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 March 31, 2021
OR

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

For the transition period from to

Commission file number: 000-32259

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

Delaware	**94-3267295**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification Number)**

410 North Scottsdale Road, Suite 1300
Tempe, Arizona 85281
(Address of principal executive offices)
(408) 470-1000
(Registrant's telephone number, including area code)

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

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

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

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

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

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

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

The number of shares outstanding of the registrant's Common Stock, $0.0001 par value, as of April 30, 2021 was 79,136,575.

ALIGN TECHNOLOGY, INC.

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PART I—FINANCIAL INFORMATION

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

	Three Months Ended March 31,	
	2021	2020
Net revenues	$ 894,771	$ 550,963
Cost of net revenues	217,673	156,607
Gross profit	677,098	394,356
Operating expenses:		
Selling, general and administrative	397,115	282,906
Research and development	54,537	41,532
Total operating expenses	451,652	324,438
Income from operations	225,446	69,918
Interest income and other income (expense), net:		
Interest income	1,643	1,986
Other income (expense), net	34,532	(18,549)
Total interest income and other income (expense), net	36,175	(16,563)
Net income before provision for (benefit from) income taxes	261,621	53,355
Provision for (benefit from) income taxes	61,245	(1,464,776)
Net income	$ 200,376	$ 1,518,131
Net income per share:		
Basic	$ 2.54	$ 19.32
Diluted	$ 2.51	$ 19.21
Shares used in computing net income per share:		
Basic	79,000	78,592
Diluted	79,798	79,028

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 March 31,	
	2021	2020
Net income	$ 200,376	$ 1,518,131
Change in foreign currency translation adjustment, net of tax	(14,451)	689
Change in unrealized gains (losses) on investments, net of tax	(20)	(194)
Other comprehensive income (loss)	(14,471)	495
Comprehensive income	$ 185,905	$ 1,518,626

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)

	March 31, 2021	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 1,131,698	$ 960,843
Accounts receivable, net of allowance for doubtful accounts of $9,882 and $10,239, respectively	718,957	657,704
Inventories	150,643	139,237
Prepaid expenses and other current assets	114,257	91,754
Total current assets	2,115,555	1,849,538
Property, plant and equipment, net	763,870	734,721
Operating lease right-of-use assets, net	82,435	82,553
Goodwill	427,561	444,817
Intangible assets, net	120,479	130,072
Deferred tax assets	1,521,922	1,552,831
Other assets	37,960	35,151
Total assets	$ 5,069,782	$ 4,829,683
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 124,298	$ 142,132
Accrued liabilities	406,672	405,582
Deferred revenues	862,872	777,887
Total current liabilities	1,393,842	1,325,601
Income tax payable	109,668	105,748
Operating lease liabilities	63,845	64,445
Other long-term liabilities	108,851	100,024
Total liabilities	1,676,206	1,595,818
Commitments and contingencies (Notes 6 and 7)		
Stockholders' equity:		
Preferred stock, $0.0001 par value (5,000 shares authorized; none issued)	—	—
Common stock, $0.0001 par value (200,000 shares authorized; 79,136 and 78,860 issued and outstanding, respectively)	8	8
Additional paid-in capital	948,362	974,556
Accumulated other comprehensive income (loss), net	29,030	43,501
Retained earnings	2,416,176	2,215,800
Total stockholders' equity	3,393,576	3,233,865
Total liabilities and stockholders' equity	$ 5,069,782	$ 4,829,683

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 March 31, 2021	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss), Net	Retained Earnings	Total
Balance as of December 31, 2020	78,860	$ 8	$ 974,556	$ 43,501	$ 2,215,800	$ 3,233,865
Net income	—	—	—	—	200,376	200,376
Net change in unrealized gains (losses) from investments	—	—	—	(20)	—	(20)
Net change in foreign currency translation adjustment	—	—	—	(14,451)	—	(14,451)
Issuance of common stock relating to employee equity compensation plans	276	—	13,133	—	—	13,133
Tax withholdings related to net share settlements of equity awards	—	—	(66,568)	—	—	(66,568)
Stock-based compensation	—	—	27,241	—	—	27,241
Balance as of March 31, 2021	79,136	$ 8	$ 948,362	$ 29,030	$ 2,416,176	$ 3,393,576

Three Months Ended March 31, 2020	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss), Net	Retained Earnings	Total
Balance as of December 31, 2019	78,433	$ 8	$ 906,937	$ (688)	$ 439,912	$ 1,346,169
Net income	—	—	—	—	1,518,131	1,518,131
Net change in unrealized gains (losses) from investments	—	—	—	(194)	—	(194)
Net change in foreign currency translation adjustment	—	—	—	689	—	689
Issuance of common stock relating to employee equity compensation plans	326	—	10,662	—	—	10,662
Tax withholdings related to net share settlements of equity awards	—	—	(45,395)	—	—	(45,395)
Stock-based compensation	—	—	22,927	—	—	22,927
Balance as of March 31, 2020	78,759	$ 8	$ 895,131	$ (193)	$ 1,958,043	$ 2,852,989

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)

	Three Months Ended March 31,	
	2021	**2020**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net income	$ 200,376	$ 1,518,131
Adjustments to reconcile net income to net cash provided by operating activities:		
Deferred taxes	28,979	(1,487,154)
Depreciation and amortization	25,635	20,738
Stock-based compensation	27,241	22,927
Non-cash operating lease cost	5,911	5,546
Allowance for doubtful accounts provisions	455	4,838
Arbitration award gain	(43,403)	—
Impairment on equity investment	—	2,900
Other non-cash operating activities	5,340	7,728
Changes in assets and liabilities:		
Accounts receivable	(67,423)	13,761
Inventories	(15,582)	(10,496)
Prepaid expenses and other assets	(34,858)	(37,244)
Accounts payable	(14,936)	(12,034)
Accrued and other long-term liabilities	(475)	(69,103)
Long-term income tax payable	3,920	6,354
Deferred revenues	106,007	22,892
Net cash provided by operating activities	227,187	9,784
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property, plant and equipment	(43,431)	(46,085)
Purchase of marketable securities	—	(5,341)
Proceeds from maturities of marketable securities	—	42,641
Proceeds from sales of marketable securities	—	278,817
Repayment on unsecured promissory note	4,594	4,419
Proceeds from arbitration award	43,403	—
Other investing activities	—	1,760
Net cash provided by investing activities	4,566	276,211
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock	13,133	10,662
Payroll taxes paid upon the vesting of equity awards	(66,568)	(45,395)
Net cash used in financing activities	(53,435)	(34,733)
Effect of foreign exchange rate changes on cash, cash equivalents, and restricted cash	(7,487)	(11,007)
Net increase in cash, cash equivalents, and restricted cash	170,831	240,255
Cash, cash equivalents, and restricted cash at beginning of the period	961,474	551,134
Cash, cash equivalents, and restricted cash at end of the period	$ 1,132,305	$ 791,389

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 months ended March 31, 2021 and 2020, our comprehensive income for the three months ended March 31, 2021 and 2020, our financial position as of March 31, 2021, our stockholders' equity for the three months ended March 31, 2021 and 2020, and our cash flows for the three months ended March 31, 2021 and 2020. The Condensed Consolidated Balance Sheet as of December 31, 2020 was derived from the December 31, 2020 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 months ended March 31, 2021 are not necessarily indicative of the results that may be expected for the year ending December 31, 2021 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, 2020.

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, 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.

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. The full extent to which the pandemic, including as a result of any new strains, business restrictions or lockdowns, and the impact of vaccinations, will directly or indirectly impact our business, results of operations, cash flows, and financial condition will depend on future developments that are highly uncertain and cannot be accurately determined.

Recent Accounting Pronouncements

New Accounting Updates Recently Adopted

In December 2019, the Financial Accounting Standards Board 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. Adoption of this standard in the first quarter of fiscal year 2021 did not have a material impact on our consolidated financial statements or related disclosures.

Note 2. Fair Value Measurements

The following tables summarize our financial assets measured at fair value on a recurring basis as of March 31, 2021 and December 31, 2020 (in thousands):

Description	Balance as of March 31, 2021	Level 1	Level 2
Cash equivalents:			
Money market funds	$ 654,211	$ 654,211	$ —
Prepaid expenses and other current assets:			
Israeli funds	3,752	—	3,752
	$ 657,963	$ 654,211	$ 3,752

Description	Balance as of December 31, 2020	Level 1	Level 2	Level 3
Cash equivalents:				
Money market funds	$ 519,228	$ 519,228	$ —	$ —
Prepaid expenses and other current assets:				
Israeli funds	3,500	—	3,500	—
Current unsecured promissory note [1]	5,408	—	—	5,408
	$ 528,136	$ 519,228	$ 3,500	$ 5,408

[1] The unsecured promissory note was paid in full by SmileDirectClub, LLC ("SDC") during the three months ended March 31, 2021. Besides the repayment on the note, on March 12, 2021, the Arbitrator ruled in favor of us on the SDC dispute and issued an award of $43.4 million along with interest. The gain of $43.4 million is recognized as a part of our other income (expense), net in our Condensed Consolidated Statement of Operation. Refer to *Note 6 "Legal Proceedings" of the Notes to Condensed Consolidated Financial Statements* for more information on the arbitration award received.

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. As a result of the settlement of foreign currency forward contracts, during the three months ended March 31, 2021 and 2020, we recognized net gains of $12.4 million and $15.6 million, respectively. As of March 31, 2021 and December 31, 2020, 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 March 31, 2021 and December 31, 2020 (in thousands):

	March 31, 2021	
	Local Currency Amount	Notional Contract Amount (USD)
Euro	€160,500	$ 188,276
Chinese Yuan	¥1,107,000	168,394
Canadian Dollar	C$92,200	73,208
British Pound	£42,990	59,182
Brazilian Real	R$222,000	38,836
Japanese Yen	¥4,071,800	36,757
Polish Zloty	PLN138,395	34,906
Israeli Shekel	ILS65,220	19,533
Mexican Peso	M$295,500	14,422
Swiss Franc	CHF6,100	6,474
Australian Dollar	A$5,800	4,412
		$ 644,400

	December 31, 2020	
	Local Currency Amount	Notional Contract Amount (USD)
Euro	€126,300	$ 155,125
Chinese Yuan	¥936,000	143,393
Canadian Dollar	C$65,000	50,791
British Pound	£32,300	43,879
Japanese Yen	¥4,249,000	41,222
Brazilian Real	R$142,000	27,264
Israeli Shekel	ILS74,000	23,094
Mexican Peso	M$140,000	7,002
Australian Dollar	A$5,800	4,447
Swiss Franc	CHF3,700	4,191
		$ 500,408

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 months ended March 31, 2020, we recognized an unrealized loss of $9.2 million within other income (expense), net in our Condensed Consolidated Statement of Operation as a result of the forward contract's fair value as of March 31, 2020.

Note 3. Balance Sheet Components

Inventories consist of the following (in thousands):

	March 31, 2021	December 31, 2020
Raw materials	$ 75,836	$ 76,404
Work in process	40,387	31,393
Finished goods	34,420	31,440
Total inventories	$ 150,643	$ 139,237

Accrued liabilities consist of the following (in thousands):

	March 31, 2021	December 31, 2020
Accrued payroll and benefits	$ 153,898	$ 170,106
Accrued expenses	85,854	77,024
Accrued income taxes	41,539	30,130
Accrued property, plant and equipment	36,857	27,692
Current operating lease liabilities	21,513	21,735
Other accrued liabilities	67,011	78,895
Total accrued liabilities	$ 406,672	$ 405,582

Accrued warranty, which is included in the "Other accrued liabilities" category of the accrued liabilities table above, consists of the following activity (in thousands):

	Three Months Ended March 31,	
	2021	2020
Balance at beginning of period	$ 12,615	$ 11,205
Charged to cost of net revenues	4,280	3,724
Actual warranty expenditures	(3,160)	(3,140)
Balance at end of period	$ 13,735	$ 11,789

Deferred revenues consist of the following (in thousands):

	March 31, 2021	December 31, 2020
Deferred revenues - current	$ 862,872	$ 777,887
Deferred revenues - long-term [1]	$ 74,226	$ 62,551

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

During the three months ended March 31, 2021 and 2020, we recognized $894.8 million and $551.0 million of net revenues, respectively, of which $125.8 million and $95.5 million was included in the deferred revenues balance at December 31, 2020 and 2019, respectively.

Our unfulfilled performance obligations, including deferred revenues and backlog, as of March 31, 2021 were $963.5 million. These performance obligations are expected to be recognized over the next one to five years.

Note 4. Goodwill and Intangible Assets

Goodwill

The change in the carrying value of goodwill for the three months ended March 31, 2021, categorized by reportable segments, is as follows (in thousands):

	Clear Aligner	Systems and Services	Total
Balance as of December 31, 2020	$ 112,691	$ 332,126	$ 444,817
Foreign currency translation adjustments	(2,374)	(14,882)	(17,256)
Balance as of March 31, 2021	$ 110,317	$ 317,244	$ 427,561

Intangible Long-Lived Assets

Acquired intangible long-lived assets were as follows, excluding intangibles that were fully amortized (in thousands):

	Weighted Average Amortization Period (in years)	Gross Carrying Amount as of March 31, 2021	Accumulated Amortization	Accumulated Impairment Loss	Net Carrying Value as of March 31, 2021
Existing technology	10	$ 99,400	$ (15,035)	$ (4,328)	$ 80,037
Customer relationships	11	55,000	(22,882)	(10,751)	21,367
Trademarks and tradenames	10	16,600	(3,318)	(4,179)	9,103
Patents and other	8	6,610	(3,989)	—	2,621
		$ 177,610	$ (45,224)	$ (19,258)	113,128
Foreign currency translation					7,351
Total intangible assets					$ 120,479

	Weighted Average Amortization Period (in years)	Gross Carrying Amount as of December 31, 2020	Accumulated Amortization	Accumulated Impairment Loss	Net Carrying Value as of December 31, 2020
Existing technology	10	$ 99,400	$ (12,719)	$ (4,328)	$ 82,353
Customer relationships	11	55,000	(21,879)	(10,751)	22,370
Trademarks and tradenames	10	16,600	(2,934)	(4,179)	9,487
Patents and other	8	6,610	(3,785)	—	2,825
		177,610	(41,317)	(19,258)	117,035
Foreign currency translation					13,037
Total intangible assets					$ 130,072

The total estimated annual future amortization expense for these acquired intangible assets as of March 31, 2021 is as follows (in thousands):

Fiscal Year Ending December 31,	Amortization
Remainder of 2021	$ 11,715
2022	14,366
2023	13,745
2024	12,805
2025	12,428
Thereafter	48,069
Total	$ 113,128

Amortization expense for the three months ended March 31, 2021 and 2020 was $3.9 million and $1.3 million, respectively.

Note 5. Credit Facility

On July 21, 2020 we entered into a 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”), replacing our previous credit facility which provided for a $200.0 million revolving line of credit with a $50.0 million letter of credit. 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. As of March 31, 2021, we had no outstanding borrowings under the 2020 Credit Facility and were in compliance with the conditions and performance requirements.

Note 6. 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. The complaint generally alleged claims under the federal securities laws and sought 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. 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. On September 9, 2020, Defendants’ motion to dismiss the amended consolidated complaint was granted in part and denied in part. Trial is scheduled for October 3, 2022. Align believes the claims that remain in the case are without merit and intends to vigorously defend itself. Align is currently unable to predict the outcome of the lawsuit 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 asserted 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 the 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 (later transferred to the U.S. District Court for the Northern District of California) on behalf of a purported class of purchasers of our common stock. The complaint alleged claims under the federal securities laws and sought monetary damages in an unspecified amount and costs and expenses incurred in the litigation. The lead plaintiff filed an amended complaint on August 4, 2020 against Align and three of our executive officers alleging similar claims as in the initial complaint on behalf of a purported class of purchasers of our common stock from April 25, 2019 to July 24, 2019. On March 29, 2021, defendants’ motion to dismiss the amended complaint was granted with leave for the lead plaintiff to file a further amended complaint. On April 22, 2021, lead plaintiff filed a notice stating it would not file a further amended

complaint. On April 23, 2021, the Court dismissed the action with prejudice and judgment was entered. Lead plaintiff filed a notice of appeal on April 28, 2021. Currently there is no schedule for the appeal. 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 a decision on the motion to dismiss in the 2020 Securities Class Action Lawsuit. The parties are required to file a status report with the Court within 14 days of the order dismissing 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 were filed 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 3Shape has filed counterclaims for breach of contract and business torts. Align's motions to dismiss the 3Shape counterclaims was recommended to be granted by the Magistrate Judge.

In 2018, 3Shape filed two separate complaints in the U.S. District Court for the District of Delaware alleging patent infringement by Align's iTero Element scanner of 3Shape patents. On August 19, 2019, the Court consolidated the two actions, and on August 30, 2019, 3Shape filed an amended complaint.

On December 11, 2018, Align filed an additional complaint 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. 3Shape filed business tort counterclaims. The Magistrate Judge recommended granting Align's motion to dismiss 3Shape's counterclaims.

On October 19, 2020, Align filed a complaint in the U.S. District Court for the Western District of Texas alleging patent infringement by 3Shape's intraoral scanners and associated software products. In response, 3Shape filed a motion to dismiss as well as business tort and patent infringement counterclaims. Align has moved to dismiss the business tort counterclaims.

Each of 3Shape and Align's District Court patent infringement complaints and all of 3Shape's business tort counterclaims seek monetary damages and/or injunctive relief. One of Align's Delaware District Court cases against 3Shape is scheduled for a jury trial beginning on July 26, 2021. The case pending in the Western District of Texas has been given an estimated trial date of October 3, 2022. No trial dates have been set in the remaining cases.

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 scanner markets. After the Court dismissed 3Shape's complaint, 3Shape filed an amended complaint on October 28, 2019. The Court denied Align's motion to dismiss the amended complaint on November 25, 2020. No trial date has been set.

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.

Antitrust Class Actions

On June 5, 2020, a dental practice named Simon and Simon, PC doing business as 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 scanner markets. Plaintiff filed an amended complaint and added VIP Dental Spas as a plaintiff on August 14, 2020. On September 9, 2020, Align moved to dismiss Plaintiffs' amended complaint. On April 8, 2021, the Judge denied Align's motion to dismiss. The court has not entered a schedule or set a trial date. Align believes the plaintiffs' claims are without merit and intends to vigorously defend itself.

On May 3, 2021, an individual named Misty Snow brought an antitrust action in the United States District Court for the Northern District of California on behalf of herself and a putative class of similarly situated individuals seeking monetary damages and injunctive relief relating to Align's alleged market activities in alleged clear aligner and intraoral scanner markets. Align has not yet responded to 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 these lawsuits and therefore cannot determine the likelihood of loss, if any, nor estimate a range of possible loss.

SDC Dispute

In April 2018, SDC Financial LLC, SmileDirectClub LLC, and the Members of SDC Financial LLC other than the Company (collectively, the "SDC Entities") initiated confidential arbitration proceedings against Align. In an award dated March 4, 2019, ("Award") an arbitrator found that Align breached a restrictive covenant 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 in the United States, and enjoined from using the SDC Entities' confidential information. The arbitrator extended the expiration date of specified aspects of the restrictive covenant 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 disputed that the SDC Entities properly determined the value of Align's "capital account" balance as of October 31, 2017. Consequently, on July 3, 2019, Align filed a confidential demand for arbitration challenging the propriety of the SDC Entities' determination. The arbitration hearing occurred in December 2020 and on March 12, 2021 the Arbitrator issued a final award in favor of Align and against SDC finding that the SDC entities owed Align an additional $43.4 million plus interest which SDC paid to Align on March 17, 2021.

In a related legal proceeding, the SDC Entities had filed a contempt petition with an Illinois court asserting that Align had no right to contest the SDC Entities; "capital account" determination in the July 3, 2019 arbitration. On September 4, 2019, the Illinois court denied in its entirety the contempt petition filed by the SDC Entities. The SDC Entities appealed and, on February 9, 2021, the Illinois Appellate Court affirmed the denial of the contempt petition. The time for SDC to seek rehearing or further appeal has passed.

On August 19, 2019, the SDC Entities filed a separate confidential arbitration proceeding alleging that Align had violated a restrictive covenant 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 asserted that Align's alleged dealings with a third-party constituted contempt of the Award. On February 5, 2021, pursuant to an agreement reached by the parties, the arbitrator dismissed the arbitration with prejudice.

On August 27, 2020, Align initiated a confidential arbitration proceeding against the SDC entities before the American Arbitration Association in San Jose, California. This arbitration relates to the Strategic Supply Agreement ("Supply Agreement") entered into between the parties in 2016. The complaint states that the SDC Entities breached the Supply Agreement's terms, causing damages to Align in an amount to be determined. On January 19, 2021, SDC filed a counterclaim alleging that Align breached the Supply Agreement. Align denies the SDC Entities' allegations in the counterclaim and will vigorously defend itself against them. This arbitration hearing is scheduled for September 27, 2021.

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

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 7. Commitments and Contingencies

Off-Balance Sheet Arrangements

As of March 31, 2021, 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 11 "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 March 31, 2021, we did not have any material indemnification claims that were probable or reasonably possible.

Note 8. Stockholders' Equity

As of March 31, 2021, the 2005 Incentive Plan (as amended) has a total reserve of 27,783,379 shares of which 4,210,089 shares are available for issuance.

Common Stock Repurchase Program

As of March 31, 2021, we have $100.0 million available for repurchase under the May 2018 Repurchase Program. Subsequent to the first quarter, on April 30, 2021, we entered into an accelerated stock repurchase agreement ("2021 ASR") to repurchase $100.0 million of our common stock. We paid $100.0 million on May 3, 2021 and received an initial delivery of approximately 0.1 million shares based on current market prices. The final number of shares to be repurchased will be based on our volume-weighted average stock price under the terms of the 2021 ASR, less an agreed upon discount.

Summary of Stock-Based Compensation Expense

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 months ended March 31, 2021 and 2020 is as follows (in thousands):

	Three Months Ended March 31,	
	2021	2020
Cost of net revenues	$ 1,306	$ 1,347
Selling, general and administrative	21,844	18,130
Research and development	4,091	3,450
Total stock-based compensation	$ 27,241	$ 22,927

Restricted Stock Units ("RSUs")

The fair value of RSUs is based on our closing stock price on the date of grant. RSUs granted generally vest over a period of four years. A summary for the three months ended March 31, 2021 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, 2020	632	$ 243.55		
Granted	149	598.37		
Vested and released	(214)	214.65		
Forfeited	(7)	298.24		
Unvested as of March 31, 2021	560	$ 348.77	1.7	$ 303,402

As of March 31, 2021, we expect to recognize $163.6 million of total unamortized compensation cost, net of estimated forfeitures, related to RSUs over a weighted average period of 2.7 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 three months ended March 31, 2021 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, 2020	227	$ 430.50		
Granted	91	675.44		
Vested and released	(101)	351.75		
Unvested as of March 31, 2021	217	$ 569.07	1.4	$ 117,620

As of March 31, 2021, we expect to recognize $60.8 million of total unamortized compensation cost, net of estimated forfeitures, related to MSUs over a weighted average period of 1.4 years.

Employee Stock Purchase Plan ("ESPP")

In May 2010, our 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 March 31, 2021, we have 253,444 shares available for future issuance.

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

	Three Months Ended March 31,	
	2021	2020
Expected term (in years)	1.0	1.0
Expected volatility	58.8 %	41.7 %
Risk-free interest rate	0.1 %	1.5 %
Expected dividends	—	—
Weighted average fair value at grant date	$ 202.74	$ 80.54

As of March 31, 2021, there was $3.9 million of total unamortized compensation costs related to employee stock purchases which we expect to be recognized over a weighted average period of 0.4 year.

Note 9. Accounting for Income Taxes

Our provision for income taxes was $61.2 million for the three months ended March 31, 2021 and our benefit from income taxes was $1,464.8 million for the three months ended March 31, 2020 representing effective tax rates of 23.4% and (2,745.3)%, respectively. Our effective tax rate differs from the statutory federal income tax rate of 21% for the three months ended March 31, 2021 primarily due to the recognition of additional tax expense resulting from state income taxes, non-deductible expenses in the U.S. and foreign income taxed at different rates, partially offset by the recognition of excess tax benefits related to stock-based compensation. Our effective tax rate differs from the statutory federal income tax rate of 21% for the three months ended March 31, 2020 mainly as a result of the recognition of a deferred tax asset and related one-time tax benefit in accordance with the completion of the intra-entity transfer of certain intellectual property rights and fixed assets to our Swiss entity and excess tax benefits related to stock-based compensation, partially offset by state income taxes and foreign income taxed at different rates.

During the three months ended March 31, 2020, we completed an intra-entity transfer of certain intellectual property rights and fixed assets to our Swiss entity. 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 three months ended March 31, 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.

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. We are no longer subject to U.S. federal tax examination for years before 2017 and U.S. state tax examination for years before 2016. Our subsidiary in Israel is under audit by the local tax authorities for years 2015 through 2018. 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 $50.0 million and $46.3 million as of March 31, 2021 and December 31, 2020, respectively, a material amount of which would impact our effective tax rate if recognized. Total interest and penalties accrued as of March 31, 2021 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 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 $32.9 million and $35.7 million as of March 31, 2021 and December 31, 2020, respectively, which primarily related to the intangible assets from our exocad acquisition.

Note 10. Net Income per Share

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

	Three Months Ended March 31,	
	2021	2020
Numerator:		
Net income	$ 200,376	$ 1,518,131
Denominator:		
Weighted average common shares outstanding, basic	79,000	78,592
Dilutive effect of potential common stock	798	436
Total shares, diluted	79,798	79,028
Net income per share, basic	$ 2.54	$ 19.32
Net income per share, diluted	$ 2.51	$ 19.21
Anti-dilutive potential common shares [1]	76	148

[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 11. Supplemental Cash Flow Information

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

	Three Months Ended March 31,	
	2021	2020
Non-cash investing and financing activities:		
Fixed assets acquired with accounts payable or accrued liabilities	$ 45,354	$ 24,121
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	$ 6,923	$ 6,236
Right-of-use assets obtained in exchange for lease obligations:		
Operating leases	$ 7,369	$ 21,602

Note 12. Segments and Geographical Information

Segment Information

We report segment information based on the management approach. The management approach designates the internal reporting used by our Chief Operating Decision Maker 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.

Summarized financial information by segment is as follows (in thousands):

	Three Months Ended March 31,	
	2021	2020
Net revenues		
Clear Aligner	$ 753,269	$ 481,611
Systems and Services	141,502	69,352
Total net revenues	$ 894,771	$ 550,963
Gross profit		
Clear Aligner	$ 584,534	$ 351,492
Systems and Services	92,564	42,864
Total gross profit	$ 677,098	$ 394,356
Income from operations		
Clear Aligner	$ 327,465	$ 166,388
Systems and Services	47,228	14,389
Unallocated corporate expenses	(149,247)	(110,859)
Total income from operations	$ 225,446	$ 69,918
Stock-based compensation		
Clear Aligner	$ 2,294	$ 2,529
Systems and Services	171	78
Unallocated corporate expenses	24,776	20,320
Total stock-based compensation	$ 27,241	$ 22,927
Depreciation and amortization		
Clear Aligner	$ 11,120	$ 10,121
Systems and Services	4,545	1,785
Unallocated corporate expenses	9,970	8,832
Total depreciation and amortization	$ 25,635	$ 20,738

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

	Three Months Ended March 31,	
	2021	2020
Total segment income from operations	$ 374,693	$ 180,777
Unallocated corporate expenses	(149,247)	(110,859)
Total income from operations	225,446	69,918
Interest income	1,643	1,986
Other income (expense), net	34,532	(18,549)
Net income before provision for (benefit from) income taxes	$ 261,621	$ 53,355

Geographical Information

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

	Three Months Ended March 31,	
	2021	2020
Net revenues [1]:		
United States	$ 383,002	$ 271,705
Switzerland	315,450	187,276
China	61,212	19,725
Other International	135,107	72,257
Total net revenues	$ 894,771	$ 550,963

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

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):

	March 31, 2021	December 31, 2020
Long-lived assets [1]:		
Switzerland	$ 267,654	$ 257,337
United States	180,709	180,539
China	121,342	113,918
Costa Rica	98,124	97,804
Other International	178,476	167,676
Total long-lived assets	$ 846,305	$ 817,274

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

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

Forward-Looking Statements

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 digital dentistry and its potential to impact our business, our intentions regarding expanding our business, 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 expectation regarding customer and consumer purchasing behavior, including expectations related to consumer demand for digital solutions, our expectations for future investments in and benefits from consumer demand sales and marketing activities, our expectations regarding the near and long-term implications of the COVID-19 pandemic on the global economy, the businesses of our customers, and us, including our preparedness to react to changing circumstances and demand, results of operations and financial condition, our expectations for our expenses and capital obligations and 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 judgments regarding the estimates used in our revenue recognition, and assessment of goodwill and intangible assets, our expectations regarding our tax positions and the judgments we make related to our tax obligations, our expectations regarding potential litigation with SDC Financial LLC, 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, 2020 as filed with the Securities and Exchange Commission.

Executive Overview of Results

COVID-19 Update

Since the first quarter of fiscal year 2020, our sales and results of operations have been impacted first by the preventative measures implemented to slow the spread of COVID-19, including the complete closure or significantly reduced operations of dental practices and, more recently, the inconsistent pace and scale of recovery in various markets. In 2021, the pandemic continues to cause general business and societal disruptions and uncertainties worldwide, although many of the most drastic measures imposed to prevent or limit the spread of the virus have been moderated. For instance, globally dental practices both public and private, have largely reopened, although many continue to operate at less than pre-pandemic capacities.

Conversely, as a result of the restrictive measures imposed to contain the spread of the virus, the demand for digital solutions has increased as society and businesses have adapted to such practices as social distancing and remote working. Our efforts to promote the digital transformation of dental practices with our clear aligners, intraoral scanners, clinical treatment planning and other offerings has allowed us to quickly respond to increased demand in the dental field. We expect a growing number of customers to realize the efficiencies and benefits of our digital solutions for their practices and patients even as the pandemic-related restrictions continue to ease.

To address the increasing demand for digital solutions, we intend to continue targeting our investment plans, including, in the areas of sales, marketing, innovation and capital expenditures. As we expand our manufacturing operations in locations such as Europe, prepare for the safe return of employees to our offices and experiment with hybrid work models in 2021, we expect our sales and marketing as well as capital expenditures to increase as we focus our efforts to meet the growing demand we anticipate for our solutions.

Nevertheless, the continuing evolution of the pandemic, including any setbacks as a result of any new virus strains or business restrictions or lockdowns, the positive impacts of vaccinations, the uncertainties regarding consumer spending as

demand for entertainment, dining, travel returns and remote working diminishes, remains highly fluid and unpredictable. As such, our recent operating results and levels of growth may not be indicative of our future performance and comparisons to prior quarters and periods in 2020. Ultimately, however, we believe the digital transition to dentistry that began before the pandemic will continue to be positive for our business, results of operations, cash flows, and financial condition and we intend to adjust spending to coincide with the pace of recovery and changes in demand.

Further discussion of the impact of the COVID-19 pandemic on our business may be found in Item 1A of this Quarterly Report on Form 10-Q under the heading *"Risk Factors."*

Key financial and operating metrics

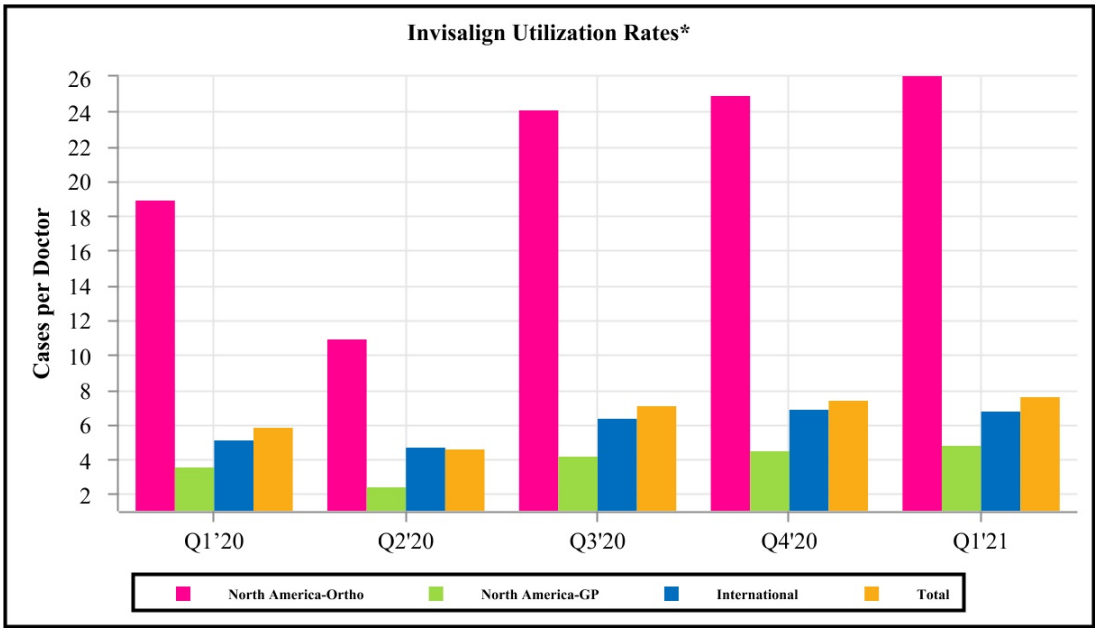
Our business strategic priorities remain focused on four principal pillars of growth: (i) International expansion; (ii) GP adoption; (iii) Patient demand & conversion; and (iv) Orthodontic utilization. We measure our performance against these strategic priorities by the achievement of key financial and operating metrics.

For the three months ended March 31, 2021, we achieved:

- Revenues of $894.8 million and revenue growth of 62.4% year-over-year;
- Clear Aligner revenues of $753.3 million with revenue growth of 56.4% year-over-year;
- Imaging Systems and CAD/CAM Services revenues of $141.5 million or 104.0% year-over-year growth including exocad's revenues;
- Clear Aligner volume increased by 65.8% year-over-year and Clear Aligner volume for teenage patients increased by 58.9% year-over-year;
- Income from operations $225.4 million and operating margin 25.2%;
- Effective tax rate was 23.4%;
- Net income of $200.4 million with diluted net income per share of $2.51;
- Cash and cash equivalents were $1.1 billion as of March 31, 2021;
- Operating cash flow was $227.2 million;
- Capital expenditures were $43.4 million and predominantly relates to increasing our manufacturing capacity and facilities; and
- Number of employees was 18,975 as of March 31, 2021 and increased 25.8% year-over-year

Other Statistical Data and Trends

- *Digital Scanner Case Submissions.* For the first quarter of 2021, total Invisalign cases submitted with a digital scanner in the Americas increased to 85.5%, up from 80.5% in the first quarter of 2020 and international scans increased to 75.1%, up from 68.7% in the first quarter of 2020. For the first quarter of 2021, 92.9% of Invisalign cases submitted by North American orthodontists were submitted digitally. Our quarterly utilization rates for the last five quarters are as follows:



* Invisalign utilization rates are calculated by the number of cases shipped divided by the number 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 the International region based on its immateriality to the quarter, however is included in the Total utilization.

- Total utilization rate in the first quarter of 2021 increased to 7.6 cases per doctor compared to 5.9 cases per doctor in the first quarter of 2020.
  - *North America:* Utilization rate among our North American orthodontist customers increased to 26.8 cases per doctor in the first quarter of 2021 compared to 18.9 cases per doctor in the first quarter of 2020 and the utilization rate among our North American GP customers increased to 4.8 cases per doctor in the first quarter of 2021 compared to 3.6 cases per doctor in the first quarter of 2020.
  - *International:* International doctor utilization rate was 6.8 cases per doctor in the first quarter of 2021 compared to 5.1 cases in the first quarter of 2020.

- *International Invisalign Growth.* For the three months ended March 31, 2021, International net revenues from Clear Aligners increased to $353.3 million compared to $195.8 million during the same period in 2020.

Results of Operations

Net Revenues by Reportable Segment

We group our operations into two reportable segments: Clear Aligner segment and 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 CAD/CAM 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 months ended March 31, 2021 and 2020 are as follows (in millions):

	Three Months Ended March 31,			
Net Revenues	**2021**	**2020**	**Change**	
Clear Aligner net revenues:				
Americas	$ 357.5	$ 255.6	$ 101.9	39.9 %
International	353.3	195.8	157.5	80.4 %
Non-case	42.5	30.2	12.3	40.8 %
Total Clear Aligner net revenues	$ 753.3	$ 481.6	$ 271.7	56.4 %
Systems and Services net revenues	141.5	69.4	72.2	104.0 %
Total net revenues	$ 894.8	$ 551.0	$ 343.8	62.4 %

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

Clear Aligner Case Volume

Case volume data which represents Clear Aligner case shipments for the three months ended March 31, 2021 and 2020 is as follows (in thousands):

	Three Months Ended March 31,			
	2021	**2020**	**Change**	
Total case volume	595.8	359.4	236.4	65.8 %

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

For the three months ended March 31, 2021, total net revenues increased by $343.8 million as compared to the same period in 2020 primarily as a result of Clear Aligner volume growth of 65.8% and an increase in the number of scanners recognized across all regions.

Clear Aligner - Americas

For the three months ended March 31, 2021, Americas net revenues increased by $101.9 million as compared to the same period in 2020 primarily due to Clear Aligner volume growth of 53.8% which increased net revenues by $137.6 million partially offset by lower Clear Aligner ASP that decreased net revenues by $35.7 million. Lower ASP was mostly due to higher promotional discounts which decreased net revenues by $19.1 million and higher net deferrals which decreased net revenues by $12.5 million.

Clear Aligner - International

For the three months ended March 31, 2021, International net revenues increased by $157.5 million as compared to the same period in 2020 primarily due to Clear Aligner volume growth of 83.2% which increased net revenues by $162.9 million partially offset by lower Clear Aligner ASP. Lower ASP was the result of higher net revenue deferrals partially offset by favorable foreign exchange rates.

Clear Aligner - Non-Case

For the three months ended March 31, 2021, non-case net revenues increased by $12.3 million as compared to the same period in 2020 due to increased Vivera volume across all regions.

Systems and Services

For the three months ended March 31, 2021, Systems and Services net revenues increased by $72.2 million as compared to the same period in 2020 due to a higher number of scanners recognized which increased net revenues by $47.2 million.

Additionally, net revenues increased by $23.6 million as a result of higher iTero service revenues mostly due to a larger scanner install base and the addition of exocad's CAD/CAM revenues.

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

	Three Months Ended March 31,		
	2021	2020	Change
Clear Aligner			
Cost of net revenues	$ 168.7	$ 130.1	$ 38.6
% of net segment revenues	*22.4 %*	*27.0 %*	
Gross profit	$ 584.5	$ 351.5	$ 233.0
Gross margin %	*77.6 %*	*73.0 %*	
Systems and Services			
Cost of net revenues	$ 48.9	$ 26.5	$ 22.5
% of net segment revenues	*34.6 %*	*38.2 %*	
Gross profit	$ 92.6	$ 42.9	$ 49.7
Gross margin %	*65.4 %*	*61.8 %*	
Total cost of net revenues	$ 217.7	$ 156.6	$ 61.1
% of net revenues	*24.3 %*	*28.4 %*	
Gross profit	$ 677.1	$ 394.4	$ 282.7
Gross margin %	*75.7 %*	*71.6 %*	

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

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

Clear Aligner

For the three months ended March 31, 2021, our gross margin percentage increased as compared to the same period in 2020 primarily due to manufacturing efficiencies driven by higher production volumes which was partially offset by lower ASP.

Systems and Services

For the three months ended March 31, 2021, our gross margin percentage increased as compared to the same period in 2020 primarily driven by manufacturing efficiencies driven by higher production volumes and higher ASP from a product mix shift.

Selling, general and administrative (in millions):

	Three Months Ended March 31,		
	2021	2020	Change
Selling, general and administrative	$ 397.1	$ 282.9	$ 114.2
% of net revenues	*44.4 %*	*51.3 %*	

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

Selling, general and administrative expense generally includes personnel-related costs including payroll, stock-based compensation and commissions for our sales force, marketing and advertising expenses including media, public relations, marketing materials, clinical education, trade shows and industry events, legal and outside service costs, equipment, software and maintenance costs, depreciation and amortization expense and allocations of corporate overhead expenses including facilities and Information Technology ("IT").

For the three months ended March 31, 2021, selling, general and administrative expense increased compared to the same period in 2020 primarily due to higher compensation related costs of $63.3 million mainly from higher salaries, fringe benefits, incentive bonuses, commissions and stock-based compensation. Higher salaries were driven by an increase in headcount of approximately 23% as we continue to invest in sales and marketing to penetrate into new markets. Additionally, we also incurred higher advertising and marketing costs of $29.6 million during the three months ended March 31, 2021.

Research and development (in millions):

	Three Months Ended March 31,		
	2021	2020	Change
Research and development	$ 54.5	$ 41.5	$ 13.0
% of net revenues	*6.1 %*	*7.5 %*	

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

Research and development expense generally includes personnel-related costs including payroll and stock-based compensation, software, equipment, material and maintenance costs, outside service costs associated with the research and development of new products and enhancements to existing products, depreciation and amortization expense and allocations of corporate overhead expenses including facilities and IT.

For the three months ended March 31, 2021, research and development expense increased compared to the same period in 2020 primarily due to higher compensation costs including higher salaries, fringe benefits, and incentive bonuses which was driven by an approximate 29% increase in headcount.

Income from operations (in millions):

	Three Months Ended March 31,		
	2021	2020	Change
Clear Aligner			
Income from operations	$ 327.5	$ 166.4	$ 161.1
Operating margin %	*43.5 %*	*34.5 %*	
Systems and Services			
Income from operations	$ 47.2	$ 14.4	$ 32.8
Operating margin %	*33.4 %*	*20.7 %*	
Total income from operations [1]	$ 225.4	$ 69.9	$ 155.5
Operating margin %	*25.2 %*	*12.7 %*	

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

[1] Refer to *Note 12 "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 March 31, 2021, our operating margin percentage increased compared to the same period in 2020 due to a higher gross margin and operating leverage on higher net revenues.

Systems and Services

For the three months ended March 31, 2021, our operating margin percentage increased compared to the same period in 2020 due to operating leverage on higher net revenues in addition to a higher gross margin.

Interest income (in millions):

	Three Months Ended March 31,		
	2021	2020	Change
Interest income	$ 1.6	$ 2.0	$ (0.3)
% of net revenues	*0.2 %*	*0.4 %*	

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

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

For the three months ended March 31, 2021, interest income decreased compared to the same period in 2020 mainly due to the divestiture of our marketable securities portfolio during the first quarter of 2020 mostly offset by interest income recognized during the three months ended March 31, 2021 from the SDC arbitration award regarding the value of Align's capital account balance.

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

	Three Months Ended March 31,		
	2021	2020	Change
Other income (expense), net	$ 34.5	$ (18.5)	$ 53.1
% of net revenues	*3.9 %*	*(3.4)%*	

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

Other income (expense), net, generally 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 March 31, 2021, other income (expense), net increased compared to the same period in 2020 primarily due to a $43.4 million gain related to the SDC arbitration award in the current period in addition to a $9.2 million unrealized loss on a foreign currency forward contract related to the exocad acquisition recognized during the same period in 2020.

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

	Three Months Ended March 31,		
	2021	2020	Change
Provision for (benefit from) income taxes	$ 61.2	$ (1,464.8)	$ 1,526.0
Effective tax rates	*23.4 %*	*(2,745.3)%*	

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

Our provision for income taxes was $61.2 million for the three months ended March 31, 2021 and our benefit from income taxes was $1,464.8 million for the three months ended March 31, 2020 representing effective tax rates of 23.4% and (2,745.3)%, respectively. Our effective tax rate differs from the statutory federal income tax rate of 21% for the three months ended March 31, 2021 primarily due to the recognition of additional tax expense resulting from state income taxes, non-deductible expenses in the U.S. and foreign income taxed at different rates, partially offset by the recognition of excess tax benefits related to stock-based compensation. Our effective tax rate differs from the statutory federal income tax rate of 21% for the three months ended March 31, 2020 mainly as a result of the recognition of a deferred tax asset and related one-time tax benefit in accordance with the completion of the intra-entity transfer of certain intellectual property rights and fixed assets to our Swiss entity and excess tax benefits related to stock-based compensation, partially offset by state income taxes and foreign income taxed at different rates.

The increase in our effective tax rate for the three months ended March 31, 2021 compared to the same period in 2020 is primarily attributable to the recognition of a deferred tax asset and related one-time tax benefit associated with the intra-entity transfer of certain intellectual property rights during the three months ended March 31, 2020, partially offset by increased tax benefits from certain foreign earnings being taxed at lower tax rates, reduced state income taxes, and non-deductible expenses in the U.S.

During the three months ended March 31, 2020, we completed an intra-entity transfer of certain intellectual property rights and fixed assets to our Swiss entity. 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 three months ended March 31, 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. The amortization of this deferred tax asset depends on the profitability of our Swiss headquarters and the recognition of this tax benefit is allowed for a maximum recovery period of 15 years.

Liquidity and Capital Resources

Liquidity and Trends

We fund our operations from product sales. As of March 31, 2021 and December 31, 2020, we had cash and cash equivalents, which are comprised of money market funds, of $1.1 billion and $960.8 million, respectively.

As of March 31, 2021 and December 31, 2020, approximately $447.3 million and $412.5 million of cash and cash equivalents was held by our foreign subsidiaries, respectively. 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 $300.0 million revolving line of credit. 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.

For 2021, we expect our investments in capital expenditures to exceed $300.0 million. Capital expenditures primarily relate to building construction and improvements as well as additional manufacturing capacity to support our international expansion. This includes our planned investment in a new manufacturing facility in Wroclaw, Poland, our first one in the EMEA region. As we expand our manufacturing operations and penetrate into newer markets, prepare for the safe return of employees to our offices and experiment with hybrid work models in 2021, we also expect to invest significantly in sales, marketing and innovation to meet the growing demand for our solutions.

As of March 31, 2021, we have $100.0 million available for repurchase under the share repurchase program authorized by our Board of Directors in May 2018. We entered into the 2021 ASR on April 30, 2021, to repurchase the remaining $100.0 million under the program.

Additional information regarding the impact of COVID-19 on our liquidity and capital resources may be found in *Item 1A* of this Quarterly Report on Form 10-Q under the heading "*Risk Factors*".

Sources and Uses of Cash

The following table summarizes our condensed consolidated cash flows for the three months ended March 31, 2021 and 2020 (in thousands):

	Three Months Ended March 31,	
	2021	2020
Net cash flow provided by (used in):		
Operating activities	$ 227,187	$ 9,784
Investing activities	4,566	276,211
Financing activities	(53,435)	(34,733)
Effect of exchange rate changes on cash, cash equivalents, and restricted cash	(7,487)	(11,007)
Net increase in cash, cash equivalents, and restricted cash	$ 170,831	$ 240,255

Operating Activities

For the three months ended March 31, 2021, cash flows from operations of $227.2 million resulted primarily from our net income of approximately $200.4 million as well as the following:

Significant non-cash activities

- Gain related to our SDC arbitration award of $43.4 million;
- Changes in deferred taxes of $29.0 million primarily related to current year amortization and adjustments to our deferred tax assets of our Swiss entity;
- Stock-based compensation of $27.2 million related to equity awards granted to employees and directors; and
- Depreciation and amortization of $25.6 million related to our investments in property, plant and equipment and intangible assets.

Significant changes in working capital

- Increase of $106.0 million in deferred revenues primarily related to increased cases volumes and timing of revenue recognition;
- Increase of $67.4 million in accounts receivable which is primarily a result of the increase in sales and timing of our collections; and
- Increase of $34.9 million in prepaid expenses and other assets due to the timing of payments and activities.

Investing Activities

Net cash provided by investing activities was $4.6 million for the three months ended March 31, 2021, which consisted of $43.4 million of proceeds from our SDC arbitration award in addition to $4.6 million received on an unsecured promissory note. These inflows were mostly offset by purchases of property and plant and equipment of $43.4 million.

Financing Activities

Net cash used in financing activities was $53.4 million for the three months ended March 31, 2021 which consisted of payroll taxes paid for equity awards through share withholdings of $66.6 million which was partially offset by $13.1 million of proceeds from the issuance of common stock.

Contractual Obligations

Our contractual obligations have not significantly changed since December 31, 2020 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 7 "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. If we are unable to generate adequate operating cash flows and need more funds beyond our available liquid investments and those available under our credit facility, we may need to suspend our stock repurchase programs or seek additional sources of capital through equity or debt financing, collaborative or other arrangements with other companies, bank financing and other sources in order to realize our objectives and to continue our operations. There can be no assurance that we will be able to obtain additional debt or equity financing on terms acceptable to us, or at all. If adequate funds are not available, we may need to make business decisions that could adversely affect our operating results such as modifications to our pricing policy, business structure or operations. Accordingly, the failure to obtain sufficient funds on acceptable terms when needed could have a material adverse effect on our business, results of operations and financial condition.

Off-Balance Sheet Arrangements

As of March 31, 2021, 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 11* "*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 United States of America. The preparation of 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, goodwill and finite-lived assets, business combination, income taxes and legal proceedings and litigations. We use authoritative pronouncements, historical experience and other assumptions as the basis for making estimates. Actual results could differ from those estimates.

There have been no material changes to our critical accounting policies and estimates from the information provided in the "Critical Accounting Policies and Estimates" section of our Management's Discussion and Analysis of Financial Condition and Results of Operations included in our Annual Report on Form 10-K for the year ended December 31, 2020.

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

There have been no material changes in our market risk during the three months ended March 31, 2021, compared to the disclosures in Part II, Item 7A of our Annual Report on Form 10-K for the year ended December 31, 2020.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of disclosure controls and procedures.

Under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, we have evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of the end of the period covered by this Quarterly Report on Form 10-Q. Based upon that evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that our disclosure controls and procedures are effective as of March 31, 2021, to provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our Chief Executive Officer and our Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure, and that such information is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission rules and forms.

Changes in internal control over financial reporting.

There were no changes in our internal control over financial reporting during the quarter ended March 31, 2021 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 6 "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 "General Risk Factors," discusses some of the risks that apply generally to companies and to owning our common stock, in particular. You should carefully review both sections, as well as our condensed 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 order we have chosen to list the risks below or the sections in which we have identified them should not be interpreted to mean we deem any risks to be more or less important or likely to occur 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.

Summary of Risk Factors

The following is a summary of the risks that are more fully described below in this "Risk Factors" section:

Risks Relating to our Business Operations and Strategy

- Our results of operations have been materially adversely affected by global and regional efforts to mitigate the spread of COVID-19 and we expect this will continue in as yet unknown ways and to varying degrees in the future.
- 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, may adversely affect net revenues, gross margin and net income.
- Competition in the markets for our products is increasing and we expect aggressive competition from existing competitors, other companies that may introduce new technologies in the future and customers who create aligners or retainers in house.
- An increasingly larger portion of our total revenues are derived from international sales and we are dependent on our international operations, which exposes us to foreign operational, political and other risks that may harm our business.
- Demand for our products may not increase as rapidly as we anticipate or may decrease due to a variety of factors, including a weakness in general economic conditions and resistance to non-traditional treatment methods.
- Our success depends on our ability to develop, successfully introduce and achieve market acceptance of new products and services.
- 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.
- 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.
- If we fail to sustain or increase revenue growth while controlling expenses, our profitability may decline.
- Our operating results have and will fluctuate in the future, which makes predicting the timing and amount of our revenues, costs and expenditures difficult.
- A disruption in the operations of a primary freight carrier or higher shipping costs could cause a decline in our net revenues or a reduction in our earnings.
- If we fail to accurately predict our volume growth and hire too many or too few technicians, 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.

- 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.
- If the security of our customer and patient information is compromised or we are unable to comply with data protection laws, our operations may be severely adversely impacted, patient care could suffer, we could be liable for related damages, and our reputation could be impaired.
- We are dependent on our marketing activities to deepen our market penetration and raise awareness of our brand and products, which may not prove successful or may become less effective or more costly to maintain in the long term.
- Our success depends in part on our proprietary technology, and if we fail to successfully obtain or 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.
- Obtaining approvals and complying with governmental regulations, particularly healthcare and data privacy compliance, is expensive and time-consuming, and any failure to obtain or maintain approvals or comply with regulations regarding our products or services or the products and services of our suppliers or customers could materially harm our sales, result in substantial penalties and cause harm to our reputation.
- If we or any vendors on whose products or services we rely for our products and service 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.
- 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 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.
- We use distributors for a portion of the importation, marketing and sales efforts related to our products and services, which exposes us to risks that may be harmful to our sales and operations.
- Our business exposes us to potential liability for the quality and safety of our products and services, how we advertise and market those products and services and how and to whom we sell them, and we may incur substantial expenses or be liable for substantial damages or penalties if we are subject to claims or litigation.
- We are subject to risks associated with our strategic investments. Impairments in the value of our investments could negatively impact our financial results.

General Risk Factors

- 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.
- Business disruptions could seriously harm our financial condition.
- Changes in, or interpretations of, accounting rules and regulations, could result in unfavorable accounting charges.
- 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 are exposed to fluctuations in currency exchange rates, which could negatively affect our financial condition and results of operations.
- 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.
- If our goodwill or long-lived assets become impaired, we may be required to record a significant charge to earnings.
- Our effective tax rate may vary significantly from period to period.
- Changes in tax laws or tax rulings could negatively impact our income tax provision and net income.
- 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.
- Historically, the market price for our common stock has been volatile.

- We cannot guarantee we will repurchase our common stock again in the future, and any repurchases may not achieve our objectives.
- Future sales of significant amounts of our common stock may depress our stock price.

Risks Relating to our Business Operations and Strategy

Our results of operations have been materially adversely affected by global and regional efforts to mitigate the spread of COVID-19 and we expect this will continue in as yet unknown ways and to varying degrees in the future.

The broad and extensive impact of the COVID-19 pandemic on virtually all aspects of our business and society generally has exacerbated many of the pre-existing risks to our business by making them more likely to occur or more impactful when they do occur. Accordingly, you should consider the risks in this risk factor in addition to, and not in lieu of, the risks identified elsewhere in these risk factors.

Moreover, any comparisons of our financial results in the first and second quarters of 2021 to the same periods in 2020 may not prove a useful means by which to evaluate the health of our business and our results of operations because of the broad and significantly adverse impact to our business and the businesses of our customers from the pandemic and recovery that followed.

COVID-19 created significant, widespread and unprecedented volatility, uncertainty, and economic instability, disrupting broad aspects of the global economy, our operations and the businesses of our customers and suppliers. Many of these effects continue to varying degrees and further outbreaks of COVID-19 globally or regionally may harm recovering consumer confidence or renew implementation of harsh preventative measures. Because COVID-19 spreads readily through airways in nasal passages and the mouth, our principal customers, dental and orthodontic practices, were an initial focus of efforts to prevent the spread of the virus leading to the complete or substantial closures of their operations; materially harming our sales and sales efforts. In particular, these preventative measures in the first and second quarters of 2020 materially adversely impacted our business and financial results. While practices across all regions have largely reopened, many continue to operate at less than pre-pandemic capacities.

The pandemic has concurrently increased demand for digital solutions such as the products and solutions we offer in the dental field. As restrictions are eased or removed entirely over the longer term, employees return to office work environments, and the availability of travel, dining, entertainment and other similar purchases and activities rebound, it is uncertain whether the increased demand for our products will continue or continue at the pace seen in recent quarters.

In response to the COVID-19 pandemic, in 2020 we implemented measures aimed at limiting 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 orders and decrees of governmental agencies. These measures included diagnostic screenings at our facilities, increased social distancing mandates, closures of physical offices, manufacturing and treatment planning facilities, including our U.S. corporate headquarters and regional facilities worldwide, implementing remote working where feasible, prohibiting non-essential travel, and converting underutilized manufacturing capacity to produce personal protective equipment. Many of these actions remain in effect to varying degrees although we may implement new or revise existing requirements as circumstances require. The actions and reactions to voluntary and involuntary requirements can be highly disruptive to our business and may ultimately prove wholly or partially ineffective. Even if effective, if employees perceive them to be inadequate or overly burdensome, or they prove difficult to maintain over extended periods of time, productivity may decline or we may experience employee unrest, slowdowns, stoppages or other demands, we may fail to timely meet customer demand or fulfill orders, the costs to maintain or implement protective measures or deliver our products may increase, and we may be subject to increased litigation, including product liability and occupational safety and condition claims.

As the economic and societal impact of the pandemic continues to unfold, we are continually evaluating macroeconomic as well as industry-specific factors, including the 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 governmental, business and societal actions in response to the pandemic;
- the impact on worldwide economic activity, employment rates and actions taken by central banks and governments;
- customer and consumer purchasing behavior changes as pandemic-related restrictions are curtailed or lifted, remote working declines and travel and discretionary spending patterns shift and our ability to timely and effectively respond to any resulting decreases or increases in demand;

- the response of employees, customers and suppliers to the easing of social distancing mandates and returning to in office or facility working, including anxieties regarding the continuing risks of the spread of the virus, vaccination requirements, and other mandates that may impact employee productivity and engagement, retention or require additional costly protective measures;
- the liquidity and financial stability of consumers, customers, and patients, including their willingness to purchase our products and services, delays paying for products or services, requests for extended payment terms, or payment defaults;
- travel and gathering restrictions, including those that adversely impair or prohibit our sales personnel from interacting with customers or that limit patients from visiting their doctors or the number of patients doctors can see in their offices;
- actions by us or our competitors such as price reductions, aggressive product promotions, changes in or the launch or termination of products or product lines, and mergers, consolidations and liquidations;
- the confidence of our customers and patients that our products and solutions are sanitary and safe to use;
- 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, doctor, consumer and patient apps, inadequately secured computing networks or servers, overheard telephone conversations, viewable computer screens, stolen passwords or access information, increased phishing and other cyber threats;
- the impact of remote working arrangements on our financial reporting systems and internal control over financial reporting, including our ability to ensure information required to be disclosed is timely and accurately recorded, processed, summarized, reported, and communicated to management, including our Chief Executive and Chief Financial Officers, as appropriate, to allow for timely decisions regarding required disclosure; and
- diversion of management as they focus on the short- and long-term ramifications of the pandemic.

The impact of the pandemic continues to evolve and we cannot predict the future impact on our business or results of operations; although it may have a material adverse effect on our business, financial condition, results of operations, cash flows and stock price as well as the businesses of our 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, may adversely affect net revenues, gross margin and net income.

Our net revenues are largely dependent on 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 majority of our net revenues; making the continued and widespread acceptance of the Invisalign System by orthodontists, GPs and consumers critical to our future success. Sales of our iTero scanners are becoming a larger percentage of our overall revenues and we expect the acquisition of exocad to complement the adoption of digital dentistry. 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 continue using wires and brackets or competitive products rather than the Invisalign System or the rates at which they utilize the Invisalign System fail to increase, 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 declines for any reason, our operating results could be harmed.

The average selling prices of our products, particularly our Invisalign System, are influenced by numerous factors, including the type and timing of products sold, price increases and reductions, product mix, product and services bundling, promotions, and foreign exchange rates. We provide volume-based discount programs to our customers. In addition, we sell a number of products at different list prices which may differ based on country and season. If we change volume-based discount programs that affect our average selling prices; if we introduce price reductions or consumer rebate programs; if we implement new or expand existing 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, some programs may be unsuccessful or may drive demand in unexpected ways. If any of the foregoing to occur, our net revenues, gross profit, gross margin and net income may decline.

Competition in the markets for our products is increasing and we expect aggressive competition from existing competitors, other companies that may introduce new technologies in the future and customers who create aligners or retainers in house.

The dental industry is in a period of immense and rapid digital transformation involving products, technologies, distribution channels and business models. While solutions such as our clear aligner and iTero scanners facilitate this transition, whether our technologies will achieve market acceptance and, if adopted, whether and when they may become obsolete as new offerings become available remains unclear.

Currently, our clear aligner system competes directly against traditional metal wires and brackets and increasingly against clear aligners manufactured and distributed by new market entrants and 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. Due in part to market opportunities and the expiration of certain of our key patents beginning in 2017, competition in the clear aligner market is increasing. The number and types of competitors are diverse and vary by segment, geography and customers, including new and well-established regional competitors, as well as larger companies or divisions of larger companies with substantial sales, marketing, research and financial capabilities, including the ability to leverage existing dental market channels to compete directly with us. Our competitors also include 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 doctors and doctors themselves who can manufacture custom aligners in their offices using modern 3D printing technology. 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 are committed to delivering our Invisalign System solutions primarily through trained and skilled doctors. Invisalign System 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 competitive promotions and sale opportunities. In addition, we may face competition from companies that introduce new technologies and we may be unable to compete with these competitors or they 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. To stimulate product and services demand, we have a history of offering volume discounts, price reductions and other promotions to targeted customers and consumers. Whether or not successful, these promotional campaigns can have unexpected and unintended consequences, including reduced gross margins, profitability and average selling prices, loss of market share, and may discourage 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.

An increasingly larger portion of our total revenues are derived from international sales and we are dependent on our international operations, which exposes us to foreign operational, political and other risks that may harm our business.

We earn an increasingly larger portion of our total revenues from international sales generated through our foreign direct and indirect operations and we expect to increase our sales and presence outside the U.S., particularly in markets we believe have high-growth potential. Moreover, many of our key production steps are performed in locations outside of the U.S. For instance, technicians use a sophisticated, internally developed computer-modeling program to prepare digital treatment plans ("ClinCheck"), which are approved by licensed doctors before being transmitted electronically to our aligner fabrication facilities. These digital files form the basis of the ClinCheck treatment plan and are used to manufacture our aligners. Our digital treatment planning and aligner fabrication are performed in multiple international locations, including large-scale operations in Mexico, Costa Rica and China and we continue to establish additional sites closer to our international customers. Also, we maintain significant regional sales and marketing operations in Switzerland, Singapore and China along with research and development operations globally, including in the U.S., Russia, Israel, and Germany. Our reliance on international operations exposes us to risks and uncertainties that may affect our business or results of operations, including:

- difficulties managing international operations, including any travel restrictions on us or our customers;
- fluctuations in currency exchange rates;
- import and export risks, penalties, controls, license requirements and restrictions;
- controlling production volume and quality of the manufacturing process;
- difficulties hiring and retaining employees, particularly employees with software and technological design and development backgrounds necessary to create, develop and perform the more technical aspects of our operations as well as to service, market and sell complex medical devices and technologies;
- the engagement in activities by our employees, contractors, partners and agents prohibited by international and local trade, labor and other laws such as those 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;

- increased expense of developing, testing, making and marketing localized versions of our products;
- political, military, social, economic, or business instability, acts of terrorism and acts of war, including increased levels of violence and military hostilities and protests in various regions of the world, including regions in which we operate such as the United States, Mexico, Hong Kong, the Middle East, Eastern Europe and Africa. 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 which may materially impair all or a portion of our business operations critical to our iTero operations. If any of these events or conditions to occur, the impact to us, our employees and customers is uncertain, particularly if emergency circumstances, armed conflicts or an escalation in political instability or violence were to occur;
- general geopolitical instability and the responses to it, such as the possibility, threat of, imposition of, or changes in sanctions, trade restrictions and tariffs, particularly involving key customer, development or manufacturing markets such as China, Mexico, Russia, Eastern Europe or other countries;
- interruptions and limitations in telecommunication services or critical systems or applications reliant on a stable and uninterrupted communications infrastructure;
- production or material transportation delays or disruption, including as a result of customs clearance, workforce unrest, slowdowns or stoppages, unionization efforts, or as a result of disasters, whether as a natural forces or human caused;
- burdens of complying with a wide variety of regional and local laws, including anti-trust, and competition 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;
- reduced intellectual property rights protections as compared to the protections afforded under the laws of the U.S.;
- longer payment cycles and greater difficulty in accounts receivable collection; and
- potential adverse tax consequences.

The potential impacts of the United Kingdom's ("UK") withdrawal from the European Union ("EU") is still unfolding and could, among other potential outcomes, adversely affect the tax, tax treaty, currency, operational, legal and regulatory regimes to which our businesses are subject, including those involving data privacy and the regulation of medical devices. The withdrawal could also, among other potential outcomes, disrupt the free movement of goods, services, people, data and information and significantly disrupt trade. Further, uncertainty around these and related issues could lead to adverse effects on the economies and political stability of the UK, EU and the other economies in which we operate.

Should any of these factors, either individually or in combination, occur they 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 or may decrease 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, debt obligations, discretionary income, 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 have or 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 or shift away from consumer spending on elective, non-urgent, or higher value procedures or a reduction in the demand for dental services generally, any of which would materially adversely affect our sales and operating results. Conversely, the pandemic may have temporarily limited options for consumer discretionary spending and demand for our products may be harmed once travel and other restrictions are eased. 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 accounts for the vast majority of our net revenues, represents a significant change from traditional metal brackets and wires orthodontic treatment, and customers and consumers may not find it cost-effective or preferable to traditional treatment. For instance, a number of dental professionals continue to believe the Invisalign treatment is appropriate for only a limited percentage of patients. Increased market acceptance of our products depends 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 depends on our ability to develop, successfully introduce and achieve market acceptance of new products and services.

Our success depends on our ability to profitably and quickly develop, manufacture, market and obtain regulatory approval or clearance of new products and services along with improvements to existing products and services. There is no assurance we can successfully develop, sell and achieve market acceptance of our products and services. The extent of, and rate at which,

market acceptance and penetration are achieved by any 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 technology, services and systems 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 and timely obtain approval or clearance by government agencies such as the FDA and analogous agencies in other countries;
- qualify for third-party reimbursement for procedures using our products;
- successfully identify, timely develop and market products and services to new and evolving target markets; and
- encourage customers to adopt new technologies and provide the needed support to make new product launches successful.

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. If we successfully innovate and develop new products and product enhancements, we may incur substantial costs doing so and our profitability may suffer. 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. Consequently, doctors may be unwilling to adopt our new products until they successfully complete one or more cases or until more historical clinical results are available.

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 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. There is no guarantee that the acquisition will achieve the desired benefits and synergies or that the exocad CAD/CAM software will continue to succeed in the marketplace.

In addition, we do not have a history of significant acquisitions and integrating exocad during the COVID-19 pandemic poses challenges which may make it difficult to achieve the expected financial, technical or strategic benefits of the acquisition in the time frames anticipated if at all. 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;
- slower adoption of or technological difficulties uniting our product and service offerings to produce solutions that efficiently and effectively integrate with the workflows between doctors, laboratories and other market participants;
- diversion of management resources;
- the inability to retain or attract key personnel;
- the failure to accurately estimate the potential markets and market shares for exocad’s 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, that we fail to adequately mitigate or control them, or that new risks and potential liabilities associated with exocad arise;
- 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;

- negative impact on our 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, intellectual property and other litigation, anti-bribery and corruption or other similar matters that are, alone or in the aggregate, materially adverse; and
- 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.

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

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, personnel and suppliers. 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, to hire, train, motivate, manage and retain employees, and ensure our suppliers remain diverse and capable enough to meet growing demand for the systems, raw materials, parts and components essential to the manufacture and delivery of our products. We may be unable to manage such growth effectively; balancing near-term efforts to meet existing demand while adding personnel, creating scalable and robust systems and operations, and automating processes needed for long term efficiencies. 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 better experiences, improve their confidence in using the Invisalign System and iTero intraoral scanners to treat more patients and provide redundancy should other facilities be temporarily or permanently unavailable. Our ability to obtain regulatory clearance and certifications for, move into, plan, construct and equip additional order acquisition, treatment planning and manufacturing facilities is subject to significant risk and uncertainty, including risks related to establishing facilities, such as hiring and retaining employees and delays and cost overruns, 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, China and Costa Rica, which may negatively impact our gross margin. If the transition into additional facilities is significantly delayed, if a facility is required to temporarily or permanently, partially or fully shut down, or demand for our products outpaces our ability to hire qualified personnel and effectively implement systems and infrastructure, we may be unable to fulfill orders timely, or at all, which may negatively impact our financial results, reputation and overall business.

In addition, because adapting production capacity and related cost structures to changing market conditions takes time, 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. Thereafter, as dental practices reopened we experienced a rapid increase in demand. If product demand decreases or increases more than forecast, we could be required to write off inventory or record excess capacity charges, we may be required to purchase or lease additional or larger facilities and additional equipment, or we may be unable to fulfill customer demand in the time frames and with the quantities they require, any of which may take time to accomplish, lower our gross margin, inhibit sales or harm our reputation, or if we are required to implement additional protective measures to safeguard our employees, productivity could decline. Production of our clear aligners and 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 revenue growth while controlling expenses, 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 and the markets we target are 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 and will continue to fluctuate in the future, which makes predicting the timing and amount of our revenues, costs and expenditures difficult.

Our quarterly and annual operating results have and will continue to fluctuate for a variety of reasons, including as a result of changing doctor and consumer product demand. 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;
- the level of confidence of doctors in our products and changes in the rates at which they recommend or utilize our products for their patients;
- weakness in consumer spending and confidence or a slowdown in domestic or international economies;
- higher manufacturing, delivery and inventory costs;
- competition in general and competitive developments in our target markets;
- changes in relationships with our dental support organizations and distributors, including timing of orders;
- changes in the timing of revenue recognition and changes in our average selling prices, including as a result of the timing of receipt of product orders and shipments, product and services mix, geographic mix, product and services deferrals, the introduction of new products and software releases, product pricing, bundling and 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;
- seasonal fluctuations, including those related to patient demographics such as teen buying habits in the U.S., 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;
- timing and fluctuation of spending around marketing and brand awareness campaigns and industry trade shows;
- 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, natural or other disasters, pandemics or general economic conditions impacting the solvency of vendors in our supply chain;
- 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 such things as the establishment of treatment planning and fabrication facilities, the hiring and deployment of personnel, and litigation;
- 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 patient 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; and
- material impairments of goodwill and long-lived assets.

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 for future revenues. As a result, if our net revenues for a particular period fall below expectations, we may be unable to reduce spending to offset any shortfall in net revenues. Due to these and other factors, we do not believe that quarter-to-quarter comparisons of our operating results are meaningful.

A disruption in the operations of a 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. If we cannot deliver our products on time and cost effectively, customers may choose alternative products causing our net revenues and gross margins to decline, possibly materially. If fuel costs increase, so do our freight costs. 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 or otherwise offset such increases in our cost of net revenues, our gross margin and financial results could be adversely affected.

If we fail to accurately predict our volume growth and hire too many or too few technicians, 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 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 ensure products are manufactured and delivered 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 too many technicians in anticipation of volume growth that does not materialize, materializes at a rate slower than anticipated, 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, attack 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, increasingly sophisticated cyber threats, and changing customer preferences. Expanded remote working and increased customer usage of online technology platforms by us, our customers and suppliers as a means to mitigate the spread of COVID-19 have increased the demands on and risks to our IT systems and personnel. Moreover, we continue 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 disruption of 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, new releases 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 and issue new releases of our customer facing software applications, such as my iTero, our ClinCheck software, MyAligntech and the Invisalign Doctor Site as well as our internal software applications upon which customer facing, manufacturing and treatment planning operations are dependent. Software applications frequently contain errors or defects, especially when first introduced or when new versions are released. The discovery of a defect, error or security vulnerability 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 cause adverse consequences, including: delay or loss of revenues, delay in market acceptance, damage to our reputation, loss of market share or increased service costs, any of which could have a material adverse effect on our business, financial condition or results of operations.

A significant portion of our clear aligner production is dependent on digital scans from our iTero and third party intraoral scanners. A failure of all or any portion of ours or third party software or other components or systems to interoperate with iTero or third party scanners, termination of interoperability with third party scanners, or a system outage for any reason could have a material adverse effect on our ability to accept scans, manufacture clear aligners or otherwise service our customers which may amongst other things, harm our sales, damage our reputation, or result in litigation.

If the information we rely on to run our businesses is 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, and fail to produce timely and accurate reports. We may also be required to respond to regulatory inquiries or actions, forced to defend against litigation or pay damages, penalties or fines, experience increases in operating and administrative expenses, find it necessary to rebuild networks or systems, lose existing customers, experience difficulties 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, expose personal and financial data of our customers and their patients, 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 or present risks in design, development, manufacture or distribution, including "bugs," security vulnerabilities, and other problems that can unexpectedly interfere with the operation of the system or compromise or exploit the safety and security of our networks. The costs to eliminate or mitigate security problems, viruses and bugs could be significant and depending on the nature and extent of the problem and the networks or products impacted, may result in network or systems 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 or developing new IT systems, 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, our operations may be severely adversely impacted, patient care could suffer, we could be liable for related damages, and our reputation could be impaired.

We retain confidential customer financial as well as patient health information. Therefore, it is critical that the facilities and infrastructure on which we depend to run our business 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 the infrastructure and systems on which we depend may be vulnerable to physical break-ins, computer viruses, programming errors or other technical malfunctions, hacking or phishing attacks by third parties, ransomware, 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 judicial or governmental orders forcing us to cease operations or modify our business practices in ways that could materially limit or restrict the products and services we provide. 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 and other forms of insurance coverage 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 Brazil, Russia and China, have enacted, and others are considering enacting, data localization or data residency laws and 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. and China to multinational requirements in the EU. For instance, China has enacted new, complex and highly restrictive cybersecurity, data localization, and cross border data transfer laws. In the EU, we must comply with the General Data Protection Regulation which serves as a harmonization of EU data-privacy laws. 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.

We are dependent on our marketing activities to deepen our market penetration and raise awareness of our brand and products, which may not prove successful or may become less effective or more costly to maintain in the long term.

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, social media influencers and other strategic

partners. We attempt to structure our advertising campaigns to increase brand awareness, adoption and goodwill; however, there is no assurance our campaigns will achieve the returns on advertising spend desired, successfully increase brand or product awareness sufficiently to sustain or increase our growth goals, or generate the goodwill and positive reputational goals we intend. Moreover, should any of these entities or individuals do, say, publish or lend support to events or causes which may be perceived by all or any portion of society negatively, our sponsorships or support of these entities may be called into question, boycotts of our products announced, and our reputation may be harmed, any of which could have an adverse effect on our gross margin and business overall. In addition, various countries restrict direct to consumer advertising of our products and we could run afoul of restrictions and be ordered to stop certain marketing activities.

Additionally, we rely heavily on data generated from our campaigns to target specific audiences and evaluate their effectiveness, particularly data generated from Internet activities on mobile devices. To obtain this data, we are dependent on third parties and popular mobile operating systems, networks, technologies, products, and standards that we do not control, such as the Android and iOS operating systems and mobile browsers. Any changes in such systems that degrade, reduce or eliminate our ability to target or measure the results of ads or increase costs to target audiences could adversely affect the effectiveness of our campaigns. For example, Apple recently released iOS 14 that includes significant data privacy changes that may limit our ability to interpret, target and measure ads effectively.

Our success depends in part on our proprietary technology, and if we fail to successfully obtain or 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. Our inability to do so could harm our competitive position.

We 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. Moreover, our foreign patent portfolio is less extensive than our U.S. portfolio. We also rely on protection of our copyrights, trademarks, 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 involved in litigation and expect to be in the future. 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 have been necessary and likely will be needed in the future to determine the validity and scope of certain of our IP rights and the IP rights claimed by third parties to determine the validity, scope or non-infringement of certain patent rights pertinent to the manufacture, use or sale of our products. Any of these 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. Moreover, independent actions by competitors, customers or others may be brought alleging that our efforts to assert or attempt to enforce our patent or other intellectual property rights constitute unfair competition or violations of antitrust laws in the United States and other jurisdictions. Any of these litigation results could adversely affect our results of operations and stock price.

Obtaining approvals and complying with governmental regulations, particularly healthcare and data privacy compliance, is expensive and time-consuming, and any failure to obtain or maintain approvals or comply with regulations regarding our products or services or the products and services of our suppliers or customers could materially harm our sales, result in substantial penalties and cause harm to our reputation.

As a supplier of medical devices and solutions, we and many of customers and suppliers are subject to extensive and frequently changing regulations under numerous federal, state, local and foreign laws. Our healthcare provider customers and distributors are also subject to a wide variety of laws and regulations that 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. For instance, regulations affecting the security and privacy of patient healthcare information held by healthcare providers and their business associates such as the U.S. Health Insurance Portability and Accountability Act ("HIPAA") 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. Our critical vendors and service providers are similarly subject to various regulations. Our failure, or the failure of our suppliers or customers to strictly adhere to clearances or approvals in the labeling, marketing and sales of our products and services could subject us to claims or litigation, including actions alleging false or misleading advertising, unfair or anti-competitive business practices or other violations of laws or regulations, which may result in costly investigations, fines, penalties, as well as material judgments, settlements or decrees. There can be no assurance that we will adequately address the business risks associated with the implementation and compliance with such laws or that we will be able to take advantage of any resulting business opportunities.

Furthermore, in general before we can sell a new medical device or market a new use of or claim for an existing product, we must obtain clearance or approval unless an exemption applies. For instance, 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 clearances or approvals of 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 successful, the time and effort required may be significant and costly. 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 and certain of our vendors 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 finding or to comply with applicable manufacturing regulations could result in enforcement actions, 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.

In addition, numerous foreign, state and federal healthcare-related laws regulate our business and the businesses of our customers, suppliers and service providers, covering areas such as:

- the 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.

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.

If we or any vendors on whose products or services we rely for our products and service 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, software 3D printing and other technologies and industries on which our products and services and based. 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, exclusion orders or injunctions that may prevent or limit our rights to sell or import our products in one or more countries. 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. 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 purchase the vast majority of our resin and polymer, the primary raw materials used in our manufacturing process for clear aligners, from a single source. Moreover, we rely on a third-party manufacturer to supply key sub-assemblies for our iTero Element scanner. If these or other suppliers encounter financial, operating or other difficulties, are unable to hire or maintain personnel, cannot timely obtain supplies, are unable to maintain manufacturing standards or controls, fail to timely deliver materials, parts or components, or if our relationship or the terms by which we contract with any of them changes, we may be unable to quickly establish or qualify replacement sources of supply and could face production interruptions, delays and inefficiencies. Finding substitute manufacturers may be expensive, time-consuming or impossible and could result in a significant interruption in the supply of one or more products, including our intraoral scanners, causing us to lose revenues and suffer damage to our customer relationships. 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 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 the success of 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 or groups of employees may harm our business. In order to provide more comprehensive sales and service coverage and pursue growth opportunities, we continue to increase the size of our sales force

domestically and internationally. 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. If we are unable to expand our sales force, 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.

We use distributors for a portion of the importation, marketing and sales efforts related to our products and services, which exposes us to risks that may be harmful to our sales and operations.

In addition to our direct sales force, we have and expect to continue to use distributors to import, market, sell, service and/or support our products. Our agreements with these distributors may be non-exclusive and terminable by either party with little notice. If any of these relationships are terminated and alternative distributors are not quickly found and trained in the use, marketing, sales and support of our products and services, our revenues and ability to sell or service our products in markets key to our growth and expansion could be adversely affected. These distributors may also choose to sell alternative or competing products or services. In addition, we may be held responsible for the actions of these distributors and their employees and agents for compliance with laws and regulations, including competition, bribery and corruption, and medical device and services marketing and sales activities. A distributor may also affect our ability to effectively market our products in certain foreign countries or regulatory jurisdictions if it holds the regulatory authorization in such countries or within such regions and causes, by action or inaction, the suspension of such marketing authorization or sanctions for non-compliance. It may be difficult, expensive, and time-consuming for us to re-establish market access or regulatory compliance in such cases.

Our business exposes us to potential liability for the quality and safety of our products and services, how we advertise and market those products and services and how and to whom we sell them, and we may incur substantial expenses or be liable for substantial damages or penalties if we are subject to claims or litigation.

Our products and services involve an inherent risk of claims concerning their design, manufacture, safety and performance, how they are marketed and advertised in a complex framework of highly regulated domestic and international laws and regulations, and how we package, bundle or and sell them to customers who may be private individuals or companies or public entities such as hospitals and clinics. Moreover, consumer products and services are routinely subject to claims of false, deceptive or misleading advertising, consumer fraud and unfair business practices. Additionally, we may be held liable if any product we develop or manufacture or services we offer or perform causes injury or is otherwise found unhealthy or unsuitable. Even if our products are safe, if they are promoted for use or used in unintended or unexpected ways or for which we have not obtained clearance or approvals (“off-label” usage), we may be investigated, fined or have our products or services enjoined or clearances rescinded by administrative agencies or we may be required to defend ourselves in litigation. Although we intend to continue to maintain insurance for product liability, business practices and other types of activities we make or offer, coverage may not be available on acceptable terms, if at all, and may not be sufficient against potential liabilities. Any claim for product liability, sales, advertising and business practices, regardless of its merit or eventual outcome, could result in significant legal defense costs and damage our reputation, increase our expenses and diverting management’s attention away from the operation of our business.

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

We have and expect to continue to make investments in promising research and technology, primarily through privately held companies, for strategic reasons and to support key business initiatives, and we may not realize a return on our strategic investments. Of the companies in which we invest, they may generate net losses and the market for their products, services or technologies may be slow to develop, if at all. Furthermore, valuations of privately held companies are inherently complex due to the lack of readily available market data. If we determine that our investments have declined in value, we may be required to record impairments which could be material and could have an adverse impact on our financial results.

General Risk Factors

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, manufacturing, 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 also depends 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.

Business disruptions could seriously harm our financial condition.

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 and subsequent recovery materially adversely impacted our sales and business operations in 2020, 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 teams in Costa Rica and other global locations create ClinCheck treatment plans using sophisticated computer software. In addition, certain of our customer facing operations are located in Costa Rica. Our aligner molds and finished aligners are fabricated in Mexico and China. Both locations in Costa Rica and Mexico as well as others 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, a significant 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.

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 routinely assess, update and refine our internal control over financial reporting for its effectiveness. Pursuant to the Sarbanes-Oxley Act of 2002 and 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.

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.

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 an investment exceeds the fair value, and the decline in fair value is deemed to be other-than-temporary, we are required to write down the value of the investment, 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, it is 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 and assessing these assumptions and predicting and forecasting future events can be difficult. Large acquisitions, such as our acquisition of exocad in 2020, require periodic 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 long-lived asset group is determined.

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 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 the first quarter of fiscal 2020 due to the relocation of our EMEA regional headquarters from the Netherlands to Switzerland. Our effective tax rate is also dependent in part on forecasts of full year results which can vary materially. 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 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.

Periodically, we may acquire, or make investments in, complementary companies, products or technologies like our acquisition of exocad in 2020. Alternatively, we may be unable 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. Additionally, as an organization we do not have a history of significant acquisitions or integrating their operations and cultures with our own. 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 or fail to uncover material issues of the acquired company or assets, including litigation or ongoing investigations, accounting irregularities or improprieties, failure to comply with regulations, governmental orders or decrees, and IT security and privacy compliance issues. Any integration process may require significant time and resources and we may not successfully evaluate or utilize the acquired technology, or we may fail to retain key personnel, or accurately forecast the financial impact of an acquired business. 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.

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

The market price of our common stock is 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 speculation in the press or investment community regarding estimates of our net revenues, operating results or other performance indicators;
- announcements by us or our competitors or new market entrants, including strategic actions, management changes, and material transactions or acquisitions;
- technical factors in the public trading markets for our stock that may produce price movements that may or may not comport with macro, industry or company-specific fundamentals, including, without limitation, the sentiment of retail investors (including as it may be expressed on financial trading and other social media sites), the amount and status of short interest in our securities, access to margin debt, trading in options and other derivatives on our common stock, fractional share trading, and other technical trading factors or strategies;
- 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 repurchase our common stock again in the future, and any repurchases may not achieve our objectives.

We have a history of recurring stock repurchase programs intended to return capital to our investors although they were suspended in 2020 primarily as a result of uncertainties regarding the pandemic. 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 resume repurchases of our common stock, or continue repurchasing our common stock if we do resume, 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 existing stockholders may adversely affect the market price of our common stock by creating the perception of difficulties or problems with our business that 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 March 31, 2021. As of March 31, 2021, we have $100.0 million available for repurchase under the $600.0 million repurchase program authorized by our Board of Directors in May 2018. Subsequent to the first quarter, on April 30, 2021, we entered into an accelerated stock repurchase agreement (“2021 ASR”) to repurchase $100.0 million of our common stock. We paid $100.0 million on May 3, 2021 and received an initial delivery of approximately 0.1 million shares based on current market prices. The final number of shares to be repurchased will be based on our volume-weighted average stock price under the terms of the 2021 ASR, less an agreed upon discount.

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

SIGNATURES

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

ALIGN TECHNOLOGY, INC.

May 5, 2021

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

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

Exhibit 31.1

CERTIFICATION

I, Joseph M. Hogan, certify that:

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

Date: May 5, 2021

/s/ JOSEPH M. HOGAN

Joseph M. Hogan
President and Chief Executive Officer

Exhibit 31.2

CERTIFICATION

I, John F. Morici, certify that:

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

Date: May 5, 2021

/s/ JOHN F. MORICI

John F. Morici

Chief Financial Officer and Senior Vice President, Global Finance

Exhibit 32.1

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

In connection with the Quarterly Report of Align Technology, Inc. (the "Company") on Form 10-Q for the period ending March 31, 2021 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: May 5, 2021

In connection with the Quarterly Report of Align Technology, Inc. (the "Company") on Form 10-Q for the period ending March 31, 2021 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: May 5, 2021