 3Shape infringed on 7 of the 9 patent claims asserted by Align, found valid 6 of the 9 claims asserted by Align, and found a violation of Section 337 stemming from 3Shape's infringement of 4 claims in 2 of Align's asserted patents. The ALJ recommended an exclusion order and cease and desist order be entered against 3Shape's unlawful importation. The Initial Determination is now subject to review by the Commissioners at the ITC. Align filed a petition for review of findings it believes are incorrect, and 3Shape also petitioned for review of the Initial Determination. On July 28, 2020, the Commission determined to review the Initial Determination in part. The current deadline for completing the investigation is September 28, 2020.

In addition to the December 10, 2018 ITC Complaint, 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. One of the District Court cases was stayed pending the parallel ITC

investigation. The remaining District Court case is in the early stages of discovery and pretrial proceedings. Trial is scheduled to begin on February 7, 2022.

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.

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. After the Court dismissed 3Shape's complaint with leave, 3Shape filed an amended complaint on October 28, 2019. On May 20, 2020, the Magistrate Judge recommended that Align's motion to dismiss the amended complaint be denied. Align's objection to the Magistrate Judge's Report and Recommendation has been fully briefed to the District Court, and the parties are waiting for a ruling.

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

Simon & Simon

On June 5, 2020, a dental practice named Simon and Simon, PC d/b/a City Smiles brought an antitrust action in the United States District Court for the Northern District of California 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. Prior to filing in the Northern District of California, on May 4, 2020, Plaintiff voluntarily dismissed a similar action in the U.S. District Court for the District of Delaware after the Magistrate Judge recommended that its complaint be dismissed. On July 28, 2020, Align filed a motion to dismiss the complaint. Align believes the plaintiffs' claims are without merit and intends to vigorously defend itself. Align is currently unable to predict the outcome of this lawsuit and therefore cannot determine the likelihood of loss, if any, nor estimate a range of possible loss.

SDC Dispute

In April 2018, the SDC Financial LLC, SmileDirectClub LLC, and the Members of SDC Financial LLC other than the Company (collectively, the "SDC Entities") instigated confidential arbitration proceedings against Align. During December 2018, the parties participated in binding arbitration proceedings and presented closing arguments on January 23, 2019. In an award dated March 4, 2019, ("Award") an arbitrator found that Align breached the non-compete provision applicable to the SDC Entities and that Align misused the SDC Entities' confidential information and violated fiduciary duties to SDC Financial LLC. As part of the Award, Align was enjoined 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 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 Circuit Court for Cook County, Illinois confirmed the Award on April 29, 2019.

As required by the Award, Align tendered its membership interests for a purchase price that SDC claims to be Align's "capital account" balance. 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. That arbitration proceeding remains pending and a hearing is currently expected to occur before the end of 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. The SDC Entities have appealed the denial of the contempt petition, and that appeal remains pending.

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. On April 27, 2020, the SDC Entities filed an amended arbitration demand, which additionally asserts that Align's alleged dealings with a third-party constitute contempt of the Award. Align denies and

intends to vigorously defend itself against all 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 disputes and therefore cannot determine the likelihood of loss nor estimate a range of possible loss.

In addition to the above, 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 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. As of June 30, 2020, the entire Agreement amount was an outstanding commitment which is expected to be paid through 2023.

Off-Balance Sheet Arrangements

As of June 30, 2020, 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 10 "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 June 30, 2020, 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 June 30, 2020, the 2005 Incentive Plan (as amended) has a total reserve of 27,783,379 shares of which 4,611,280 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 our stock-based awards and employee stock purchase plans for the three and six months ended June 30, 2020 and 2019 is as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Cost of net revenues	\$ 891	\$ 1,278	\$ 2,238	\$ 2,390
Selling, general and administrative	20,203	18,037	38,333	34,927
Research and development	3,913	3,152	7,363	6,194
Total stock-based compensation	\$ 25,007	\$ 22,467	\$ 47,934	\$ 43,511

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 six months ended June 30, 2020 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)
Unvested as of December 31, 2019	696	\$ 190.60		
Granted	289	264.97		
Vested and released	(288)	149.86		
Forfeited	(22)	231.28		
Unvested as of June 30, 2020	675	\$ 238.47	1.6	\$ 185,207

As of June 30, 2020, we expect to recognize \$126.0 million of total unamortized compensation cost, net of estimated forfeitures, related to RSUs over a weighted average period of 2.6 years.

Market-performance Based Restricted Stock Units (“MSUs”)

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. The maximum number of MSUs which will be eligible to vest range from 250% to 300% of the MSUs initially granted and the vesting period is three years.

A summary for the six months ended June 30, 2020 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)
Unvested as of December 31, 2019	244	\$ 331.35		
Granted	156	242.04		
Vested and released	(173)	120.39		
Unvested as of June 30, 2020	227	\$ 430.50	1.6	\$ 62,365

As of June 30, 2020, we expect to recognize \$46.1 million of total unamortized compensation cost, net of estimated forfeitures, related to MSUs over a weighted average period of 1.6 years.

Employee Stock Purchase Plan (“ESPP”)

In May 2010, our stockholders approved the 2010 Employee Stock Purchase Plan (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 June 30, 2020, we have 379,304 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:

	Six Months Ended June 30,	
	2020	2019
Expected term (in years)	1.0	1.4
Expected volatility	41.7 %	48.6 %
Risk-free interest rate	1.5 %	2.5 %
Expected dividends	—	—
Weighted average fair value at grant date	\$ 80.54	\$ 90.36

As of June 30, 2020, there was \$5.7 million of total unamortized compensation costs related to employee stock purchases which we expect to be recognized over a weighted average period of 0.5 year.

Note 12. Common Stock 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 (“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 2019, we repurchased on the open market approximately 0.8 million shares of our common stock at an average price of \$264.93 per share, including commissions, for an aggregate purchase price of \$200.0 million. We also entered into an ASR to repurchase \$200.0 million of our common stock which was completed in September 2019. We received a total of 1.1 million shares for an average share price of \$176.61.

As of June 30, 2020, we have \$100.0 million available for repurchase under the May 2018 Repurchase Program.

Note 13. Accounting for Income Taxes

During the six months ended June 30, 2020, we completed an intra-entity transfer of certain intellectual property rights and fixed assets to our Swiss subsidiary, where our Europe, Middle East and Africa (“EMEA”) regional headquarters is located beginning January 1, 2020. The transfer of intellectual property rights did not result in a taxable gain; however, it did result in a step-up of the Swiss tax deductible basis in the transferred assets, and accordingly, created a temporary difference between the book basis and the tax basis of such intellectual property rights. Consequently, this transaction resulted in the recognition of a deferred tax asset and related one-time tax benefit of approximately \$1,493.5 million during the six months ended June 30, 2020, which is the net impact of the deferred tax asset recognized as a result of the additional Swiss tax deductible basis in the transferred assets and certain costs related to the transfer of fixed assets and inventory.

Our benefit from income taxes was \$32.9 million for the three months ended June 30, 2020 and our provision for income taxes was \$43.1 million for the three months ended June 30, 2019, representing effective tax rates of 44.8% and 22.2%, respectively. Our benefit from income taxes was \$1,497.7 million for the six months ended June 30, 2020 and our provision for income taxes was \$51.9 million for the six months ended June 30, 2019, representing effective tax rates of 7,437.0% and 18.6%, respectively. Our effective tax rate differs from the statutory federal income tax rate of 21% for the three months ended June 30, 2020 primarily due to the recognition of additional tax benefits resulting from changes in annual effective tax rate caused by a shift in jurisdictional mix of forecasted annual income. Our effective tax rate differs from the statutory federal income tax rate of 21% for the six months ended June 30, 2020 mainly as a result of the aforementioned intra-entity transfer and the recognition of excess tax benefits related to stock-based compensation, partially offset by unrecognized tax benefits associated with certain foreign payments. Our effective tax rate differs from the statutory federal income tax rate of 21% for the three and six months ended June 30, 2019 mainly as a result of the recognition of excess tax benefits related to stock-based compensation and certain foreign earnings, primarily from the Netherlands and Costa Rica, being taxed at lower tax rates.

The increase in our effective tax rate for the three months ended June 30, 2020 compared to the same period in 2019 is primarily attributable to the tax impact of a higher annual forecasted effective tax rate driven by changes in the jurisdictional mix of forecasted income. The increase in our effective tax rate for the six months ended June 30, 2020 compared to the same period in 2019 is primarily attributable to the recognition of a deferred tax asset related to the intra-entity transfer of certain intellectual property rights during the six months ended June 30, 2020. While the recognition of a deferred tax asset would

normally cause a reduction in tax rate, due to our net loss before tax for the six months ended June 30, 2020, it has the effect of increasing the effective tax rate.

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 continue to assess the realizability of the deferred tax assets as we take into account new information.

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 Switzerland. 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 2013.

Our total gross unrecognized tax benefits, excluding interest and penalties, were \$57.0 million and \$46.7 million as of June 30, 2020 and December 31, 2019, respectively, a material amount of which would impact our effective tax rate if recognized. Our total interest and penalties accrued as of June 30, 2020 was not material. We have elected to recognize interest and penalties related to unrecognized tax benefits as a component of income taxes. The timing and resolution of income tax examinations is uncertain, and the amounts ultimately paid, if any, upon resolution of issues raised by the taxing authorities may differ materially from the amounts accrued for each year. Although it is possible that our balance of gross unrecognized tax benefits could materially change in the next 12 months, given the uncertainty in the development of ongoing income tax examinations, we are unable to estimate the full range of possible adjustments to this balance.

Our total deferred tax liabilities were \$35.4 million as of June 30, 2020, which were primarily related to the intangible assets from our exocad acquisition. Our deferred tax liabilities as of December 31, 2019 were not material.

As of December 31, 2019, undistributed earnings of our foreign subsidiaries totaled \$452.6 million and substantially all of the earnings previously determined to be not indefinitely reinvested have been repatriated. Under the Global Intangible Low-Taxed Income provisions of the Tax Cuts and Jobs Act, U.S. income taxes have already been provided on the undistributed earnings that is indefinitely reinvested in our international operations; therefore, the tax impact upon distribution is limited to mainly state income and withholding taxes and is not significant.

Note 14. Net Income (Loss) per Share

Basic net income (loss) 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. Due to our net loss for the three months ended June 30, 2020, the potential common stock instruments such as RSUs, MSUs and ESPP were not included in the computation of diluted net loss per share as the effect of including these shares would have been anti-dilutive.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Numerator:				
Net income (loss)	\$ (40,602)	\$ 147,142	\$ 1,477,529	\$ 218,990
Denominator:				
Weighted average common shares outstanding, basic	78,769	79,943	78,681	79,901
Dilutive effect of potential common stock	—	647	335	764
Total shares, diluted	78,769	80,590	79,016	80,665
Net income (loss) per share, basic	\$ (0.52)	\$ 1.84	\$ 18.78	\$ 2.74
Net income (loss) per share, diluted	\$ (0.52)	\$ 1.83	\$ 18.70	\$ 2.71
Anti-dilutive potential common shares ¹	733	139	231	111

¹ Represents RSUs and MSUs not included in the calculation of diluted net income per share as the effect would have been anti-dilutive.

Note 15. Supplemental Cash Flow Information

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

	Six Months Ended June 30,	
	2020	2019
Non-cash investing and financing activities:		
Fixed assets acquired with accounts payable or accrued liabilities	\$ 13,199	\$ 12,202
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	\$ 12,817	\$ 9,020
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	\$ 25,545	\$ 21,066
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 Imaging Systems and CAD/CAM services ("Systems and Services") segment. The Systems and Services segment was formerly known as the Scanner and Services segment prior to our acquisition of exocad on April 1, 2020 (Refer to Note 4 "Business Combination" of the Notes to Condensed Consolidated Financial Statements for additional details on the exocad acquisition).

- 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 and Invisalign First.
 - Non-Comprehensive Products include, but are not limited to, Invisalign Moderate, Lite and Express packages and Invisalign Go.
 - Non-Case includes, but not limited to, Vivera retainers along with our training and ancillary products for treating malocclusion.
- Our Systems and Services segment consists of our iTero intraoral scanning systems, which includes a single hardware platform and restorative or orthodontic software options, OrthoCAD services and ancillary products, as well as exocad's software solution that integrates workflows to dental labs and dental practices.

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 June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Net revenues				
Clear Aligner	\$ 298,341	\$ 496,702	\$ 779,952	\$ 965,907
Systems and Services	53,973	103,995	123,325	183,761
Total net revenues	\$ 352,314	\$ 600,697	\$ 903,277	\$ 1,149,668
Gross profit				
Clear Aligner	\$ 192,366	\$ 366,142	\$ 543,858	\$ 717,500
Systems and Services	31,962	66,147	74,826	116,885
Total gross profit	\$ 224,328	\$ 432,289	\$ 618,684	\$ 834,385
Income (loss) from operations				
Clear Aligner	\$ 38,916	\$ 244,029	\$ 205,304	\$ 402,670
Systems and Services	2,893	39,267	17,282	67,526
Unallocated corporate expenses	(114,809)	(106,806)	(225,668)	(206,005)
Total income (loss) from operations	\$ (73,000)	\$ 176,490	\$ (3,082)	\$ 264,191
Depreciation and amortization				
Clear Aligner	\$ 9,697	\$ 9,455	\$ 19,818	\$ 18,545
Systems and Services	5,005	1,854	6,790	3,362
Unallocated corporate expenses	8,843	7,863	17,675	15,581
Total depreciation and amortization	\$ 23,545	\$ 19,172	\$ 44,283	\$ 37,488
Impairments and other charges				
Clear Aligner	\$ —	\$ —	\$ —	\$ 29,782
Total impairments and other charges	\$ —	\$ —	\$ —	\$ 29,782
Litigation settlement gain				
Clear Aligner	\$ —	\$ (51,000)	\$ —	\$ (51,000)
Total litigation settlement gain	\$ —	\$ (51,000)	\$ —	\$ (51,000)

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Total segment income from operations	\$ 41,809	\$ 283,296	\$ 222,586	\$ 470,196
Unallocated corporate expenses	(114,809)	(106,806)	(225,668)	(206,005)
Total income (loss) from operations	(73,000)	176,490	(3,082)	264,191
Interest income	473	3,465	2,459	6,098
Other income (expense), net	(966)	13,892	(19,515)	8,146
Net income (loss) before provision for (benefit from) income taxes and equity in losses of investee	\$ (73,493)	\$ 193,847	\$ (20,138)	\$ 278,435

Geographical Information

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Net revenues ¹ :				
United States	\$ 140,859	\$ 296,655	\$ 412,564	\$ 575,660
Switzerland ²	105,495	—	292,771	—
The Netherlands ²	—	192,188	—	366,932
China	46,377	44,823	66,102	87,439
Other International	59,583	67,031	131,840	119,637
Total net revenues	\$ 352,314	\$ 600,697	\$ 903,277	\$ 1,149,668

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

² During the first quarter of 2020, we implemented a new international corporate structure. This changed the structure of our international procurement and sales operations from the Netherlands to Switzerland.

Tangible long-lived assets, which includes Property, plant and equipment, net, and Operating lease right-of-use assets, net, are presented below by geographic area (in thousands):

	June 30, 2020	December 31, 2019
Long-lived assets ¹ :		
Switzerland ²	\$ 215,689	\$ 7,755
United States	180,815	164,451
China	96,565	73,174
Costa Rica	84,348	82,083
The Netherlands ²	999	226,286
Other International	159,113	134,225
Total long-lived assets	\$ 737,529	\$ 687,974

¹ Long-lived assets are attributed to countries based on the location of our entity that owns or leases the assets.

² As a result of the new international corporate structure changes, most of the long-lived assets were transferred from our Netherlands entity to our Switzerland entity during the first quarter of 2020.

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 and intentions regarding our strategic objectives and the means to achieve them, our beliefs regarding the impact of technological innovation in general, and in our solutions and products in particular, on target markets, our beliefs regarding digital dentistry and its potential to impact our business, our expectations for the impact of the exocad acquisition, our beliefs regarding the potential for clinical solutions and their utilization to increase sales of our Invisalign system as well as the complementary products and solutions themselves, our expectations regarding product mix and product adoption, our expectations regarding the utilization rates for our products, including the impact of marketing on those rates and causes for periodic fluctuations of the rates, 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 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 expectations regarding competition, our expectations regarding the implications of the COVID-19 pandemic and the health, safety and economic recovery from it, on the global economy, the businesses of our customers, and us, including our preparedness to react to changing circumstances and overall on our revenues, results of operations and financial condition, our expectations for our expenses and capital expenditures in particular, the actions we will take to control spending and for investments, our intentions regarding the investment of our international earnings from operations, our belief regarding the sufficiency of our cash balances and borrowing capacity, 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, 2019 as filed with the Securities and Exchange Commission.

Overview

Align Technology, Inc. ("We", "Our", "Align") is a global medical device company engaged in the design, manufacture and marketing of Invisalign® clear aligners, iTero® intraoral scanners and services for orthodontics, and restorative and aesthetic dentistry, and exocad® computer-aided design and computer-aided manufacturing ("CAD/CAM") software for dental laboratories and dental practitioners. Align's products are intended primarily for the treatment of malocclusion or the misalignment of teeth and are designed to help dental professionals achieve the clinical outcomes that they expect and the results patients desire. Our goal is to establish clear aligners as the principal solution for the treatment of malocclusions and our Invisalign clear aligners as the treatment solution of choice by orthodontists, general dental practitioners and patients globally. To date, over 8.5 million people worldwide have been treated with our Invisalign System.

To encourage consumers to treat malocclusions with clear aligners under the direction and supervision of licensed dental professionals, we bring to market solutions we believe will strengthen our digital dental platform for doctors, labs and partners, including establishing the iTero intraoral scanner and related services as the preferred 3D digital scanning solution and integrating newly acquired CAD/CAM solutions and workflows into the markets for clear aligner orthodontics and dental restorative treatments. We intend to continue focusing on these efforts through execution of our strategic growth drivers. *For a further description of our strategic growth drivers, please review the Business Strategy section of our Annual Report on Form 10-K filed with the Securities and Exchange Commission on February 28, 2020.*

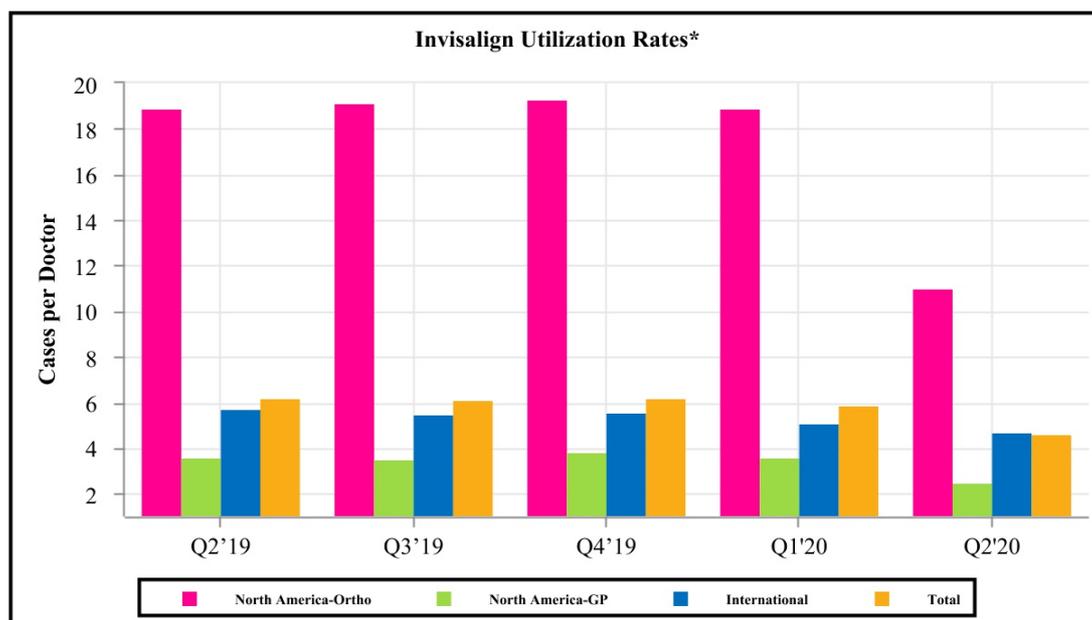
The successful execution of our business strategy may be affected by a number of factors including:

- *New Products, Feature Enhancements and Technology.* We believe product innovation to treat a wide range of cases from simple to complex drives greater treatment predictability, clinical applicability and ease of use for the dental professionals we serve which supports adoption of Invisalign treatment in their practices. Furthermore, we believe the digital revolution in dentistry is an important aspect of the experience for our customers and their patients, encouraging the utilization of our Invisalign solution. It therefore comprises an important component of our digital approach.
 - *Invisalign:* Since 2018, we have launched or announced various new offerings including our Invisalign treatment with Mandibular Advancement, Invisalign Go, Invisalign First and Invisalign Moderate. In each instance, we have broadened and strengthened our reach into key markets and demographics central to our strategic plans.
 - *iTero Scanner:* Over the last two years, we have expanded or announced several new aspects of our intraoral digital scanning solutions including the iTero Element, iTero Element Foundation and the iTero Element 5D Imaging system, for which we announced in March 2020 that we had obtained U.S. FDA 501(K) clearance. The approval of the iTero Element 5D Imaging system opens the U.S. markets for sales of this unique solution that combines 3D data, intra-oral color photos and NIRI images into a single, integrated scan improving doctor experiences and improving engagement opportunities and communications with their patients. The iTero Element 5D aids in the detection and monitoring of interproximal caries lesions above the gingiva without using harmful radiation.
- *exocad.* On April 1, 2020, we completed the acquisition of privately-held exocad Global Holdings GmbH (“exocad”), a German dental CAD/CAM software company that offers fully integrated workflows to dental labs and dental practices. We believe the acquisition strengthens our digital platform by adding exocad's expertise in restorative dentistry, implantology, guided surgery, and smile design to extend our digital solutions and paves the way for new, seamless cross-disciplinary dentistry in lab and at chairside. exocad also broadens our reach in digital dentistry with close to 200 partners and more than 35,000 licenses installed worldwide.

To further the transformation of dental practices to the digital age, we introduced virtual solutions such as Invisalign® Virtual Appointment and Invisalign® Virtual Care; solutions that facilitate the safe, effective and successful treatment of patients by conveniently connecting doctors and their patients throughout their treatment plans. We believe that over the long term, clinical solutions, treatment tools and virtual solutions will increase adoption of clear aligners, sales of our intraoral scanners and integration of exocad CAD/CAM solutions chairside and in dental workflows; however, it is difficult to predict the rate and success of adoption of each and all of these products and solutions, which may vary by region and channel.

- *Invisalign Adoption.* Our goal is to establish Invisalign clear aligners 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.” Although we believe the closure, reduced operations and slow reopening of many dental and orthodontic practices in the first and second quarters of 2020 negatively impacted the number of patients seen and orders for clear aligners submitted, the use of iTero and other digital scanners for Invisalign case submissions in place of PVS impressions continues to be a positive catalyst for Invisalign utilization.

For the second quarter of 2020, total Invisalign cases submitted with a digital scanner in the Americas increased to 85.8%, up from 80.5% in the first quarter of 2020, including 95.9% of all cases submitted in the second quarter of 2020 by North American orthodontists. International scans increased to 72.0%, up from 68.7% in the first quarter of 2020. Our quarterly utilization rates for the last five quarters are as follows:



*Invisalign utilization rates are calculated by the # of cases shipped divided by the # of doctors to whom cases were shipped. Our International region includes Europe, Middle East and Africa ("EMEA") and Asia Pacific ("APAC"). Latin America ("LATAM") is excluded from above chart as it is immaterial.

- Total utilization rate in the second quarter of 2020 decreased to 4.6 cases per doctor compared to 6.2 cases per doctor in the second quarter of 2019.
 - *North America:* Utilization rate among our North American orthodontist customers decreased to 11.0 cases per doctor in the second quarter of 2020 compared to 18.9 cases per doctor in the second quarter of 2019 and the utilization rate among our North American GP customers decreased to 2.5 cases per doctor in the second quarter of 2020 compared to 3.6 cases per doctor in the second quarter of 2019. The decrease in utilization rates for the second quarter of 2020 is due primarily to COVID-19 related practice closures.
 - *International:* International doctor utilization rate was 4.7 cases per doctor in the second quarter of 2020 compared to 5.7 cases in the second quarter of 2019.

We expect global utilization rates to continue to recover from COVID-19 practice closure related decreases absent additional or more restrictive practice closures and thereafter to steadily improve as doctors' clinical confidence in the use of Invisalign clear aligners increases with advancements in products and technology and as COVID-19 restrictions create demand for treatments that reduce or minimize the need for physical interactions between dental professionals and their patients. In addition, 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 by 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 beyond the impact of COVID-19 pandemic-related preventative measures, including seasonal trends in our business and adoption rates for 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 six months ended June 30, 2020, we trained 8,125 new Invisalign doctors of which 3,175 were trained in the Americas region and 4,950 in the International region. In 2019, we trained a total of 22,275 new Invisalign doctors, of which 9,765 were trained in the Americas region and 12,510 in the International region.
- *International Invisalign Growth.* Our future growth is dependent upon the continued penetration and expansion of Invisalign product usage in international markets. Accordingly, we continue to focus our efforts towards increasing Invisalign clear aligner adoption by dental professionals internationally. Starting in the first quarter of 2020, the outbreak of COVID-19 caused significant disruption and uncertainty to our business, employees, doctors' practices, their patients and consumers beginning in China and spreading globally thereafter. While the negative impact of COVID-19 on sales decreased as the second quarter of 2020 progressed, we remain prepared to react should the

localized spread of the virus result in additional preventative measures that adversely impact us or our customers. *For a further discussion of COVID-19 and its impact on our business, see the section entitled "COVID-19 Update" below.* Prior to the impact of COVID-19, beginning in the second quarter of 2019, we experienced slower growth rates than prior periods in China primarily due to the U.S.-China trade war and resulting economic uncertainty which caused headwind for consumer demand especially for consumption of luxury goods and considered purchases. We also believe there has been increased competitive activity from wires and bracket manufacturers and clear aligner suppliers. Notwithstanding these issues in China, we continue to see growth opportunities with international orthodontists and GP customers, particularly with adopters of digital dentistry platforms and as we continue to segment our sales and marketing resources and programs specifically around each customer channel. We continue 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. For instance, we increased our sales presence in APAC in the first half of 2020 and will continue to strategically invest in regions as we deem appropriate for long term success. We expect International revenues 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.

- *Increasing Competition.* Starting in the second quarter of 2019, we began experiencing 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 companies, 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 low prices. In the third quarter of 2019, we increased investment in consumer demand with a new advertising campaign for North America and in the second half of 2020 are looking at further investments to create additional demand for Invisalign treatment and to drive teens and parents to dental professionals for those treatments. In addition, we launched new sales tools and professional marketing materials and we also expect to see increased productivity from sales representatives we added in the U.S. in 2019 and those more recently added in APAC in 2020. 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.

COVID-19 Update

Beginning in the first quarter of fiscal year 2020 and continuing into the second quarter, our sales and results of operations were markedly impacted by the COVID-19 pandemic. As a result, we began to experience a sudden downturn in sales initially in Asia, China in particular, starting in January. As the virus spread beyond China and into Europe and thereafter the Americas in early March, a rapid deceleration of all sales commenced shortly thereafter as the practices of many of our customers were severely curtailed or completely closed.

By the end of the second quarter of 2020, dental practices across every region had largely reopened and were seeing patients, with recovery in the Orthodontic channel leading the GP channel. For the six months ended June 30, 2020, we recorded net revenues of \$903.3 million, a decrease of 21.4% compared to the same period in 2019. For the three months ended June 30, 2020, clear aligner case volume was 221.9 thousand, a decrease of 41.4% compared to the same period in 2019 and for the three months ended June 30, 2020, Systems and Services net revenues decreased by 48.1% compared to the same period in 2019.

In the short term, our business may be particularly susceptible to the impact of the COVID-19 pandemic. On the one hand, all or a material portion of our products may be viewed as discretionary purchases and therefore more susceptible to any global or regional recession that may result from efforts to prevent or delay the spread of the virus. Moreover, efforts to slow or prevent a recurrence of the spread of the virus are likely to continue causing disruption and uncertainties in the markets resulting in curtailed operations by our customers and their patients for an indeterminate period of time. This in turn could impact our operations as purchasing decisions are delayed or lost, logistics complexities as a result of closed customer offices, sales and marketing efforts are postponed, and manufacturing operations are curtailed to adjust to declining sales. On the other hand, COVID-19 has also demonstrated the benefits of digital dentistry and virtual appointments, which may motivate doctors to use more digital solutions such as Align's products and services including the iTero scanner and Invisalign system.

As we assess the possible future short and long-term impacts to revenue, operations and financial condition from the COVID-19 pandemic, we are continually evaluating macroeconomic as well as industry-specific factors. For instance, among the many factors we continue to monitor are governmental and societal reactions to the virus, the potential impacts of delays in the restarting of global and regional economic activities, the impact of unemployment on discretionary spending and health insurance coverage, patient reluctance or fear of exposure as a result of orthodontic or dental office visits and other external factors related to COVID-19 that are beyond our control. For example, many jurisdictions have imposed a wide range of

restrictions on the physical movement of our employees and vendors to limit the spread of COVID-19. Furthermore, if the COVID-19 pandemic or the speed and timeframe in which dental practices reopen and demand for our products increases has a substantial impact on our employees or suppliers, our operations, including our ability to obtain the materials needed to manufacture our products and to actually manufacture and deliver our products to customers, may suffer, and in turn our results of operations, financial condition and overall financial performance may be harmed. Furthermore, if our employees or their families are sickened by COVID-19, our ability to respond or mitigate the impact of COVID-19 may be adversely impacted.

Moreover, we are continuing to provide certain help and take further actions to respond to changes in our environment, including the COVID-19 pandemic, quickly and effectively. As a result of the COVID-19 pandemic, we instructed employees at many of our offices across the globe (including our corporate headquarters) to work from home on a temporary basis. We have also taken additional measures in response to the COVID-19 pandemic including screening our employees, providing them with personal protective equipment, and altering work environments to facilitate social distancing.

Furthermore, we are working to mitigate the impact of social distancing for our customers and their patients. These efforts include moving most of our clinical education program critical to doctor engagement online, launching our Invisalign Virtual Appointment tool and launching the Invisalign Virtual Care Program.

Moreover, as it relates to our products we have provided advice regarding the safety and efficacy of various treatment options doctors are considering as their practices adapt to patient concerns and governmental requirements limiting or reducing the frequency of in-patient appointments, we have purchased equipment to manufacture personal protective equipment and distributed the equipment to doctors and hospitals, and we have redirected shipments to optimize patient care, as needed. Our support to doctors also extends to the financial challenges they may encounter, including providing the assistance of industry experts and helping as they consider strategic relationships with lenders that can help improve their cash flow.

The COVID-19 pandemic continues to impact our employees, customers and the global economy in unprecedented ways. At this time, we believe the markets we serve are recovering from COVID-19 preventative measures at differing rates and times corresponding with regional outbreaks and recoveries. However, the strategic re-implementation of preventative COVID-19 measures in one or more of our principal markets remains possible and could materially impact our business and results of operations in the third quarter of 2020 and beyond.

Please refer to “Risk Factors” for further discussion of the impact of the COVID-19 pandemic on our business.

2020 Expenses

Overall, we expect expenses in 2020 to slightly increase over 2019 levels; however, as a result of the financial impacts of COVID-19, we expect to control our discretionary spend, such as travel and meeting related expenses, and focus investments in the following key areas:

- Manufacturing capacity and facilities to enhance our regional capabilities;
- Sales and marketing, including additional direct sales force personnel and consumer marketing; and
- Product and technology innovation to enhance product efficiency and operational productivity.

We believe that these investments will position us to take advantage of a recovering market, increasing our revenues and growing our market share over the long term, but they could negatively impact our results of operations, particularly in the near term.

Results of Operations

Net Revenues by Reportable Segment

We group our operations into two reportable segments: Clear Aligner segment and Imaging Systems and CAD/CAM Services (“Systems and Services”) 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 and Invisalign First.

- Non-Comprehensive Products include, but are not limited to, Invisalign Moderate, Lite and Express packages and Invisalign Go.
- Non-Case includes, but is not limited to, Vivera retainers along with our training and ancillary products for treating malocclusion.
- Our Systems and Services segment consists of our iTero intraoral scanning systems, which includes a single hardware platform and restorative or orthodontic software options, OrthoCAD services and ancillary products, as well as exocad's software solution that integrates workflows to dental labs and dental practices.

Net revenues for our Clear Aligner and Systems and Services segments by region for the three and six months ended June 30, 2020 and 2019 are as follows (in millions):

Net Revenues	Three Months Ended June 30,				Six Months Ended June 30,			
	2020	2019	Net Change	% Change	2020	2019	Net Change	% Change
Clear Aligner revenues:								
Americas	\$ 123.3	\$ 248.5	\$ (125.3)	(50.4)%	\$ 378.9	\$ 493.9	\$ (115.0)	(23.3)%
International	155.2	216.5	(61.2)	(28.3)%	351.1	411.3	(60.3)	(14.7)%
Non-case	19.8	31.7	(11.9)	(37.5)%	50.0	60.7	(10.7)	(17.6)%
Total Clear Aligner net revenues	\$ 298.3	\$ 496.7	\$ (198.4)	(39.9)%	\$ 780.0	\$ 965.9	\$ (186.0)	(19.3)%
Systems and Services net revenues	54.0	104.0	(50.0)	(48.1)%	123.3	183.8	(60.4)	(32.9)%
Total net revenues	\$ 352.3	\$ 600.7	\$ (248.4)	(41.3)%	\$ 903.3	\$ 1,149.7	\$ (246.4)	(21.4)%

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 six months ended June 30, 2020 and 2019 is as follows (in thousands):

Region	Three Months Ended June 30,				Six Months Ended June 30,			
	2020	2019	Net Change	% Change	2020	2019	Net Change	% Change
Americas	101.0	212.7	(111.7)	(52.5)%	314.5	425.9	(111.4)	(26.2)%
International	120.9	165.8	(44.9)	(27.1)%	266.8	312.0	(45.2)	(14.5)%
Total case volume	221.9	378.5	(156.6)	(41.4)%	581.3	737.9	(156.6)	(21.2)%

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

For the three and six months ended June 30, 2020, total net revenues decreased by \$248.4 million and \$246.4 million as compared to the same periods in 2019 primarily as a result of lower Clear Aligner volumes and lower Systems and Services net revenues in most regions.

Clear Aligner - Americas

For the three months ended June 30, 2020, Americas net revenues decreased by \$125.3 million as compared to the same period in 2019 primarily due to lower Clear Aligner volume which decreased revenues by \$130.5 million. The volume decrease was slightly offset by higher ASP, which increased net revenues by \$5.3 million. Higher ASP was a result of lower net deferrals which increased net revenues by \$6.7 million, in addition to July 2019 price increases across most products and higher revenues from other case revenues contributed \$5.4 million to the revenue growth. The ASP increases were partially offset by higher promotional discounts and unfavorable foreign exchange rates that reduced net revenues by \$7.3 million.

For the six months ended June 30, 2020, Americas net revenues decreased by \$115.0 million as compared to the same period in 2019 primarily due to lower Clear Aligner volume that decreased revenues by \$129.0 million. The volume decrease was partially offset by higher ASP which increased net revenues by \$14.2 million as a result of July 2019 price increases across most products which contributed \$18.4 million to the revenue growth, and lower net deferrals which increased net revenues by \$11.5 million. In addition, net revenues increased slightly due to a product mix shift towards products with higher ASP.

primarily driven by decreased SDC revenues which carried a lower ASP. The ASP increases were partially offset by higher promotional discounts that reduced net revenues by \$17.9 million in addition to unfavorable foreign exchange rates.

Clear Aligner - International

For the three months ended June 30, 2020, International net revenues decreased by \$61.2 million as compared to the same period in 2019 primarily due to decreased Clear Aligner volume which decreased revenues by \$58.6 million. In addition, Clear Aligner ASP decreased slightly as a result of higher promotional discounts and unfavorable foreign exchange rates that reduced net revenues by \$15.0 million partially offset by July 2019 price increases across most products which increased revenues by \$6.8 million and lower net deferrals and increased other case revenues which increased net revenues by \$6.2 million.

For the six months ended June 30, 2020, International net revenues decreased by \$60.3 million as compared to the same period in 2019 primarily due to lower Clear Aligner volume which decreased net revenues by \$59.6 million. In addition, we had lower ASP which was a result of higher promotional discounts that reduced net revenues by \$15.8 million, unfavorable foreign exchange rates and a product mix shift towards lower priced products that combined reduced net revenues by \$11.9 million. The ASP decreases were mostly 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 \$16.5 million, and lower net deferrals that increased net revenues by \$9.3 million.

Clear Aligner - Non-Case

For the three and six months ended June 30, 2020, non-case net revenues, consisting of Vivera Retainers, training fees and other product revenues, decreased by \$11.9 million and \$10.7 million as compared to the same periods in 2019. This was primarily due to decreased Vivera volume and training revenues across all regions.

Systems and Services

For the three months ended June 30, 2020, Systems and Services net revenues decreased by \$50.0 million as compared to the same period in 2019 primarily due to a lower number of scanners recognized decreasing net revenues by \$46.8 million, lower scanner ASP decreasing net revenues by \$4.2 million and lower iTero service revenues. These decreases were slightly offset by the addition of exocad revenues from our acquisition.

For the six months ended June 30, 2020, Systems and Services net revenues decreased by \$60.4 million as compared to the same period in 2019 primarily due to a lower number of scanners recognized which decreased net revenues by \$46.8 million and a lower scanner ASP which decreased net revenues by \$21.7 million. The ASP decrease was mostly due to higher promotional discounts and a product mix shift to lower priced scanners. These decreases were partially offset by higher services revenues which increased net revenues by \$8.1 million mostly due to a larger scanner install base and the addition of exocad revenues from our acquisition.

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

	Three Months Ended June 30,			Six Months Ended June 30,		
	2020	2019	Change	2020	2019	Change
Clear Aligner						
Cost of net revenues	\$ 106.0	\$ 130.6	\$ (24.6)	\$ 236.1	\$ 248.4	\$ (12.3)
% of net segment revenues	35.5 %	26.3 %		30.3 %	25.7 %	
Gross profit	\$ 192.4	\$ 366.1	\$ (173.8)	\$ 543.9	\$ 717.5	\$ (173.6)
Gross margin %	64.5 %	73.7 %		69.7 %	74.3 %	
Systems and Services						
Cost of net revenues	\$ 22.0	\$ 37.8	\$ (15.8)	\$ 48.5	\$ 66.9	\$ (18.4)
% of net segment revenues	40.8 %	36.4 %		39.3 %	36.4 %	
Gross profit	\$ 32.0	\$ 66.1	\$ (34.2)	\$ 74.8	\$ 116.9	\$ (42.1)
Gross margin %	59.2 %	63.6 %		60.7 %	63.6 %	
Total cost of net revenues	\$ 128.0	\$ 168.4	\$ (40.4)	\$ 284.6	\$ 315.3	\$ (30.7)
% of net revenues	36.3 %	28.0 %		31.5 %	27.4 %	
Gross profit	\$ 224.3	\$ 432.3	\$ (208.0)	\$ 618.7	\$ 834.4	\$ (215.7)
Gross margin %	63.7 %	72.0 %		68.5 %	72.6 %	

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

Cost of net revenues for our Clear Aligner and Systems and Services 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 and six months ended June 30, 2020, our gross margin decreased as compared to the same periods in 2019 primarily due to lower clear aligner volumes resulting in higher costs per case.

Systems and Services

For the three and six months ended June 30, 2020, our gross margin decreased compared to the same periods in 2019 primarily driven by a decrease in manufacturing volumes and lower ASP. These factors were offset in part by lower service support costs.

Selling, general and administrative (in millions):

	Three Months Ended June 30,			Six Months Ended June 30,		
	2020	2019	Change	2020	2019	Change
Selling, general and administrative	\$ 257.0	\$ 267.9	\$ (11.0)	\$ 539.9	\$ 515.1	\$ 24.8
% of net revenues	72.9 %	44.6 %		59.8 %	44.8 %	

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

Selling, general and administrative expense includes personnel-related costs including payroll, commissions and stock-based compensation 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 June 30, 2020, selling, general and administrative expense decreased compared to the same period in 2019 primarily due to a decrease in advertising and marketing costs of \$12.6 million and a decrease in travel related costs of \$11.3 million due to the impact of COVID-19. These decreases were partially offset by higher equipment, software and maintenance expenses of \$7.7 million and legal and outside service costs of \$5.9 million including transaction costs related to our acquisition of exocad.

For the six months ended June 30, 2020, selling, general and administrative expense increased compared to the same period in 2019 primarily due to higher expenses from equipment, software and maintenance costs of \$13.3 million, legal and outside service costs of \$9.5 million including transaction costs related to our acquisition of exocad and higher compensation related costs of \$9.6 million mainly from increased headcount resulting in higher salaries expense, fringe benefits and stock-based compensation partially offset by lower incentive compensation. These increases were offset in part by a decrease in travel related costs of \$9.5 million due to the impact of COVID-19.

Research and development (in millions):

	Three Months Ended June 30,			Six Months Ended June 30,		
	2020	2019	Change	2020	2019	Change
Research and development	\$ 40.4	\$ 38.9	\$ 1.5	\$ 81.9	\$ 76.4	\$ 5.5
% of net revenues	11.5 %	6.5 %		9.1 %	6.6 %	

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 six months ended June 30, 2020, research and development expense increased compared to the same period in 2019 primarily due to higher equipment and material costs in addition to higher compensation costs mainly from increased headcount resulting in higher salaries expense, fringe benefits and stock-based compensation which was partially offset by lower incentive compensation.

Impairments and other charges (in millions):

	Three Months Ended June 30,			Six Months Ended June 30,		
	2020	2019	Change	2020	2019	Change
Impairments and other charges	\$ —	\$ —	\$ —	\$ —	\$ 29.8	\$ (29.8)
% of net revenues	— %	— %		— %	2.6 %	

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

During the six months ended June 30, 2019, we recorded impairments and other charges of \$29.8 million due to costs related to the Invisalign store closures. The impairments and other charges are comprised of operating lease right-of-use assets impairments of \$14.2 million, store leasehold improvement and other fixed asset impairments of \$14.3 million, and employee severance and other expenses of \$1.3 million (Refer to Note 8 “Impairments and Other Charges” and Note 9 “Legal Proceedings” of the Notes to Condensed Consolidated Financial Statements for more information).

Litigation settlement gain (in millions):

	Three Months Ended June 30,			Six Months Ended June 30,		
	2020	2019	Change	2020	2019	Change
Litigation settlement gain	\$ —	\$ (51.0)	\$ 51.0	\$ —	\$ (51.0)	\$ 51.0
% of net revenues	— %	(8.5) %		— %	(4.4) %	

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

For the three and six months ended June 30, 2019, we recorded a gain of \$51.0 million due to the litigation settlement with Straumann.

Income (loss) from operations (in millions):

	Three Months Ended June 30,			Six Months Ended June 30,		
	2020	2019	Change	2020	2019	Change
Clear Aligner						
Income from operations	\$ 38.9	\$ 244.0	\$ (205.1)	\$ 205.3	\$ 402.7	\$ (197.4)
Operating margin %	13.0 %	49.1 %		26.3 %	41.7 %	
Systems and Services						
Income from operations	\$ 2.9	\$ 39.3	\$ (36.4)	\$ 17.3	\$ 67.5	\$ (50.2)
Operating margin %	5.4 %	37.8 %		14.0 %	36.7 %	
Total income (loss) from operations ¹	\$ (73.0)	\$ 176.5	\$ (249.5)	\$ (3.1)	\$ 264.2	\$ (267.3)
Operating margin %	(20.7)%	29.4 %		(0.3)%	23.0 %	

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 Condensed Consolidated Income from Operations.

Clear Aligner

For the three months ended June 30, 2020, our operating margin decreased compared to the same period in 2019 primarily due to a lower Clear Aligner gross margin due to decreased volumes and a gain recognized from the litigation settlement with Straumann during the second quarter of 2019.

For the six months ended June 30, 2020, our operating margin decreased compared to the same period in 2019 primarily due to a lower Clear Aligner gross margin due to decreased volumes and a gain recognized from the litigation settlement with Straumann during the second quarter of 2019. These decreases were offset in part by costs recognized in the first quarter of 2019 related to the Invisalign store closures.

Systems and Services

For the three and six months ended June 30, 2020, our operating margin decreased compared to the same periods in 2019 primarily driven by a lower Systems and Services gross margin primarily due to a lower number of scanners recognized.

Interest income (in millions):

	Three Months Ended June 30,			Six Months Ended June 30,		
	2020	2019	Change	2020	2019	Change
Interest income	\$ 0.5	\$ 3.5	\$ (3.0)	\$ 2.5	\$ 6.1	\$ (3.6)
% of net revenues	0.1 %	0.6 %		0.3 %	0.5 %	

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

Interest income includes interest earned on cash, cash equivalents, investment balances and our unsecured promissory note.

For the three and six months ended June 30, 2020, interest income decreased compared to the same periods in 2019 mainly due to the divestiture of our marketable securities portfolio during the first quarter of 2020 and lower interest rates.

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

	Three Months Ended June 30,			Six Months Ended June 30,		
	2020	2019	Change	2020	2019	Change
Other income (expense), net	\$ (1.0)	\$ 13.9	\$ (14.9)	\$ (19.5)	\$ 8.1	\$ (27.7)
% of net revenues	(0.3)%	2.3 %		(2.2)%	0.7 %	

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 June 30, 2020, other income (expense), net decreased compared to the same period in 2019 primarily due to the \$15.8 million gain from the sale of our investment in SDC that was recorded during the three months ended June 30, 2019. This decrease was partially offset by net foreign exchange gains in the three months ended June 30, 2020 as compared to net foreign exchange losses in the same period in 2019.

For the six months ended June 30, 2020, other income (expense), net decreased compared to the same period in 2019 primarily due to the \$15.8 million gain from the sale of our investment in SDC that was recorded during the six months ended June 30, 2019 and higher losses in the current period including a \$10.2 million loss on a foreign currency forward contract related to the exocad acquisition in addition to foreign exchange net losses.

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

	Three Months Ended June 30,			Six Months Ended June 30,		
	2020	2019	Change	2020	2019	Change
Equity in losses of investee, net of tax	\$ —	\$ 3.6	\$ (3.6)	\$ —	\$ 7.5	\$ (7.5)
% of net revenues	— %	0.6 %		— %	0.7 %	

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

For the three and six months ended June 30, 2020, there were no equity in losses of investee, net of tax. 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 (Refer to Note 6 “Equity Method Investments” of the Notes to Condensed Consolidated Financial Statements for details on equity method investments).

Provision for (benefit from) income taxes (in millions):

	Three Months Ended June 30,			Six Months Ended June 30,		
	2020	2019	Change	2020	2019	Change
Provision for (benefit from) income taxes	\$ (32.9)	\$ 43.1	\$ (76.0)	\$ (1,497.7)	\$ 51.9	\$ (1,549.6)
Effective tax rates	44.8 %	22.2 %		7,437.0 %	18.6 %	

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

During the six months ended June 30, 2020, we completed an intra-entity transfer of certain intellectual property rights and fixed assets to our Swiss subsidiary, where our EMEA regional headquarters is located beginning January 1, 2020. The transfer of intellectual property rights did not result in a taxable gain; however, it did result in a step-up of the Swiss tax deductible basis in the transferred assets, and accordingly, created a temporary difference between the book basis and the tax basis of such intellectual property rights. Consequently, this transaction resulted in the recognition of a deferred tax asset and related one-time tax benefit of approximately \$1,493.5 million during the six months ended June 30, 2020, which is the net impact of the deferred tax asset recognized as a result of the additional Swiss tax deductible basis in the transferred assets and certain costs related to the transfer of fixed assets and inventory.

Our benefit from income taxes was \$32.9 million for the three months ended June 30, 2020 and our provision for income taxes was \$43.1 million for the three months ended June 30, 2019, representing effective tax rates of 44.8% and 22.2%, respectively. Our benefit from income taxes was \$1,497.7 million for the six months ended June 30, 2020 and our provision for income taxes was \$51.9 million for the six months ended June 30, 2019, representing effective tax rates of 7,437.0% and 18.6%, respectively. Our effective tax rate differs from the statutory federal income tax rate of 21% for the three months ended June 30, 2020 primarily due to the recognition of additional tax benefits resulting from changes in annual effective tax rate caused by a shift in jurisdictional mix of forecasted annual income. Our effective tax rate differs from the statutory federal income tax rate of 21% for the six months ended June 30, 2020 mainly as a result of the aforementioned intra-entity transfer and the recognition of excess tax benefits related to stock-based compensation, partially offset by unrecognized tax benefits associated with certain foreign payments. Our effective tax rate differs from the statutory federal income tax rate of 21% for the three and six months ended June 30, 2019 mainly as a result of the recognition of excess tax benefits related to stock-based compensation and certain foreign earnings, primarily from the Netherlands and Costa Rica, being taxed at lower tax rates.

The increase in our effective tax rate for the three months ended June 30, 2020 compared to the same period in 2019 is primarily attributable to the tax impact of a higher annual forecasted effective tax rate driven by changes in the jurisdictional mix of forecasted income. The increase in our effective tax rate for the six months ended June 30, 2020 compared to the same period in 2019 is primarily attributable to the recognition of a deferred tax asset related to the intra-entity transfer of certain intellectual property rights during the six months ended June 30, 2020. While the recognition of a deferred tax asset would normally cause a reduction in tax rate, due to our net loss before tax for the six months ended June 30, 2020, it has the effect of increasing the effective tax rate.

Liquidity and Capital Resources

We fund our operations from product sales. As of June 30, 2020 and December 31, 2019, we had the following cash and cash equivalents and short-term marketable securities (in thousands):

	June 30, 2020	December 31, 2019
Cash and cash equivalents	\$ 404,359	\$ 550,425
Marketable securities, short-term	—	318,202
Total	\$ 404,359	\$ 868,627

Cash equivalents and marketable securities are comprised of money market funds and highly liquid debt instruments which primarily include commercial paper, corporate bonds, U.S. government agency bonds, U.S. government treasury bonds and certificates of deposit.

As of June 30, 2020, approximately \$244.2 million of cash and cash equivalents was held by our foreign subsidiaries. Our intent is to permanently reinvest our earnings from our international operations going forward, and our current plans do not require us to repatriate them to fund our U.S. operations as we generate sufficient domestic operating cash flow and have access to external funding under our revolving line of credit.

On April 1, 2020, we paid \$420.8 million, net of \$9.2 million cash acquired, from our cash on hand to complete our acquisition of exocad.

Our business has been materially adversely affected by the COVID-19 pandemic and the global and regional efforts by governments to mitigate its spread, and we expect the adverse impacts to our business to continue. We believe that our current cash balances and the borrowing capacity under our credit facility, if necessary, will be sufficient to fund our business for at least the next 12 months. However, as a result of the COVID-19 pandemic, we expect to experience reduced cash flow from operations as a result of decreased revenues and slower collections on our accounts receivable. For additional information regarding the impact of COVID-19 on our liquidity and capital resources, refer to *Item 1A "Risk Factors."*

Cash flows (in thousands):

	Six Months Ended June 30,	
	2020	2019
Net cash flow provided by (used in):		
Operating activities	\$ 69,684	\$ 294,561
Investing activities	(172,326)	(321,020)
Financing activities	(36,376)	(188,381)
Effect of exchange rate changes on cash, cash equivalents, and restricted cash	(7,172)	1,467
Net decrease in cash, cash equivalents, and restricted cash	\$ (146,190)	\$ (213,373)

Operating Activities

For the six months ended June 30, 2020, cash flows from operations of \$69.7 million resulted primarily from our net income of approximately \$1.5 billion as well as the following:

Significant non-cash activities

- Deferred taxes of \$1.5 billion related to the one-time tax benefit associated with the intra-entity sale of certain intellectual property rights;
- Stock-based compensation of \$47.9 million related to equity awards granted to employees and directors;

- Depreciation and amortization of \$44.3 million related to our investments in property, plant and equipment and intangible assets;
- Allowance for doubtful accounts of \$12.6 million related to slower collections; and
- Non-cash operating lease cost of \$11.1 million.

Significant changes in working capital

- Decrease of \$106.6 million in accrued and other long-term liabilities due to timing of payment and activities;
- Decrease of \$64.6 million in accounts receivable which is primarily a result of the decrease in net revenues due to the impact of COVID-19;
- Increase of \$40.9 million in deferred revenues corresponding primarily to cases eligible under our additional aligner policy and timing of revenue recognition; and
- Increase of \$31.1 million in prepaid expenses and other assets due to the timing of payments and activities.

Investing Activities

Net cash used in investing activities was \$172.3 million for the six months ended June 30, 2020 which primarily consisted of cash paid for the acquisition of exocad of \$420.8 million, net of cash acquired, purchases of property and plant and equipment purchases of \$80.5 million and purchases of marketable securities of \$5.3 million. These outflows were partially offset by maturities and sales of marketable securities of \$321.5 million and payments of \$11.1 million received on an unsecured promissory note issued by SDC in exchange for tendering our shares to them.

For the remainder of 2020 we expect to invest an additional \$90.0 million to \$100.0 million in capital expenditures related to building purchases and improvements as well as additional manufacturing capacity to support our international expansion.

Financing Activities

Net cash used in financing activities was \$36.4 million for the six months ended June 30, 2020 which consisted of payroll taxes paid for equity awards through share withholdings of \$47.0 million which was partially offset by \$10.7 million of proceeds from the issuance of common stock.

Common Stock Repurchases

As of June 30, 2020, we have \$100.0 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, 2019 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 balances and the borrowing capacity under our credit facility, if necessary, will be sufficient to fund our business for at least the next 12 months. However, as a result of the COVID-19 pandemic, we expect to experience reduced cash flow from operations as a result of decreased revenues and slower collections on our accounts receivable. 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 June 30, 2020, 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 10 “Commitments and Contingencies” of the Notes to Consolidated Financial Statements* included in our Annual Report on Form 10-K.

Critical Accounting Policies and Estimates

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

Other than the addition of the Business Combinations policy and the amendment of the Systems and Services (formerly named "Scanner") Revenue Recognition policy, 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, 2019. The addition of the Business Combinations policy and the amendment of the Systems and Services Revenue Recognition policy are discussed in *Note 1 "Summary of Significant Accounting Policies" of the Notes to Condensed Consolidated Financial Statements*.

Recent Accounting Pronouncements

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

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

In the normal course of business, we are exposed to foreign currency exchange rate and interest rate risks that could impact our financial position and results of operations. In addition, we are subject to the broad market risk that is created by the global market disruptions and uncertainties resulting from the COVID-19 pandemic. Please refer to *Item 1A "Risk Factors"* for further discussion of the impact of the COVID-19 pandemic on our business.

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 June 30, 2020, we had no investments 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 June 30, 2020, 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 primarily 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. Prior to the closing of the

exocad acquisition on April 1, 2020, we entered into a Euro foreign currency forward contract with a notional contract amount of €376.0 million. During the six months ended June 30, 2020, we recognized a loss of \$10.2 million within other income (expense), net in our Condensed Consolidated Statement of Operation. 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.

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 June 30, 2020, 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 June 30, 2020 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

For a discussion of legal proceedings, refer to Note 9 "Legal Proceedings" of the Notes to Condensed Consolidated Financial Statements in Part I, Item 1 of this Form 10-Q.

ITEM 1A. RISK FACTORS

The following discussion is divided into two sections. The first, entitled "Risks Relating to our Business," discusses some of the risks that may affect our business, results of operations and financial condition. The second, captioned "Risks Related to our Common Stock," discusses some of the risks related to owning our common stock. You should carefully review both sections, as well as our consolidated financial statements and notes thereto and other information appearing in this Quarterly Report on Form 10-Q, for important information regarding these and other risks that may affect us. The fact we have chosen to list one section before the other or we have identified risks in either section earlier than others should not be interpreted to mean we deem any risks to be more or less important or more likely to occur than others or, if any do occur, that their impact may be any less significant than others. These risk factors should be considered in connection with evaluating the forward-looking statements contained in this report because they could cause our actual results and conditions to differ materially from those statements. Before you invest in Align, you should know that investing involves risks, including those described below. The risks below are not the only ones we face. If any of the risks actually occur, our business, financial condition and results of operations could be negatively affected, the trading price of our common stock could decline, and you may lose all or part of your investment.

Risks Relating to our Business

Our results of operations have been materially adversely affected by the COVID-19 pandemic and the global and regional efforts by governments to mitigate its spread and we expect the adverse impacts to our business to continue.

The spread of COVID-19 has created significant, widespread and unprecedented volatility, uncertainty, and economic instability, disrupting the global economy, our operations and the businesses of our customers and suppliers. Protective and preventative efforts to stop or minimize its spread have and continue to center on minimizing its transmission through decreased social interactions (social distancing). As a result of measures imposed by the governments in certain affected regions starting in the first quarter of 2020, many commercial activities, businesses and schools were suspended as part of quarantines and other measures intended to contain this pandemic. Because COVID-19 spreads readily through airways in nasal passages and the mouth, our principal customers, dentists and orthodontists and their patients, were an initial primary focus of the protective and preventative efforts. For instance, in many countries governments and dental regulatory associations acted quickly to prohibit non-essential dental procedures; thereby materially limiting or preventing our customers from conducting most or all business activities and materially adversely harming our sales and sales efforts. Since then, the preventative measures have been reduced such that by the end of the second quarter of 2020, dental practices across every region had largely reopened and were seeing patients, although at varying degrees of previous capacities based on differing regions and times.

In response to COVID-19, we implemented numerous measures to minimize its spread for the health and safety of our employees, customers, patients and the communities in which we live and work as well as in accordance with guidelines, orders and decrees of governmental agencies throughout the world. These measures included diagnostic screenings at our facilities, increased social distancing at clinical and manufacturing facilities, temporary closures of physical offices, manufacturing and treatment planning facilities, including our corporate headquarters in the U.S. and regional headquarters in Europe, the Americas and Asia, mandating that a large percentage of our global workforce work remotely, prohibiting non-essential travel, and converting our manufacturing facilities to produce personal protective equipment. The actions we have taken and any further health and safety measures we may be required or choose to implement in response to the pandemic are and may be highly disruptive to our business, and may ultimately prove insufficient to prevent employees or their relatives from getting ill, potentially severely, and potentially impacting our operations. Even if these measures are completely or partially effective, if employees perceive them to be inadequate, or alternatively, overly burdensome, or they prove difficult to maintain over extended periods of time, productivity may decline or we may experience employee unrest, slowdowns or stoppages or other demands, we may be unable to timely meet customer demand or fulfill existing orders, the costs to deliver our products may increase or we may be required to store products that cannot be delivered to closed orthodontic and dental offices, and we may be subject to increased litigation, including for claims related to product liability and worker safety and working conditions.

As the economic impact of the implementation of the various protective and preventative measures continues to unfold, we are continually evaluating macroeconomic as well as industry-specific factors, including how and to what extent our business and financial results are or may be impacted as well as those of our customers and suppliers, and the financial health and stability of businesses and consumers overall depends on numerous evolving factors, many of which we cannot control nor accurately predict. Examples include:

- the duration, scope, and severity of the pandemic;
- future governmental actions mandated, or business and societal actions taken, in response to the pandemic;
- the speed and time frames in which dental practices reopen and demand for our products increases and our ability to timely and effectively respond;
- the impact on worldwide economic activity and employment rates and actions taken by central banks and governments;
- demand for products and services, particularly those that may be deemed discretionary or that can be delayed or cancelled, particularly in an environment of high unemployment;
- the liquidity and financial stability of consumers, customers, and patients, including their willingness to purchase our products and services at existing, or any, prices and delays paying for products or services, requests for extended payment terms, or payment defaults;
- the ability or willingness of our suppliers or others in our supply chains to timely provide materials and make deliveries on our behalf;
- travel restrictions, including those that adversely impair or prohibit patients from visiting their physicians and our sales personnel from interacting with customers;
- diversion of management as they focus on the short- and long-term ramifications of the pandemic;
- actions by our competitors such as price reductions, aggressive product promotions, and mergers and consolidations;
- the confidence of our customers and patients that our products and solutions are sanitary and safe to use;
- trade restrictions and sanctions;

- restrictions or limitations on the ability of our customers to effectively use digital platforms and applications when governmental mandates or societal pressures limit physical interactions with patients; and
- data privacy and cybersecurity risks from new or expanded use of remote working and/or teledentistry by our suppliers, customers, and us, including new or expanded use of online service platforms, products and solutions such as video conferencing applications, inadequately secured computing networks or servers, overheard telephone conversations, viewable computer screens, stolen passwords or access information, increased phishing and other online cyber threats.

A sustained downturn may also result in the carrying value of our goodwill or other intangible assets, including those as a result of the exocad acquisition that closed in April 2020, exceeding their fair value, which may require us to recognize an impairment to those assets.

The effects of the pandemic, including remote working arrangements for employees, may also impact our financial reporting systems and internal control over financial reporting, including our ability to ensure information required to be disclosed in our current, quarterly and annual reports under the Securities Exchange Act of 1934, as amended, is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow for timely decisions regarding required disclosure.

Events are changing rapidly and we cannot at this time predict the impact on our business or results of operations; however, the pandemic or the perception of its effects could continue to have a material adverse effect on our business, financial condition, results of operations, cash flows and stock price in the future. Moreover, the pandemic could worsen in countries that are already afflicted, could continue to spread to additional countries, or could return to countries where the pandemic was thought to have been partially contained, each of which could further adversely impact our operations, the businesses of our orthodontist and dentist customers, and economic activity generally.

Our net revenues are dependent primarily on our Invisalign System and iTero Scanners and any decline in sales or average selling price of these products for any reason, would adversely affect net revenues, gross margin and net income.

Our net revenues are largely dependent on the sales of our Invisalign System of clear aligners and iTero intraoral scanners. Of the two, we expect net revenues from the sale of the Invisalign System, primarily our comprehensive products, will continue to account for the vast majority of our net revenues for the foreseeable future. Continued and widespread acceptance of the Invisalign System by orthodontists, GPs and consumers is critical to our future success. Our iTero scanners are used by dental professionals for restorative and orthodontic procedures as well as Invisalign System case submissions. Sales of our iTero scanners have grown, becoming a larger percentage of our overall revenues and as a means to further adoption of digital dentistry and the Invisalign System, and we expect the acquisition of exocad Global Holdings GmbH ("exocad") will complement our iTero scanners to support sales of our Invisalign System. If orthodontists and GPs experience a reduction in consumer demand for orthodontic services, if consumers prove unwilling to adopt Invisalign System treatment as rapidly or in the volumes we anticipate and at the prices offered, if orthodontists or GPs choose to use wires and brackets or competitive products rather than Invisalign, if sales of our iTero scanners decline or fail to grow sufficiently or as expected, if the acquisition of exocad does not produce the results expected, or if the average selling price of our products decline for any reason, particularly in the case of our Invisalign System as a result of a shift in product mix towards lower priced products or as a result of promotions, or competition, 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.

The dental industry is in a period of immense and rapid transformation involving products, technologies, distribution channels and business models, much of which is based on digital transformation involving information technology, data, artificial intelligence, scanning, 3D printing, software and algorithms. While our clear aligner and iTero scanners facilitate this transition, there remains significant uncertainty concerning the technologies that will achieve market acceptance and, if adopted, whether and when they may become obsolete as new offerings become available.

Currently, our clear aligner products compete directly against traditional metal brackets and wires and increasingly against clear aligner products manufactured and distributed by new market entrants as well as traditional manufacturers of wires and brackets, both within and outside the U.S., and from traditional medical device companies, laboratories, startups and, in some cases, doctors themselves. Although the number and type of competitors varies by segment, geography and customer, we encounter a wide variety of competitors, including new and 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 of our key patents beginning in 2017, competition in the clear aligner market has

increased. Competitors include existing larger companies able to leverage existing dental market channels to compete directly with us, direct-to-consumer (“DTC”) companies that provide clear aligners using a remote teledentistry model requiring little or no in-office care from trained and licensed physicians, and doctors themselves who can manufacture custom aligners in their offices using modern 3D printing technology. In addition, corresponding foreign patents began expiring in 2018 which has resulted in increased international competition. Large consumer product companies may also enter the orthodontic supply market.

The manipulation and movement of teeth and bone is a delicate process with potentially painful and debilitating results if not appropriately performed and monitored. Accordingly, we remain committed to delivering our solutions primarily through trained and skilled doctors. Invisalign Treatment requires a doctor's prescription and an in person physical examination of the patient's dentition before beginning treatment; however, with the advent of DTC providers accompanied by significant advertising campaigns, there has been a shift away from traditional practices that may impact our primary selling channels. We also believe doctors are sampling alternative products and/or taking advantage of wires and brackets bundles that essentially give clear aligners away for free or at reduced prices. In addition, we may also face competition in the future from new companies that introduce new technologies. We may be unable to compete with these competitors or 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 new technologies, 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 and profitability, loss of market share, and result in the reduction of dental professionals' efforts and commitment to use our products, any of which could materially adversely affect 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 clinical treatment plans (“ClinCheck”), 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 and we are continuing to establish these functions closer to our international customers to improve doctor and patient experiences and our operational efficiency. Also, in addition to research and development efforts conducted in the U.S., Russia, Israel and now Germany with the acquisition of exocad, we have operations in Israel and China where we assemble wands and manufacture our intraoral scanner. 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 managing international operations, including any travel restrictions on us or our customers such as those recently imposed domestically and globally in response to the COVID-19 pandemic;
- fluctuations in currency exchange rates;
- import and export controls, license requirements and restrictions;
- controlling production volume and quality of the manufacturing process;
- political, military, social, economic, or business instability, acts of terrorism and acts of war, including increased levels of violence in Juarez, Mexico, Hong Kong 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 may be called for additional active duty under emergency circumstances. We cannot predict the full impact of these conditions on us, particularly if emergency circumstances or an escalation in political situations occur. 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;
- general geopolitical instability and the responses to it, such as the possibility of sanctions, trade restrictions and changes in tariffs, including recent sanctions against China and Russia and tariffs imposed by the U.S. and China and the possibility of additional tariffs or other trade restrictions between the U.S. and Mexico;
- interruptions and limitations in telecommunication services;
- production or material transportation delays or disruption, including as a result of customs clearance, violence, protests, workforce unrest, slowdowns or stoppages, police and military actions, or as a result of natural disasters, such as earthquakes or volcanic eruptions and pandemics like the current COVID-19 pandemic;
- burdens of complying with a wide variety of regional and local laws, including competition and anti-bribery laws;

- the impact of government-led initiatives to encourage the purchase or support of domestic vendors, which can affect the willingness of customers to purchase products from, or collaborate to promote interoperability of products with, companies whose headquarters or primary operations are not domestic;
- unexpected issues and expenses related to our corporate structure reorganization;
- reduced intellectual property rights protections as compared to the U.S.;
- longer payment cycles and greater difficulty in accounts receivable collection; and
- potential adverse tax consequences.

The United Kingdom's ("U.K.") withdrawal from the European Union ("EU") on January 31, 2020, 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. 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. As the withdrawal continues to unfold, the actual implications of Brexit in their entirety are unlikely to be known for years.

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

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 penetrate international markets 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 markets we believe to have high-growth potential. Our international operations are subject to risks that are customarily encountered in non-U.S. operations, including:

- local political and economic instability;
- the engagement in 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 U.S. 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;
- increased expense of developing, testing and making localized versions of our products; and
- health pandemics such as COVID-19 and natural disasters including weather and fires such as those common in California and recently in Australia.

Any of these factors, either individually or in combination, 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 and resistance to non-traditional treatment methods.

Consumer spending habits are affected by, among other things, pandemics, prevailing economic conditions, levels of employment, salaries and wage rates, consumer confidence and consumer perception of current and future economic conditions. A decrease in U.S. or certain international economies or an uncertain economic outlook, both of which are occurring as a result of the COVID-19 pandemic, 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, non-urgent, or higher value procedures or a reduction in the demand for dental services generally, each of which would materially adversely affect 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 and CAD/CAM software. In addition, Invisalign treatment, which currently accounts for the vast majority of our net revenues, represents a significant change from traditional orthodontic treatment involving metal brackets and wires, and customers and consumers may not find it cost-effective or 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 the Invisalign treatment is appropriate for only a limited percentage of 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 and treatment methods.

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

Our success depends on our ability to profitably develop, manufacture, market and obtain regulatory approval or clearance of new products and improvements to existing products. There is no assurance we can successfully develop, sell and achieve market acceptance of new or improved products and services. 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, including our ability to:

- correctly predict, timely develop and cost effectively manufacture or bring to market solutions that meet future customer needs and preferences with the features and functionality they desire or expect;
- allocate our research and development funding to products with higher growth prospects;
- ensure compatibility of our computer operating systems and hardware configurations with those of our customers;
- anticipate and rapidly respond to new competitive products, product offerings and technological innovations;
- differentiate our products and product offerings from our competitors as well as other products in our own portfolio and successfully articulate the benefits of those differences to our customers;
- innovate and develop new technologies and applications;
- qualify for third-party reimbursement for procedures using our products;
- obtain and adequately protect our 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 revenues. 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 may be difficult to gain market share and acceptance, particularly if doctors require education to understand the benefits of the new products or measure their success only after extended periods of time required to treat patients. For instance, it can take up to 24 months or longer to treat patients using our Invisalign System. Similarly, in 2018 we introduced our mandibular advancement treatment and expect it will require significant time and effort on our part to educate doctors of its benefits. Consequently, doctors may be unwilling to rapidly adopt our new products until they successfully complete one or more cases 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 governments. Any failure to successfully develop and introduce or achieve market acceptance of new products or enhancements to existing products could materially adversely affect our operating results and cause our net revenues to decline.

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 customers. In addition, we sell a number of products at different list prices which also differ based on region or country. If we change volume-based discount programs that affect our average selling prices; if we introduce price reductions or consumer rebate programs; if we expand discount programs or participation in these programs increases; if our critical accounting estimates materially differ from actual behavior or results; or if our geographic, channel, or 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. Moreover, we may find that some programs are unsuccessful or, if successful, may drive demand in unexpected ways. Were any of the foregoing to occur, our net revenues, gross profit, gross margin and net income may decline.

We may not achieve the anticipated benefits from our recent acquisition of exocad in the timeframe expected, or at all, which may have an adverse effect on our business and our financial results.

We closed our acquisition of exocad on April 1, 2020. We acquired exocad for its dental CAD/CAM software technology and employees. We believe exocad's tools and features for diagnostic, restorative, implant, and orthodontic workflows will strengthen and extend our digital solutions; helping pave the way for new, seamless cross-discipline dentistry in labs and in practices; extending our Invisalign and iTero solutions while broadening our reach in digital dentistry to exocad's existing and future customer base. However, for a variety of reasons, many of which are outside our control or ability to predict, there can be no guarantee that the acquisition will achieve the desired benefits and synergies or will result in additional sales of either Invisalign or iTero solutions or that the exocad software will continue to succeed in the marketplace.

In addition, successful post-acquisition integrations are difficult to accomplish under normal circumstances for companies with a history of acquisitions. As an organization, we do not have a history of significant acquisitions and attempting to integrate exocad in the midst of the COVID-19 pandemic poses challenges. As such, we may experience difficulties achieving the expected financial, technical or strategic benefits of the acquisition. Potential risks we may experience include:

- difficulties integrating the business of exocad in the timeframes expected or as anticipated and without adversely impacting our existing operations or the operations of exocad;
- technological difficulties uniting our product and service offerings to produce solutions that efficiently and effectively integrate with the workflows between physicians, laboratories and other market participants;
- slower adoption or lack of acceptance of CAD/CAM software in general alone or in combination with other rapidly evolving and groundbreaking advances that are fundamentally changing the dental industry and the way new and existing participants market and provide products and services to consumers;
- diversion of management resources;
- the inability to retain or attract key personnel;
- the failure to accurately estimate the potential markets and market shares for the companies' products, the nature and extent of competitive responses to the acquisition and the ability to achieve or exceed projected market growth rates;
- difficulties cost-effectively integrating and dealing with tax, employment, logistics, and other related issues unique to international operations, particularly when travel restrictions make collaboration efforts more difficult;
- the potential that our due diligence did not uncover risks and potential liabilities associated with the exocad;
- changes in consumer spending habits as a result of, among other things, prevailing economic conditions, levels of employment, salaries and wages and consumer confidence;
- the failure to successfully manage relationships with Align and exocad's historic customers, suppliers and strategic partners and develop new relationships;
- product development delays and errors;
- possible inconsistencies in standards, internal controls, procedures and policies which may make it more difficult to implement and harmonize company-wide financial reporting, forecasting and budgeting, accounting, billing, information technology and other systems;
- all or material portions of the expected synergies and benefits of the acquisition may change or disappear or may take longer to realize, particularly if the impact of the pandemic to the economy overall, or more specifically to orthodontic and dental practices, is lengthy or significant;
- negative impact on our GAAP and non-GAAP results of operations, financial condition, and liquidity from acquisition-related costs, charges, amortization of intangible assets and/or asset or goodwill impairment charges;
- outcomes or rulings in known, or as yet to be discovered, regulatory enforcement, litigation, anti-bribery and corruption or other similar matters that are, alone or in the aggregate, materially adverse;
- our ability to protect our intellectual property rights as well as protect our IT networks from cybersecurity threats and ensure customer and sensitive personal and health data remain secure;
- the potential impact of the acquisition on our future tax rates;
- the failure to successfully advocate the benefits or value proposition of the combined entity or its products to analysts and investors which may harm the market price of our common stock; and
- expectations regarding the continued growth of our international markets and difficulties predicting customer and consumer purchasing behavior, particularly in the midst and aftermath of the COVID-19 pandemic.

If we cannot successfully integrate exocad with our existing business, our results of operations and financial condition could be adversely affected, possibly materially.

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 growing 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 constantly fluctuating, often substantially, exchange rates. As a result, negative movements in exchange rates against the U.S. dollar have and may increasingly adversely affect our net revenues and net income in our consolidated financial statements. We enter into currency forward contract transactions in an effort to cover some of our exposure to currency fluctuations but there is no assurance these transactions will 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 inefficiencies 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 continue to establish additional order acquisition, treatment planning and manufacturing facilities closer to our international customers in order to provide doctors with a better experience, improve their confidence in using Invisalign to treat patients more often and provide redundancy should other facilities be temporarily or permanently unavailable. 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 facilities may be located in higher cost regions compared to Mexico and Costa Rica, which may negatively impact our gross margin. If the transition into additional facilities is significantly delayed or demand for our products exceeds our current expectations, we may be unable to fulfill orders timely, which may negatively impact our financial results, reputation 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. For instance, as a result of the COVID-19 pandemic sales in the final weeks of the first quarter of 2020 declined substantially and operations at our manufacturing facilities declined shortly thereafter. If product demand decreases, remains lower or we fail to forecast demand accurately or if we are required to implement additional protective measures to safeguard employees in manufacturing facilities and offices, we could be required to write off inventory or record excess capacity charges, productivity could decline, or we may be required to purchase or lease additional or larger facilities and additional equipment, any of which may take time to accomplish and may 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, our profitability may decline.

If we are to sustain or increase profitability in future periods, we need to continue increasing our net revenues, while controlling expenses. Because our business is evolving, it is difficult to predict our future operating results or levels of growth or declines, and we have not in the past and may be unable in the future to sustain or regain our historical growth rates which may cause our profitability to decline.

Our operating results have fluctuated in the past and may fluctuate in the future, making it difficult to predict the timing and amount of revenues, costs and expenditures.

Our operating results have fluctuated in the past and we expect our future quarterly and annual operating results to fluctuate for a variety of reasons, particularly as we focus on adjusting to the impacts for COVID-19 and, under ordinary circumstances, increasing doctor and consumer demand for our products. 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;
- changes in geographic, channel, or product mix;
- weakness in consumer spending and confidence as a result of high unemployment or a slowdown in the global, U.S. or other economies;
- higher manufacturing, delivery and inventory costs;
- competition in general and competitive developments in the market;
- changes in relationships with our dental support organizations and distributors, including timing of orders;
- changes in the timing of when revenues are recognized, including as a result of the timing of receipt of product orders and shipments, the introduction of new products and software releases, product offerings or promotions, modifications to our terms and conditions such as payment terms, or as a result of new accounting pronouncements or changes to critical accounting estimates including, without limitation, those estimates based on such matters as our predicted usage of additional aligners;
- the creditworthiness, liquidity and solvency of our customers and their ability to timely make payments when due;
- fluctuations in currency exchange rates against the U.S. dollar;
- our inability to scale, suspend or reduce production based on variations in product demand;
- increased participation in our customer rebate or discount programs could adversely affect our average selling prices;
- seasonal fluctuations, including those related to patient demographics such as teen buying habits in China and Europe as well as 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;
- increased advertising or marketing efforts or aggressive price competition from competitors;
- changes to our effective tax rate;
- unanticipated delays and disruptions in the manufacturing process caused by insufficient capacity or availability of raw materials, turnover in the labor force or the introduction of new production processes, power outages or natural or other disasters, pandemics or general economic conditions impacting the solvency of vendors in our supply chain beyond our control;
- underutilization of manufacturing and treat facilities;
- major changes in available technology or the preferences of customers may cause our current product offerings to become less competitive or obsolete;
- costs and expenditures in connection with litigation;
- costs and expenditures in connection with the establishment of treatment planning and fabrication facilities in international locations;
- costs and expenditures in connection with the hiring and deployment of direct sales force personnel;
- unanticipated delays in our receipt of patient records made through intraoral scanners for any reason;
- disruptions to our business due to political, economic or other social instability or any governmental regulatory or similar actions, including the impact of epidemics and pandemics such as COVID-19, any of which results in changes in consumer spending habits, limiting or restricting customer visits to orthodontists or general practitioners, 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;
- material impairments in the value of our privately held companies; and
- timing of industry tradeshow.

To respond to these and other factors, we may make business decisions that adversely affect our operating results such as modifications to our pricing policy and payment terms, promotions, development efforts, product releases, business structure or operations. Most of our expenses, such as employee compensation and lease obligations, are relatively fixed in the short term. Moreover, our expense levels are based, in part, on our expectations regarding future revenues. As a result, if our net revenues for a particular period fall below expectations, 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. If the operations of these carriers are disrupted for any reason, we may be unable to timely deliver our products to our customers. For instance, domestically and in certain international locations carriers are experiencing significant demand increases as a result of more online orders from consumers sheltering in place because of COVID-19. Alternatively, carriers are also experiencing a greater number of closed businesses making it difficult to deliver our products to our customers. If we cannot deliver our products on time and cost effectively, our customers may choose competitive offerings or create their own aligners causing our net revenues and gross margins to decline, possibly materially. 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, or hire technicians faster than our actual growth projections, the delivery time of our products could be delayed or our costs may exceed our revenues, each of which could adversely affect our results of operations.

Treatment planning is a key step leading to our manufacturing process which relies on sophisticated computer software. This requires new technicians to undergo a relatively long training process, often up to 120 days or longer. As a result, if we are unable to accurately predict our volume growth, we may have an insufficient 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. Conversely, if we hire and train technicians in anticipation of volume growth that does not materialize, materializes at a rate we do not anticipate, or if volumes decline, our costs and expenditures may outpace our revenue growth, harming our gross margins, operating expenses and financial results.

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 ("IT systems"). All IT 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 such systems. To effectively manage this growth, our IT 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. Expanded remote working and increased customer usage of online technology platforms by us, our customers and suppliers to facilitate efforts to mitigate the spread of COVID-19 through social distancing have increased the demands on our IT systems and personnel. Moreover, 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 software, MyAligntech and the Invisalign Doctor Site. Software applications frequently contain errors or defects, especially when first introduced or when new versions are released. The discovery of a defect or error in our software applications or IT systems, incompatibility with customers' computer operating systems and hardware configurations with a new release or upgraded version or the failure of our primary IT systems may result in various consequences, including, among others: delay or loss of revenues or delay in market acceptance, damage to our reputation, loss of market share to competition 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 on to run our businesses were to be found to be inaccurate or unreliable, if we fail to properly maintain our IT systems and data integrity, or if we fail to develop new capabilities to meet our business needs in a timely manner, we could suffer operational disruptions, have customer disputes, fail to produce timely and accurate reports, have regulatory or other legal problems, experience increases in operating and administrative expenses, lose existing customers, have difficulty in attracting new customers or 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 parties 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 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.

There can be no assurance that our process of improving existing IT systems, developing new IT systems to support our expanding operations, integrating new IT systems, protecting confidential patient health information, and improving service levels will not be delayed or that additional IT systems issues will not arise in the future. Failure to adequately protect and maintain the integrity of our IT 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 financial as well as patient health 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. For example, some companies have experienced an increase in phishing and social engineering attacks from third parties in connection with the COVID-19 pandemic. If we fail to meet our customer and patients' expectations regarding the security of their 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 IT 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 coverage.

We are also subject to 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 or approved countries. Some countries, including Russia and China, have enacted, and others are 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 implement new or expand existing data storage protocols, build new storage facilities, and/or devote additional resources to comply with the requirements of such laws, any of which could have significant cost implications. 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, we must comply with the General Data Protection Regulation which serves as a harmonization of EU 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 compliance 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.

In order to deepen our market penetration and raise awareness of our brand and products, we may increase the amount we spend on marketing activities, which may not ultimately prove successful or an effective use of our resources.

To increase awareness of our products and services domestically and internationally, we may increase the amount we spend on marketing activities. Our marketing efforts and costs are significant and include national and regional campaigns involving television, print media, social media and, more recently, alliances with professional sports teams and other strategic partners. We attempt to structure our advertising campaigns in ways we believe most likely to increase brand awareness and adoption; however, there is no assurance our campaigns will achieve the returns on advertising spend desired or successfully increase brand or product awareness sufficiently to sustain or increase our growth goals, which could have an adverse effect on our gross margin and business overall.

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 are costly and could distract our management and cause a decline in our results of operations and stock price.

Our success depends in part on our ability to maintain existing intellectual property ("IP") rights and to obtain and maintain further IP protection for our products, both in the U.S. and in other countries. Our inability to do so could harm our competitive position.

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 IP 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 IP laws. Certain of our key patents began to expire in 2017, which have resulted in increased competition and less expensive competitive 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 IP we are currently, have in the past been, and may in the future be involved in litigation. The potential effects on our business operations resulting from litigation, 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 IP 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.

Obtaining approvals and complying with regulations enforced by the FDA and foreign regulatory authorities is expensive and time-consuming, and any failure to obtain or maintain approvals for our products or services or failure to comply with regulations could materially harm our sales, result in substantial penalties and cause harm to our reputation.

Our products are considered medical devices and are subject to extensive and widely varying regulations in the U.S. and internationally. 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. Internationally, similar requirements apply on a country by country basis. In the U.S., 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.

It takes significant time, effort and expense to obtain and maintain FDA approvals of our products and services. In other countries, the requirements to obtain and maintain similar approvals may differ materially from those of the FDA. Moreover, there is no guarantee we will successfully obtain or maintain approvals in all or any of the countries in which we do business now or in the future. Even if we are successful, the time and effort may take significantly longer, and costs may be significantly greater. The impact of COVID-19 on normal governmental operations may delay our efforts to obtain and maintain approvals, possibly significantly. If approvals to market our products or services are delayed, whether in the U.S. or other countries, we may be unable to market our products or services in markets we deem important to our business. Were any of these risks to occur, our domestic or international operations may be materially harmed, and our business as a whole adversely impacted.

In addition, our failure to comply with applicable regulatory requirements could result in enforcement actions in the U.S. and other countries. For example, enforcement actions by the FDA may include one or more 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 previously granted; and
- criminal prosecution.

We must also 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 satisfactorily correct an adverse inspection or 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 enforcement action by the FDA or foreign governments could have a material adverse effect on us.

The sourcing and availability of metals that may be used in the manufacture of, or contained in, our products may be affected by laws and regulations in the U.S. or internationally regarding the use of minerals obtained from certain regions of the world like the Democratic Republic of Congo and adjoining countries. These laws and regulations may decrease the number of suppliers capable of supplying our needs for certain metals, thereby negatively affecting our ability to manufacture products in sufficient quantities or at competitive prices. We may furthermore suffer financial and reputational harm if customers require, and we are unable to deliver, certification that our products are conflict free. Regardless, compliance with these laws and regulations will require time and effort by our personnel and others and we will incur additional costs.

We are required to annually assess our internal control over financial reporting and any adverse results from such assessment may result in a loss of investor confidence in our financial reports and have an adverse effect on our stock price.

We have implemented and routinely assess, update and refine our internal control over financial reporting for its effectiveness. 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. Our internal controls may become inadequate because of changes in conditions including changes in personnel, updates and upgrades to existing software including our ERP software system, changes in accounting standards or interpretations of existing standards, 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 increases 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), the timely filing of our financial reports could be delayed or we could be required to restate past reports, and cause us to lose investor confidence in the accuracy and completeness of our financial reports in the future, 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 treatment planning 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 IP 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 IP 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. We periodically receive letters from third parties drawing our attention to their patent rights. While we do not believe 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 IP 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 key machines and materials, 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 may be unable 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. If this manufacturer fails to deliver its components, if we lose its services or if we fail to negotiate or maintain acceptable terms, we may be unable to timely deliver our products and our business may be harmed. Furthermore, any difficulties encountered by this manufacturer with respect to obtaining supplies, hiring personnel and maintaining acceptable manufacturing standards, controls, procedures and policies could disrupt our ability to timely deliver our products. 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 train and maintain our key sales force personnel 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 our direct sales force and the loss of the services of key personnel may harm our business. In order to provide more comprehensive sales and service coverage, we have increased the size of our sales force to pursue growth opportunities within and outside of our existing geographic markets. Moreover, as we focus on market penetration, we have begun to segregate sales personnel to focus on specific markets such as orthodontists and GPs. It can take up to twelve months or more to train sales representatives to successfully market and sell our products and for them to establish strong customer relationships. As a result, if we are unable to retain our key sales personnel or quickly replace them with individuals of equivalent technical expertise and qualifications, if we are unable to successfully instill technical expertise in new and existing sales representatives, if we fail to establish and maintain strong relationships with our customers, or if our efforts at specializing our selling techniques prove unsuccessful or not cost-effective, 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.

As compliance with healthcare regulations becomes more costly and difficult for us or our customers, we may be unable to grow our business.

Participants in the healthcare industry are subject to extensive and frequently changing regulations under numerous federal, state, local and foreign laws administered by various governmental entities, 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 foreign, 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 unhealthy or 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 sufficient coverage against potential liabilities. A product liability claim, regardless of its merit or eventual outcome, could result in significant legal defense costs and damage our reputation. 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.

Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.

Our global operations may be disrupted by natural or human induced disasters including, earthquakes, tsunamis, floods, drought, hurricanes, typhoons, wildfires, extreme weather conditions, power shortages, telecommunications failures, materials scarcity and price volatility, and medical epidemics or health pandemics. For instance, the COVID-19 pandemic has materially harmed our sales and business operations, the operations of our customers and the global economy overall. Climate change may increase both the frequency and severity of natural disasters and, consequently, risks to our operations and growth. The occurrence of business disruptions could harm our growth and expansion, result in significant losses, seriously harm our revenue, profitability and financial condition, adversely affect our competitive position, increase our costs and expenses, and require substantial expenditures and recovery time in order to fully resume operations. 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 and, we have and are building additional facilities in China. 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 significant delays receiving their aligners and a decrease in service levels for a period of time. Moreover, our corporate headquarters and a portion of our research and development activities are located in California, which suffers from earthquakes, periodic droughts, and wildfires affecting the health and safety of our employees. Any such business interruptions could materially and adversely affect our business, financial condition and results of operations.

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

We prepare our consolidated financial statements in conformity with U.S. GAAP. These principles are subject to interpretation by the SEC and various bodies formed to interpret and create appropriate accounting policies. A change in these policies or in the way these policies are interpreted by us or regulators 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 or economic environment, such as what we are currently experiencing in connection with the COVID-19 pandemic, it becomes necessary to assess the value of our investments more frequently and 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, but assessing these assumptions and predicting and forecasting future events can be materially more difficult in rapidly changing and unprecedented economic circumstances such as those we are experiencing with the COVID-19 pandemic. Large acquisitions, such as our recent acquisition of exocad, require ongoing fair value assessments of goodwill and purchased assets to determine if they have become impaired. Consequently, 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 our corporate structure reorganization, including the relocation of our EMEA regional headquarters to Switzerland.

We reorganized our corporate structure and intercompany relationships in January 2020 in an effort to more closely align our international business activities and to achieve financial and operational efficiencies. The implementation of this reorganization plan included the move of our EMEA regional headquarters from the Netherlands to Switzerland which has been time-consuming and costly, may be disruptive to our business, and may not be more efficient or effective in the future. This relocation is accompanied by a number of risks and uncertainties that may affect our results of operations and statement of cash flows, including:

- failure to retain key employees who possess specific knowledge or expertise and upon whom we are depending upon for the timely and successful transition;
- difficulties in hiring employees in Switzerland with the necessary skills and expertise; and
- increased costs due to transition of 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 global economic environment, changes in legal entity structure and/or activities performed within our entities, changes in tax laws, regulations and/or rates, new or changes to accounting pronouncements, 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, changes in overall levels of pretax earnings, the future levels of tax benefits of stock-based compensation, settlement of income tax audits and non-deductible goodwill impairments. For example, our effective tax rate varied significantly in our first quarter of fiscal 2020 due to the relocation of our EMEA regional headquarters from the Netherlands to Switzerland effective January 1, 2020. Our effective tax rate is also dependent in part on forecasts of full year results and could vary materially with the impact of the COVID-19 outbreak to the global economic environment. Furthermore, we may continue to experience significant variation in our effective tax rate related to excess tax benefits on stock-based compensation, particularly in the first quarter of each year when the majority of our equity awards vest.

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. The OECD has 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.

We are subject to risks associated with our strategic investments. Impairments in the value of our investments and unsecured promissory note 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 have experienced a decline in value or our unsecured promissory note with SmileDirectClub is determined to be uncollectible, which may be more likely as a result of the COVID-19 pandemic, particularly if its impact to global and domestic economies is sustained and widespread or any recovery is slow, we may be required to record impairments which could be material and could have an adverse impact on our financial results.

We may acquire other businesses, products or technologies in the future which could require significant management attention, disrupt our business, dilute shareholder value and adversely affect our results of operations.

In order to remain competitive or achieve long-term business objectives, we may acquire, or make investments in, complementary companies, products or technologies. Alternatively, we may not be able to find suitable acquisition targets in the future, and we may not be able to complete acquisitions on favorable terms, if at all. If we do complete acquisitions, we may not ultimately strengthen our competitive position or achieve our goals or desired synergies, and any acquisitions we complete could be viewed negatively by our customers, securities analysts and investors. In addition, if we fail to successfully integrate any acquisitions or the technologies acquired, our revenue and results of operations could be adversely affected or we may inherit IT security and privacy compliance issues when we integrate acquired products and systems. Any integration process may require significant time and resources and we may not successfully evaluate or utilize the acquired technology or personnel, or accurately forecast the financial impact of an acquired business, including accounting charges. We may have to pay cash, incur debt or issue equity securities to pay for any acquisition, any of which could adversely affect our liquidity, financial condition or the value of our common stock. The sale of equity or issuance of debt to finance any acquisition could result in dilution to our shareholders. The occurrence of indebtedness would result in increased fixed obligations and could also include covenants or other restrictions that would impede our ability to manage our operations.

Moreover, opposition to one of more acquisitions could lead to negative ratings by analysts or investors, give rise objections by one or more stockholders or result in shareholder activism, any of which could harm our stock price. Acquisitions can also lead to large non-cash charges that can have an adverse effect on our results of operations as a result of write-offs for items such as future impairments of intangible assets and goodwill or the recording of stock-based compensation.

Risks Related to our Common Stock

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:

- the impact on global and regional economies as a result of the COVID-19 pandemic;
- quarterly variations in our results of operations and liquidity or changes in our forecasts and guidance;
- 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;
- announcements by competitors or new market entrants;
- strategic actions by us or our competitors, such as management changes, material transactions or acquisitions;

- announcements regarding stock repurchases, sales of our common stock, credit agreements and debt issuances;
- announcements of technological innovations or new products or product offerings by us, our customers or competitors;
- key decisions in pending litigation
- sales of stock by us, our officers or directors; 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 its securities and we have not been excepted from such litigation.

We cannot guarantee we will continue to repurchase our common stock, and any repurchases may not achieve our objectives.

We have a history of recurring stock repurchase programs intended to return capital to our investors. Any authorization or continuance of our share repurchase programs is contingent on a variety of factors, including our financial condition, results of operations, business requirements, and our board of directors' continuing determination that share repurchases are in the best interests of our stockholders and in compliance with all applicable laws and agreements. There is no assurance that we will continue to repurchase stock consistent with historical levels or at all, or that our stock repurchase programs will have a beneficial impact on our stock price.

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.

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

There were no stock repurchases during the three months ended June 30, 2020. As of June 30, 2020, we have \$100.0 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 program).

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 herewith
31.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				*
31.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				*
32.1 †	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				*
101.INS	Inline 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	Inline XBRL Taxonomy Extension Schema Document				*
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document				*
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document				*
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document				*
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document				*
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101)				*

† Furnished herewith

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: July 31, 2020

/s/ JOSEPH M. HOGAN

Joseph M. Hogan
President and Chief Executive Officer

CERTIFICATION

I, John F. Morici, certify that:

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

Date: July 31, 2020

/s/ JOHN F. MORICI

John F. Morici

Chief Financial Officer and Senior Vice President, Global Finance

**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 June 30, 2020 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: July 31, 2020

In connection with the Quarterly Report of Align Technology, Inc. (the "Company") on Form 10-Q for the period ending June 30, 2020 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: July 31, 2020