UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)			
•	NT TO SECTION 13 OR 15(d) OF THE SECU	RITIES EXCHANGE ACT OF 1934	
	For the quarterly period ended September 30, 2021 OR		
☐ TRANSITION REPORT PURSUAN	NT TO SECTION 13 OR 15(d) OF THE SECU	TRITIES EXCHANGE ACT OF 1934	
	For the transition period from to		
	Commission file number: 000-32259		
ALI	GN TECHNOLOGY, I (Exact name of registrant as specified in its charter)	NC.	
Delaware		94-3267295	
(State or other jurisdiction in incorporation or organization		(I.R.S. Employer Identification Number)	
	410 North Scottsdale Road, Suite 1300 Tempe, Arizona 85281 (Address of principal executive offices) (602) 742-2000 (Registrant's telephone number, including area code)		
	Securities registered pursuant to Section 12(b) of the Act:		
Title of each class Common Stock, \$0.0001 par value	Trading Symbol ALGN	Name of each exchange on which registered The NASDAQ Stock Market LLC (NASDAQ Global Market)	
	has filed all reports required to be filed by Section 13 or 1 e registrant was required to file such reports), and (2) has be	• •	_
	submitted electronically every Interactive Data File require on this (or for such shorter period that the registrant was require		on S-
	a large accelerated filer, an accelerated filer, a non-accelerated filer," "accelerated filer," "smaller reporting company" at		
Large accelerated filer	Accelerate		
Non-accelerated filer Emerging growth company	Smaller re	porting company	
3 33 1- 1	if the registrant has elected not to use the extended transition ion 13 (a) of the Exchange Act.	n period for complying with any new or revised	
Indicate by check mark whether the registrant is a	shell company (as defined in Rule 12b-2 of the Exchange A	ct). Yes □ No ⊠	
The number of shares outstanding of the registrant	e's Common Stock, \$0.0001 par value, as of October 28, 202	1 was 78,853,069.	
	1		

ALIGN TECHNOLOGY, INC.

INDEX

PART I	FINANCIAL INFORMATION	<u>3</u>
ITEM 1.	FINANCIAL STATEMENTS (UNAUDITED):	3
	CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS	3
	CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME	<u>4</u>
	CONDENSED CONSOLIDATED BALANCE SHEETS	<u>5</u>
	CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY	<u>6</u>
	CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS	<u>8</u>
	NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS	9
ITEM 2.	MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF	
	<u>OPERATIONS</u>	<u>24</u>
ITEM 3.	QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK	<u>33</u>
ITEM 4.	CONTROLS AND PROCEDURES	<u>34</u>
PART II	OTHER INFORMATION	<u>34</u>
ITEM 1.	<u>LEGAL PROCEEDINGS</u>	<u>34</u>
ITEM 1A.	RISK FACTORS	<u>34</u>
ITEM 2.	<u>UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS</u>	<u>55</u>
ITEM 3.	<u>DEFAULTS UPON SENIOR SECURITIES</u>	<u>55</u>
ITEM 4.	MINE SAFETY DISCLOSURES	<u>55</u>
ITEM 5.	OTHER INFORMATION	<u>55</u>
ITEM 6.	<u>EXHIBITS</u>	<u>56</u>
SIGNATURES		57

Invisalign, Align, the Invisalign logo, ClinCheck, Made to Move, Invisalign Assist, Invisalign Teen, Invisalign Go, Vivera, SmartForce, SmartTrack, SmartStage, SmileView, iTero, iTero Element, Orthocad, iCast, iRecord and exocad, among others, are trademarks and/or service marks of Align Technology, Inc. or one of its subsidiaries or affiliated companies and may be registered in the United States and/or other countries.

PART I—FINANCIAL INFORMATION

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

	Three Mo Septen			nths Ended mber 30,		
	2021	2020	2021		2020	
Net revenues	\$ 1,015,906	\$ 734,144	\$ 2,921,485	\$	1,637,421	
Cost of net revenues	260,750	200,056	730,693		484,649	
Gross profit	755,156	534,088	2,190,792		1,152,772	
Operating expenses:						
Selling, general and administrative	428,409	312,492	1,257,445		852,365	
Research and development	65,587	44,527	177,839		126,420	
Total operating expenses	493,996	357,019	1,435,284		978,785	
Income from operations	261,160	177,069	755,508		173,987	
Interest income and other income (expense), net:						
Interest income	401	329	2,427		2,788	
Other income (expense), net	427	7,147	34,476		(12,368)	
Total interest income and other income (expense), net	828	7,476	36,903		(9,580)	
Net income before provision for (benefit from) income taxes	261,988	184,545	 792,411		164,407	
Provision for (benefit from) income taxes	81,019	45,174	211,352		(1,452,493)	
Net income	\$ 180,969	\$ 139,371	\$ 581,059	\$	1,616,900	
Net income per share:						
Basic	\$ 2.29	\$ 1.77	\$ 7.36	\$	20.54	
Diluted	\$ 2.28	\$ 1.76	\$ 7.29	\$	20.45	
Shares used in computing net income per share:						
Basic	 78,904	78,824	 78,971		78,729	
Diluted	79,516	79,163	79,677		79,078	

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

	Three Months Ended September 30,						ths Ended iber 30,												
	2021			2021			2021			2021			2021 2020				2021		2020
Net income	\$	180,969	\$	139,371	\$	581,059	\$	1,616,900											
Change in foreign currency translation adjustment, net of tax		(12,037)		15,810		(25,902)		25,793											
Change in unrealized gains (losses) on investments, net of tax		20		_		_		(194)											
Other comprehensive income (loss)		(12,017)		15,810		(25,902)		25,599											
Comprehensive income	\$	168,952	\$	155,181	\$	555,157	\$	1,642,499											

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

(unaudited)

(unaudited)				
	S	eptember 30, 2021		December 31, 2020
ASSETS				
Current assets:				
Cash and cash equivalents	\$	1,237,822	\$	960,843
Accounts receivable, net of allowance for doubtful accounts of \$9,174 and \$10,239, respectively		855,037		657,704
Inventories		207,116		139,237
Prepaid expenses and other current assets		155,332		91,754
Total current assets		2,455,307		1,849,538
Property, plant and equipment, net		1,002,769		734,721
Operating lease right-of-use assets, net		92,727		82,553
Goodwill		426,594		444,817
Intangible assets, net		115,794		130,072
Deferred tax assets		1,502,250		1,552,831
Other assets		54,668		35,151
Total assets	\$	5,650,109	\$	4,829,683
			_	
LIABILITIES AND STOCKHOLDERS' EQUITY				
Current liabilities:				
Accounts payable	\$	174,916	\$	142,132
Accrued liabilities		545,286		405,582
Deferred revenues		1,070,113		777,887
Total current liabilities		1,790,315		1,325,601
Income tax payable		125,986		105,748
Operating lease liabilities		74,352		64,445
Other long-term liabilities		142,694		100,024
Total liabilities		2,133,347		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; 78,852 and 78,860 issued and outstanding, respectively)		8		8
Additional paid-in capital		972,450		974,556
Accumulated other comprehensive income (loss), net		17,599		43,501
Retained earnings		2,526,705		2,215,800
Total stockholders' equity		3,516,762		3,233,865
Total liabilities and stockholders' equity	\$	5,650,109	\$	4,829,683

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

	Comm	on St	ock	_ Additional		Accumulated Other Comprehensive					
Three Months Ended September 30, 2021	Shares		Amount		Paid-In Capital		Income (Loss), Net		Retained Earnings		Total
Balance as of June 30, 2021	78,948	\$	8	\$	895,831	\$	29,616	\$	2,458,955	\$	3,384,410
Net income					_				180,969		180,969
Net change in unrealized gains (losses) from investments	_		_		_		20		_		20
Net change in foreign currency translation adjustment	_		_		_		(12,037)		_		(12,037)
Issuance of common stock relating to employee equity compensation plans	69		_		12,490		_		_		12,490
Tax withholdings related to net share settlements of equity awards	_		`		(2,454)		_		_		(2,454)
Common stock repurchased and retired	(165)		_		(1,819)		_		(113,219)		(115,038)
Equity forward contract related to accelerated stock repurchase	_		_		40,000		_		_		40,000
Stock-based compensation	_		_		28,402		_		_		28,402
Balance as of September 30, 2021	78,852	\$	8	\$	972,450	\$	17,599	\$	2,526,705	\$	3,516,762

	Common Stock		- Additional		Accumulated Other Comprehensive																			
Nine Months Ended September 30, 2021	Shares		Amount		Amount		Amount		Amount		Amount		Amount		Amount		Amount		Paid-In Capital		come (Loss), Net			Total
Balance as of December 31, 2020	78,860	\$	8	\$	974,556	\$	43,501	\$	2,215,800	\$ 3,233,865														
Net income	_		_		_		_		581,059	581,059														
Net change in foreign currency translation adjustment	_		_		_		(25,902)		_	(25,902)														
Issuance of common stock relating to employee equity compensation plans	434		_		25,623		_		_	25,623														
Tax withholdings related to net share settlements of equity awards	_		_		(107,343)		_		_	(107,343)														
Common stock repurchased and retired	(442)		_		(4,884)		_		(270,154)	(275,038)														
Stock-based compensation	_		_		84,498		_		_	84,498														
Balance as of September 30, 2021	78,852	\$	8	\$	972,450	\$	17,599	\$	2,526,705	\$ 3,516,762														

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

	Comm	Common Stock		_ Additional		Accumulated Other Comprehensive				
Three Months Ended September 30, 2020	Shares		Amount		aid-In Capital	Inc	ome (Loss), Net	Net Retained Earnings		Total
Balance as of June 30, 2020	78,781	\$	8	\$	918,495	\$	9,101	\$	1,917,441	\$ 2,845,045
Net Income	_		_		_		_		139,371	139,371
Net change in foreign currency translation adjustment	_		_		_		15,810		_	15,810
Issuance of common stock relating to employee equity compensation plans	68		_		9,652		_		_	9,652
Tax withholdings related to net share settlements of equity awards	_		_		(1,636)		_		_	(1,636)
Stock-based compensation	_		_		25,229		_		_	25,229
Balance as of September 30, 2020	78,849	\$	8	\$	951,740	\$	24,911	\$	2,056,812	\$ 3,033,471

	Commo	on St	ock	Additional Paid-In								Additional Paid-In				Accumulated Other omprehensive			
Nine Months Ended September 30, 2020	Shares		Amount		Capital	ome (Loss), Net	Retained Earnings		Total										
Balance as of December 31, 2019	78,433	\$	8	\$	906,937	\$ (688)	\$	439,912	\$ 1,346,169										
Net income	_		_		_	_		1,616,900	1,616,900										
Net change in unrealized gains (losses) from investments	_		_		_	(194)		_	(194)										
Net change in foreign currency translation adjustment	_		_		_	25,793		_	25,793										
Issuance of common stock relating to employee equity compensation plans	416		_		20,314	_		_	20,314										
Tax withholdings related to net share settlements of equity awards	_		_		(48,674)	_		_	(48,674)										
Stock-based compensation	_		_		73,163	_		_	73,163										
Balance as of September 30, 2020	78,849	\$	8	\$	951,740	\$ 24,911	\$	2,056,812	\$ 3,033,471										

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

Nine Months Ended

	September			
	2021		2020	
CASH FLOWS FROM OPERATING ACTIVITIES:				
Net income	\$ 581,059	\$	1,616,900	
Adjustments to reconcile net income to net cash provided by operating activities:				
Deferred taxes	48,104		(1,502,459	
Depreciation and amortization	79,141		68,769	
Stock-based compensation	84,498		73,163	
Non-cash operating lease cost	19,364		16,819	
Allowance for doubtful accounts provisions	1,559		13,090	
Arbitration award gain	(43,403)		_	
Other non-cash operating activities	14,092		14,189	
Changes in assets and liabilities, net of effects of acquisition:				
Accounts receivable	(216,081)		(101,888	
Inventories	(83,249)		(11,774	
Prepaid expenses and other assets	(74,736)		(28,251	
Accounts payable	13,495		21,837	
Accrued and other long-term liabilities	107,159		(28,343	
Long-term income tax payable	20,263		119	
Deferred revenues	348,430		128,585	
Net cash provided by operating activities	 899,695		280,756	
CASH FLOWS FROM INVESTING ACTIVITIES:				
Acquisition, net of cash acquired	(8,002)		(420,788	
Purchase of property, plant and equipment	(292,002)		(101,757	
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		17,828	
Proceeds from arbitration award	43,403		_	
Other investing activities	(3,712)		1,760	
Net cash used in investing activities	(255,719)		(186,840	
CASH FLOWS FROM FINANCING ACTIVITIES:	<u> </u>			
Proceeds from issuance of common stock	25,623		20,314	
Common stock repurchases	(275,038)		_	
Payroll taxes paid upon the vesting of equity awards	(107,344)		(48,674	
Net cash used in financing activities	 (356,759)		(28,360	
Effect of foreign exchange rate changes on cash, cash equivalents, and restricted cash	 (10,241)		(568	
Net increase in cash, cash equivalents, and restricted cash	 276,976		64,988	
Cash, cash equivalents, and restricted cash at beginning of the period	961,474		551,134	
Cash, cash equivalents, and restricted cash at beginning of the period	\$ 	\$	616,122	
Cash, Cash equivalents, and restricted Cash at end of the period	\$ 1,238,450	Ф	616,1	

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

Note 1. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying unaudited Condensed Consolidated Financial Statements have been prepared by Align Technology, Inc. ("we", "our", or "Align") in accordance with the rules and regulations of the Securities and Exchange Commission ("SEC") and contains all adjustments, including normal recurring adjustments, necessary to state fairly our results of operations for the three and nine months ended September 30, 2021 and 2020, our comprehensive income for the three and nine months ended September 30, 2021 and 2020, our financial position as of September 30, 2021, our stockholders' equity for the three and nine months ended September 30, 2021 and 2020, and our cash flows for the nine months ended September 30, 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 and nine months ended September 30, 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 and 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. Further, we could also be materially adversely affected by supply chain disruptions, including shortages and inflationary pressures, uncertain or reduced demand, labor shortages, delays in collection of outstanding receivables and the impact of any initiatives or programs that we may undertake to address financial and operational challenges faced by our customers.

Recent Accounting Pronouncements

(i) New Accounting Updates Recently Adopted

In December 2019, the Financial Accounting Standards Board ("FASB") issued Accounting Standard Update ("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.

(ii) Recent Accounting Updates Not Yet Effective

We continue to monitor new accounting pronouncements issued by the FASB and do not believe any of the recently issued accounting pronouncements will have an impact on our consolidated financial statements or related disclosures.

Note 2. Fair Value Measurements

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

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

Level 2 — Observable inputs other than quoted prices included in Level 1, such as quoted prices for similar assets or liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the asset or liability. We obtain fair values for our Level 2 investments. Our custody bank and asset managers independently use professional pricing services to gather pricing data which may include quoted market prices for identical or comparable financial instruments, or inputs other than quoted prices that are observable either directly or indirectly, and we are ultimately responsible for these underlying estimates.

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

The following tables summarize our financial assets measured at fair value on a recurring basis as of September 30, 2021 and December 31, 2020 (in thousands):

Description			Se	Balance as of eptember 30, 2021	Level 1	Level 2
Cash equivalents:						
Money market funds		9	\$	582,227	\$ 582,227	\$ _
Prepaid expenses and other current assets:						
Israeli funds				4,170	_	4,170
		3	\$	586,397	\$ 582,227	\$ 4,170
Description		e as of December 31, 2020		Level 1	Level 2	Level 3
Cash equivalents:	_					
Money market funds	\$	519,228	\$	519,228	\$ _	\$ _
Money market funds Prepaid expenses and other current assets:	\$	519,228	\$	519,228	\$ _	\$ _
3	\$	519,228 3,500	\$	519,228 —	\$ 3,500	\$ _ _
Prepaid expenses and other current assets:	\$,		519,228 — —	\$	\$ 5,408

¹ The unsecured promissory note was paid in full by SmileDirectClub, LLC ("SDC") during the nine months ended September 30, 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 during the nine months ended September 30, 2021. Refer to *Note 6 "Legal Proceedings" of the Notes to Condensed Consolidated Financial Statements* included for more information on the arbitration.

Investments in Privately Held Companies

Investments in equity securities of privately held companies without readily determinable fair values was \$8.6 million as of September 30, 2021 and not material as of December 31, 2020 and are reported as nonrecurring investments within other assets in our Condensed Consolidated Balance Sheet. Our investments in equity securities are considered Level 3 in the fair value hierarchy since the investments are in private companies without quoted market prices and we adjust the carrying value based on observable price changes. The adjustments to the carrying value of these investments was not material during the nine months ended September 30, 2021 and 2020.

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 September 30, 2021 and 2020, we recognized net gains of \$14.7 million and net losses of \$12.1 million, respectively, and during the nine months ended September 30, 2021 and 2020, we recognized net gains of \$14.1 million and \$0.6 million, respectively. As of September 30, 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 September 30, 2021 and December 31, 2020 (in thousands):

	September	r 30, 2021
	Local Currency Amount	Notional Contract Amount (USD)
Euro	€192,600	\$ 222,456
Chinese Yuan	¥1,021,000	157,701
Canadian Dollar	C\$100,000	78,563
Japanese Yen	¥6,097,800	54,496
British Pound	£40,250	54,296
Brazilian Real	R\$285,000	52,073
Polish Zloty	PLN142,000	35,710
Mexican Peso	M\$310,000	15,065
Israel Shekel	ILS38,400	11,914
Swiss Franc	CHF10,600	11,356
Australian Dollar	A\$5,900	4,252
		\$ 697,882

	December	r 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 \in 376.0 million. During the nine months ended September 30, 2020, we recognized a loss of \$10.2 million within other income (expense), net in our Condensed Consolidated Statement of Operations.

Note 3. Balance Sheet Components

Inventories consist of the following (in thousands):

		September 30, 2021	De	cember 31, 2020
Raw materials	<u>.</u>	\$ 104,017	\$	76,404
Work in process		51,527		31,393
Finished goods		51,572		31,440
Total inventories	<u>-</u>	\$ 207,116	\$	139,237

Accrued liabilities consist of the following (in thousands):

	Se	September 30, 2021		ecember 31, 2020
Accrued payroll and benefits	\$	229,743	\$	170,106
Accrued expenses		62,828		42,536
Accrued sales and marketing expenses		55,310		34,488
Accrued property, plant and equipment		41,389		27,692
Accrued income taxes		35,152		30,130
Accrued professional fees		29,488		20,617
Current operating lease liabilities		22,170		21,735
Other accrued liabilities		69,206		58,278
Total accrued liabilities	\$	545,286	\$	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):

		iea			
		2021	2020		
Balance at beginning of period	\$	12,615	\$	11,205	
Charged to cost of net revenues		13,400		8,047	
Actual warranty expenditures		(11,040)		(8,229)	
Balance at end of period	\$	14,975	\$	11,023	

Deferred revenues consist of the following (in thousands):

	September 30, 2021	D	December 31, 2020
Deferred revenues - current	\$ 1,070,113	\$	777,887
Deferred revenues - long-term ¹	\$ 108,387	\$	62,551

 $^{^{\}rm 1}$ Included in Other long-term liabilities within our Condensed Consolidated Balance Sheet

During the three months ended September 30, 2021 and 2020, we recognized \$1.0 billion and \$734.1 million of net revenues, respectively, of which \$112.6 million and \$99.6 million was included in the deferred revenues balance at December 31, 2020 and 2019, respectively.

During the nine months ended September 30, 2021 and 2020, we recognized \$2.9 billion and \$1.6 billion of net revenues, respectively, of which \$349.7 million and \$263.3 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 September 30, 2021 were \$1.2 billion. These performance obligations are expected to be recognized over the next one to five years.

Note 4. Goodwill and Intangible Assets

During the three months ended September 30, 2021, we completed an immaterial business combination which increased goodwill and existing technology intangible assets.

Goodwill

The change in the carrying value of goodwill for the nine months ended September 30, 2021, categorized by reportable segments, is as follows (in thousands):

	Systems and Clear Aligner Services			Total		
Balance as of December 31, 2020	\$	112,691	\$	332,126	\$	444,817
Additions from acquisition		3,646				3,646
Foreign currency translation adjustments		(3,062)		(18,807)		(21,869)
Balance as of September 30, 2021	\$	113,275	\$	313,319	\$	426,594

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)	as of eptember 30, 2021	Accumulated Amortization	Accumulated Impairment Loss	Net Carrying Value as of otember 30, 2021
Existing technology	10	\$ 104,531	\$ (19,923)	\$ (4,328)	\$ 80,280
Customer relationships	11	55,000	(24,888)	(10,751)	19,361
Trademarks and tradenames	10	16,600	(4,087)	(4,179)	8,334
Patents and other	8	6,511	(4,296)	_	2,215
		\$ 182,642	\$ (53,194)	\$ (19,258)	 110,190
Foreign currency translation		 			5,604
Total intangible assets					\$ 115,794

	Weighted Average Amortization Period (in years)	Amount as	Carrying of December 2020	Accumulated Amortization	Accumulate Impairment L		D	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 September 30, 2021 is as follows (in thousands):

Fiscal Year Ending December 31,	Amortization
Remainder of 2021	\$ 4,158
2022	15,392
2023	14,772
2024	13,831
2025	13,455
Thereafter	48,582
Total	\$ 110,190

Amortization expense for the three months ended September 30, 2021 and 2020 was \$4.4 million and \$4.1 million, respectively, and amortization expense for the nine months ended September 30, 2021 and 2020 was \$12.2 million and \$9.5 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. The 2020 Credit Facility allows for an alternative rate to be identified if LIBOR is no longer available. 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 September 30, 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. On June 30, 2021, counsel for the parties signed a Stipulation and Agreement of Settlement to resolve all claims for \$16 million. The settlement amount will be funded by insurance proceeds and consequently, we recorded a short term liability and a receivable for this amount in our condensed consolidated financial statements. Lead Plaintiff filed a motion seeking preliminary approval of the settlement on July 15, 2021. A hearing on that motion was held on October 21, 2021 and the Court indicated it will thereafter grant preliminary approval of the settlement. The settlement is subject to notice to class members and final approval by the Court.

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 then current 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 and filed its opening appeal brief with the United States Court of Appeals for the Ninth Circuit on September 1, 2021. Respondents' brief in opposition is due November 22, 2021. 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 is stayed pending resolution of the appeal in 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 filed counterclaims for breach of contract and business torts. Align's motion to dismiss these 3Shape counterclaims was granted.

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 Court granted Align's motion to dismiss 3Shape's business tort counterclaims. The case is currently stayed.

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 business tort and patent infringement counterclaims. Align moved to dismiss the business tort counterclaims. The Court granted Align's motion

to dismiss all of the business tort counterclaims except for a counterclaim of fraudulent inducement. Align filed a separate motion to dismiss on that counterclaim which is pending.

3Shape and Align's District Court patent infringement complaints and 3Shape's 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 May 31, 2022. The case pending in the Western District of Texas has been given a jury 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. 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 U.S. 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. A jury trial is scheduled to begin in this matter on November 20, 2023. 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 U.S. 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. Plaintiff filed an amended complaint on July 30, 2021 adding new plaintiffs and various state law claims. Align moved to dismiss the first amended complaint. On September 30, 2021, the Court dismissed the complaint and granted Plaintiffs leave to amend. Plaintiffs filed a second amended complaint on October 21, 2021. Align has not yet responded to the second amended 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 U.S., 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 claimed 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. 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. SDC paid the amount due to Align on March 17, 2021.

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 alleges 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 is set for hearing in the first quarter of 2022.

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 ordinary 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

Other Commitments

In 2018, we entered into a purchase agreement, as amended, with an existing single source supplier which requires us to purchase aligner material for a minimum amount of approximately \$425.9 million over a five year period through 2022. On June 24, 2021, we amended the agreement which requires an additional minimum aligner material purchase of approximately \$348.0 million from 2023 through 2026.

Off-Balance Sheet Arrangements

As of September 30, 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 September 30, 2021, we did not have any material indemnification claims that were probable or reasonably possible.

Note 8. Stockholders' Equity

As of September 30, 2021, the 2005 Incentive Plan (as amended) has a total reserve of 27,783,379 shares of which 4,236,601 shares are available for issuance.

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 and nine months ended September 30, 2021 and 2020 is as follows (in thousands):

	Three Months Ended September 30,				Nine Months Ended September 30,			
	 2021		2020		2021		2020	
Cost of net revenues	\$ 1,451	\$	1,247	\$	4,175	\$	3,485	
Selling, general and administrative	22,229		19,951		67,131		58,284	
Research and development	4,722		4,031		13,192		11,394	
Total stock-based compensation	\$ 28,402	\$	25,229	\$	84,498	\$	73,163	

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 nine months ended September 30, 2021 is as follows:

	Number of Shares Underlying RSUs (in thousands)	Weighted Averag Grant Date Fair Va		Aggregate Intrinsic Value (in thousands)
Unvested as of December 31, 2020	632	\$ 243.	55	
Granted	162	599.	47	
Vested and released	(254)	215.	09	
Forfeited	(33)	343.	14	
Unvested as of September 30, 2021	507	\$ 365.	16 1.4	\$ 337,271

As of September 30, 2021, we expect to recognize \$132.3 million of total unamortized compensation cost, net of estimated forfeitures, related to RSUs over a weighted average period of 2.3 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. MSUs vest over a period of three years and the maximum number eligible to vest in the future is 250% of the MSUs initially granted.

A summary for the nine months ended September 30, 2021 is as follows:

	Number of Shares Underlying MSUs (in thousands)	eighted Average nt Date Fair Value	Weighted Average Remaining Contractual Term (in years)	Intrin	regate sic Value ousands)
Unvested as of December 31, 2020	227	\$ 430.50			
Granted	177	658.02			
Vested and released	(230)	513.73			
Unvested as of September 30, 2021	174	\$ 551.57	1.2	\$	115,851

As of September 30, 2021, we expect to recognize \$45.4 million of total unamortized compensation cost, net of estimated forfeitures, related to MSUs over a weighted average period of 1.2 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. In May 2021, the 2010 Purchase Plan was amended and restated to increase the maximum number of shares available for purchase to 4,400,000 shares. As of September 30, 2021, we have 2,194,566 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 Month Septembe		Nine Months Ended September 30,					
	 2021	2020	2021	2020				
Expected term (in years)	 1.2	1.0	1.1	1.0				
Expected volatility	51.1 %	71.7 %	52.7 %	55.0 %				
Risk-free interest rate	0.1 %	0.1 %	0.1 %	0.9 %				
Expected dividends	_	_	_	_				
Weighted average fair value at grant date	\$ 257.89 \$	117.32	\$ 246.84	\$ 96.94				

As of September 30, 2021, there was \$15.0 million of total unamortized compensation costs related to employee stock purchases which we expect to be recognized over a weighted average period of 0.7 year.

Note 9. Common Stock Repurchase Programs

In May 2018, our Board of Directors authorized a plan to repurchase up to \$600.0 million of our common stock ("May 2018 Repurchase Program"). As of September 30, 2021, the authorization under the May 2018 Repurchase Program was completed.

In May 2021, our Board of Directors authorized a plan to repurchase up to \$1.0 billion of our common stock ("May 2021 Repurchase Program"). As of September 30, 2021, we have \$825.0 million available for repurchase under the May 2021 Repurchase Program.

Accelerated Stock Repurchase Agreements ("ASRs")

During 2021, we entered into the following ASRs providing for the repurchase of our common stock based on the volume-weighted average price during the term of the agreement, less an agreed upon discount. The table below sets forth information regarding our repurchases following table summarizes the information regarding repurchases of our common stock during the nine months ended September 30, 2021:

Agreement Date	Repurchase Program	Amount Paid (in millions)	Completion Date	Total Shares Received	A	werage Price per Share
April 30, 2021	May 2018	\$ 100.0	July 30, 2021	171,322	\$	583.70
May 17, 2021	May 2021	\$ 100.0	August 31, 2021	161,707	\$	618.40
August 2, 2021	May 2021	\$ 75.0	September 27, 2021	109,239	\$	686.91

As of September 30, 2021, all the ASRs have been completed and the repurchased shares retired.

Subsequent to the third quarter, on October 29, 2021, we entered into an ASR to repurchase \$100.0 million of our common stock. We paid \$100.0 million 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 ASR, less an agreed upon discount.

Note 10. Accounting for Income Taxes

Our provision for income taxes was \$81.0 million and \$45.2 million for the three months ended September 30, 2021 and 2020, respectively representing effective tax rates of 30.9% and 24.5%, respectively. Our provision for income taxes was \$211.4 million for the nine months ended September 30, 2021 and our benefit from income taxes was \$1,452.5 million for the nine months ended September 30, 2020, representing effective tax rates of 26.7% and (883.5)%, respectively. Our effective tax rate differs from the statutory federal income tax rate of 21% for the three and nine months ended September 30, 2021 primarily due to foreign income taxed at different rates, state income taxes, and non-deductible expenses in the U.S., 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 September 30, 2020 primarily due to state income taxes and non-deductible expenses in the U.S., partially offset by a tax benefit resulting from settlement of an income tax audit. Our effective tax rate differs from the statutory federal income tax rate of 21% for the nine months ended September 30, 2020 mainly as a result of the recognition of tax benefits associated with the intra-entity transfer of certain intellectual property rights and fixed assets completed last year.

During the nine months ended September 30, 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 nine months ended September 30, 2020, which is the net impact of the deferred tax asset recognized as a result of the additional Swiss tax deductible basis in the transferred assets and certain costs related to the transfer of fixed assets and inventory.

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 2014.

Our total gross unrecognized tax benefits, excluding interest and penalties, were \$64.6 million and \$46.3 million as of September 30, 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 September 30, 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 \$32.3 million and \$35.7 million as of September 30, 2021 and December 31, 2020, respectively, which were primarily related to the intangible assets from our exocad acquisition.

Note 11. 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):

	Tì	ree Mo Septen		Nine Months Ended September 30,				
	2021		2020	2020 2021			2020	
Numerator:							_	
Net income	\$ 18	0,969	\$ 139,371	\$	581,059	\$	1,616,900	
Denominator:								
Weighted average common shares outstanding, basic	7	8,904	78,824		78,971		78,729	
Dilutive effect of potential common stock		612	339		706		349	
Total shares, diluted	7	9,516	79,163		79,677		79,078	
Net income per share, basic	\$	2.29	\$ 1.77	\$	7.36	\$	20.54	
Net income per share, diluted	\$	2.28	\$ 1.76	\$	7.29	\$	20.45	
Anti-dilutive potential common shares ¹		83	65		67		66	

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 12. Supplemental Cash Flow Information

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

	September 30,							
	2021		2020					
Non-cash investing and financing activities:								
Acquisition of property, plant and equipment in accounts payable and accrued liabilities	\$ 72,531	\$	43,147					
Cash paid for amounts included in the measurement of lease liabilities:								
Operating cash flows from operating leases	\$ 21,626	\$	19,384					
Right-of-use assets obtained in exchange for lease obligations:								
Operating leases	\$ 31,635	\$	44,915					

Note 13. 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.

		Three Mor Septen			nded 0,		
		2021	2020		2021		2020
Net revenues		_	 _		_		
Clear Aligner	\$	837,593	\$ 620,764	\$	2,431,821	\$	1,400,716
Systems and Services		178,313	113,380		489,664		236,705
Total net revenues	\$	1,015,906	\$ 734,144	\$	2,921,485	\$	1,637,421
Gross profit	<u>==</u>						
Clear Aligner	\$	638,169	\$ 463,747	\$	1,869,368	\$	1,007,605
Systems and Services		116,987	70,341		321,424		145,167
Total gross profit	\$	755,156	\$ 534,088	\$	2,190,792	\$	1,152,772
Income from operations							
Clear Aligner	\$	346,957	\$ 261,774	\$	1,022,048	\$	467,078
Systems and Services		65,791	34,912		177,694		52,194
Unallocated corporate expenses		(151,588)	(119,617)		(444,234)		(345,285)
Total income from operations	\$	261,160	\$ 177,069	\$	755,508	\$	173,987
Stock-based compensation	_						
Clear Aligner	\$	2,824	\$ 2,003	\$	7,750	\$	6,628
Systems and Services		169	322		514		553
Unallocated corporate expenses		25,409	22,904		76,234		65,982
Total stock-based compensation	\$	28,402	\$ 25,229	\$	84,498	\$	73,163
Depreciation and amortization							
Clear Aligner	\$	13,191	\$ 10,413	\$	36,481	\$	30,231
Systems and Services		5,827	5,092		14,994		11,882
Unallocated corporate expenses		8,596	8,981		27,666		26,656
Total depreciation and amortization	\$	27,614	\$ 24,486	\$	79,141	\$	68,769

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 Mor Septen			Nine Mor Septen		
	2021 2020		2021		2020	
Total segment income from operations	\$ 412,748	\$	296,686	\$ 1,199,742	\$	519,272
Unallocated corporate expenses	(151,588)		(119,617)	(444,234)		(345,285)
Total income from operations	261,160		177,069	755,508		173,987
Interest income	401		329	2,427		2,788
Other income (expense), net	427		7,147	34,476		(12,368)
Net income before provision for (benefit from) income taxes	\$ 261,988	\$	184,545	\$ 792,411	\$	164,407

Geographical Information

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

	Three Moi Septen				Nine Mon Septen	
	2021	2020		2021		2020
Net revenues ¹ :						
U.S.	\$ 448,858	\$	332,414	\$	1,266,258	\$ 744,978
Switzerland	323,036		219,910		1,004,820	512,681
China	86,766		76,825		214,418	142,927
Other International	157,246		104,995		435,989	236,835
Total net revenues	\$ 1,015,906	\$	734,144	\$	2,921,485	\$ 1,637,421

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):

	Se	ptember 30, 2021	Decei	nber 31, 2020
Long-lived assets ¹ :				
Switzerland	\$	428,786	\$	257,337
U.S.		204,530		180,539
China		125,558		113,918
Costa Rica		94,308		97,804
Other International		242,314		167,676
Total long-lived assets	\$	1,095,496	\$	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, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). 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 sales and marketing activities; our expectations regarding the near and long-term implications of the COVID-19 pandemic on the global economy, including global supply chain issues; our preparedness and our customers' 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; our intentions 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 predicted level of operating expenses and gross margins and other factors beyond our control; our expectations regarding staying in compliance with laws and regulations currently applicable to, or which may become applicable to, our business both in the United States and internationally; 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 Part I, Item 2 "Management's Discussion and Analysis of Financial Condition and Results of Operations," and in particular, the risks discussed below in Part II, Item 1A "Risk Factors." We undertake no obligation to revise or update these forward-looking statements. Given these risks and uncertainties, readers are cautioned not to place undue reliance on such forward-looking statements.

The following discussion and analysis of our financial condition and results of operations should be read together with our condensed consolidated financial statements and related notes included elsewhere in this Quarterly Report on Form 10-Q 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 (the "SEC").

Executive Overview of Results

COVID-19 Update

The outbreak of COVID-19 virus in late 2019 and the pandemic that followed has caused significant volatility and uncertainty in the global and regional economies. This has led to changes in consumer and business behavior, fear and market fluctuations, and restrictions on business and individual activities, all of which has materially impacted supply and demand in broad sectors of the world markets. For us, sales and results of operations were initially materially impacted by the preventative measures implemented to slow the spread, including the complete closure or significantly reduced operations of dental practices. In subsequent quarters, our business rebounded sharply, although the inconsistent pace and scale of recovery generally continues to reverberate throughout global markets, evidenced by significant shortages of raw materials, energy, components, transportation and delivery services, and labor. Additionally, variants of the COVID-19 virus continue to drive unpredictability and hamper the normalization of supply and demand as businesses react to new or renewed localized preventative measures intended to slow the spread of the virus. Notwithstanding these setbacks, in general, the scale and time during which these additional measures are implemented are less impactful on our customers and their patients than the most drastic measures imposed in 2020. For instance, globally both public and private dental practices largely remain open, 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 practices such 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 the number of customers that realize the efficiencies and benefits of our digital solutions for their practices and patients to continue to grow even as the pandemic-related restrictions remain unpredictable.

To address the increasing demand for digital solutions, we intend to continue targeting our investment plans in sales, marketing and innovation as well as our capital expenditures, particularly as we expand our manufacturing operations in locations such as Europe, in order to meet the anticipated demand for our solutions.

Nevertheless, the continuing evolution of the pandemic, including the setbacks occurring as a result of new virus strains and the continuing business restrictions and lockdowns, supply chain shortages and delays, the positive impacts of vaccinations, the uncertainties regarding consumer spending as demand for entertainment, dining, and travel returns and remote working diminishes, remains highly fluid and unpredictable. Consequently, the COVID-19 pandemic has caused, and is expected to continue causing for an unknown period of time, disruptions to many of the norms we have historically experienced in the cadence of our quarterly results of operations. As such, our recent operating results and levels of growth may not be indicative of our future performance. 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 Part II, Item 1A of this Quarterly Report on Form 10-Q under the heading "Risk Factors."

Key financial and operating metrics

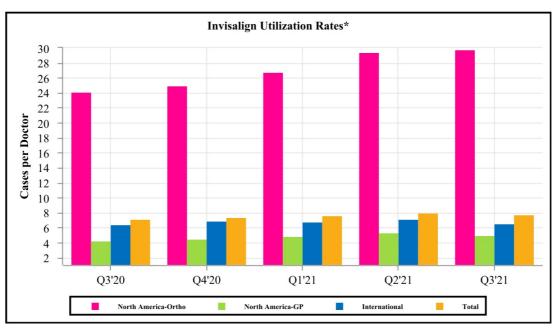
Our business strategic priorities remain focused on four principal pillars of growth: (i) international expansion; (ii) general practitioners ("GP") adoption; (iii) patient demand & conversion; and (iv) orthodontic utilization. We measure our performance against these strategic priorities by the achievement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

For the three months ended September 30, 2021, we achieved the following, taking into consideration that percentage changes from prior year financial results include the impact of COVID-19 and do not necessarily reflect our future growth rates:

- Revenues of \$1.0 billion, an increase of 38.4% year-over-year;
- Clear Aligner revenues of \$837.6 million, an increase of 34.9% year-over-year reflecting the expanding opportunity for Invisalign treatment among adults globally, as well as the underlying orthodontic market as we continue to build awareness of the Invisalign brand and drive utilization among teens and younger patients through increased consumer marketing.
 - Americas Clear Aligner revenues of \$408.4 million, an increase of 34.3% year-over-year;
 - International Clear Aligner revenues of \$375.5 million, an increase of 33.5% year-over-year;
 - Clear Aligner volume increase of 32.1% year-over-year and Clear Aligner volume for teenage patients increase of 26.6% year-over-year;
- Imaging Systems and CAD/CAM Services revenues of \$178.3 million, an increase of 57.3% year-over-year reflecting strong growth across all regions with continued adoption of the iTero Element 5D and 5D Plus Series of next generation scanners and imaging systems launched in February 2021, as well as increased average selling prices ("ASP") predominately due to favorable product mix shift towards higher priced scanners;
- Income from operations of \$261.2 million and operating margin of 25.7%;
- Effective tax rate of 30.9%;
- Net income of \$181.0 million with diluted net income per share of \$2.28;
- Cash and cash equivalents of \$1.2 billion as of September 30, 2021;
- Operating cash flow of \$355.0 million;
- · Capital expenditures of \$124.3 million, predominantly related to increases to our manufacturing capacity and facilities; and
- Number of employees was 21,590 as of September 30, 2021, an increase of 25.4% year-over-year.

Other Statistical Data and Trends

• *Digital Scanner Case Submissions*. For the third quarter of 2021, total Invisalign cases submitted with a digital scanner in the Americas increased to 87.9%, up from 83.2% in the third quarter of 2020 and international scans increased to 79.3%, up from 72.1% in the third quarter of 2020. For the third quarter of 2021, 96.1% 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 third quarter of 2021 increased to 7.7 cases per doctor compared to 7.1 cases per doctor in the third quarter of 2020.
 - *North America*: Utilization rate among our North American orthodontist customers increased to 29.7 cases per doctor in the third quarter of 2021 compared to 24.1 cases per doctor in the third quarter of 2020 and the utilization rate among our North American GP customers increased to 5.0 cases per doctor in the third quarter of 2021 compared to 4.2 cases per doctor in the third quarter of 2020.
 - *International:* International doctor utilization rate was 6.5 cases per doctor in the third quarter of 2021 compared to 6.4 cases in the third quarter of 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 and nine months ended September 30, 2021 and 2020 are as follows (in millions):

Three Months Ended

		Septe			September 30,										
Net Revenues	2021	2020	Cha	nge		2021		2020		Ch	ange				
Clear Aligner net revenues:	 														
Americas	\$ 408.4	\$ 304.1	\$ 104.3	34.3 %	\$	1,166.4	\$	683.0	\$	483.4		70.8 %			
International	375.5	281.2	94.3	33.5 %		1,118.5		632.3		486.2		76.9 %			
Non-case	53.7	35.4	18.3	51.6 %		146.9		85.4		61.5		72.1 %			
Total Clear Aligner net revenues	\$ 837.6	\$ 620.8	\$ 216.8	34.9 %	\$	2,431.8	\$	1,400.7	\$	1,031.1		73.6 %			
Systems and Services net revenues	178.3	113.4	64.9	57.3 %		489.7		236.7		253.0		106.9 %			
Total net revenues	\$ 1,015.9	\$ 734.1	\$ 281.8	38.4 %	\$	2,921.5	\$	1,637.4	\$	1,284.1		78.4 %			

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 and nine months ended September 30, 2021 and 2020 is as follows (in thousands):

		Three Mon Septem			Nine Months Ended September 30,								
	2021	2020	Chang	ge	2021	2020	Change						
Total case volume	655.1	496.1	159.1	32.1 %	1,916.5	1,077.4	839.2	77.9 %					

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

For the three and nine months ended September 30, 2021, total net revenues increased by \$281.8 million and \$1.3 billion, respectively, as compared to the same periods in 2020 primarily as a result of increases in Clear Aligner volume of 32.1% and 77.9%, respectively, and an increase in the number of scanners recognized across most regions.

Clear Aligner - Americas

For the three months ended September 30, 2021, Americas net revenues increased by \$104.3 million as compared to the same period in 2020 primarily due to a 36.4% increase in Clear Aligner volume which resulted in higher net revenues of \$110.7 million, partially offset by lower Clear Aligner ASP that decreased net revenues by \$6.4 million. Lower ASP was mostly due to higher promotional discounts which decreased net revenues by \$8.5 million and higher net deferrals which decreased net revenues by \$4.2 million. The decreases in ASP were partially offset by favorable foreign exchange which increased net revenues by \$5.0 million.

For the nine months ended September 30, 2021, Americas net revenues increased by \$483.4 million, as compared to the same period in 2020, primarily due to a 81.6% increase in Clear Aligner volume which resulted in higher net revenues of \$557.3 million, partially offset by lower Clear Aligner ASP that decreased net revenues by \$73.9 million. Lower ASP was mostly due to higher net deferrals which decreased revenues by \$55.4 million and higher promotional discounts which decreased net revenues by \$42.5 million. The decreases in ASP were partially offset by favorable product mix shift which increased net revenues by \$22.4 million.

Clear Aligner - International

For the three months ended September 30, 2021, International net revenues increased by \$94.3 million, as compared to the same period in 2020, primarily due to a 27.0% increase in Clear Aligner volume which resulted in higher net revenues of \$75.8 million. Higher Clear Aligner ASP increased net revenues by \$18.5 million mostly due to lower promotional discounts and favorable exchange rates.

For the nine months ended September 30, 2021, International net revenues increased by \$486.2 million, as compared to the same period in 2020, primarily due to a 73.5% increase in Clear Aligner volume which resulted in higher net revenues of \$464.8 million. Higher Clear Aligner ASP increased net revenues by \$21.4 million mostly due to favorable exchange rates

which increased net revenues by \$65.3 million and favorable product mix shift which increased net revenues by \$18.3 million. The increases in ASP were partially offset by higher net deferrals which decreased net revenues by \$62.6 million.

Clear Aligner - Non-Case

For the three and nine months ended September 30, 2021, non-case net revenues increased by \$18.3 million and \$61.5 million, as compared to the same periods in 2020, due to increased Vivera volume across all regions.

Systems and Services

For the three months ended September 30, 2021, Systems and Services net revenues increased by \$64.9 million, as compared to the same period in 2020, due to a higher number of scanners recognized which increased net revenues by \$27.0 million. Higher scanner ASP increased net revenues by \$16.4 million mostly due to favorable product mix shift towards higher priced scanners. Additionally, net revenues increased by \$21.5 million primarily as a result of higher iTero service revenues mostly due to a larger scanner install base.

For the nine months ended September 30, 2021, Systems and Services net revenues increased by \$253.0 million, as compared to the same period in 2020, due to a higher number of scanners recognized which increased net revenues by \$138.3 million. Higher scanner ASP increased net revenues by \$39.1 million mostly due to favorable product mix shift towards higher priced scanners. Additionally, net revenues increased by \$75.5 million as a result of higher iTero service revenues mostly due to a larger scanner install base and additional exocad CAD/CAM revenues.

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

Cost of net	,	- •	Three N	Months Ende	ed			Nine Months Ended September 30,									
	2021			2020		(Change		2021			2020	20		Change		
<u>Clear</u> <u>Aligner</u>																	
Cost of net revenues	\$ 199.4		\$	157.0		\$	42.4	\$	562.5		\$	393.1		\$	169.4		
% of net segment revenues	23.8	%		25.3	%				23.1	%		28.1	%				
Gross profit	\$ 638.2		\$	463.7		\$	174.4	\$	1,869.4		\$	1,007.6		\$	861.8		
Gross margin %	76.2	%		74.7	%				<i>76</i> .9	%		71.9	%				
<u>Systems</u> <u>and</u> <u>Services</u>																	
Cost of net revenues	\$ 61.3		\$	43.0		\$	18.3	\$	168.2		\$	91.5		\$	76.7		
% of net segment revenues	34.4	%		38.0	%				34.4	%		<i>38.7</i>	%				
Gross profit	\$ 117.0		\$	70.3		\$	46.6	\$	321.4		\$	145.2		\$	176.3		
Gross margin %	65.6	%		62.0	%				65.6	%		61.3	%				
<u>Total</u> cost of net revenues	\$ 260.8		\$	200.1		\$	60.7	\$	730.7		\$	484.6		\$	246.0		
% of net revenues	25.7	%		27.3	%				25.0	%		29.6	%				
Gross profit	\$ 755.2		\$	534.1		\$	221.1	\$	2,190.8		\$	1,152.8		\$	1,038.0		
Gross margin %	74.3	%		72.7	%				<i>7</i> 5.0	%		70.4	%				

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 and nine months ended September 30, 2021, our gross margin percentage increased, as compared to the same periods in 2020, primarily due to manufacturing efficiencies driven by higher production volumes.

Systems and Services

For the three and nine months ended September 30, 2021, our gross margin percentage increased, as compared to the same period in 2020, as a result of higher ASP from a product mix shift and an increase in service revenues which was partially offset by higher freight costs.

Selling, general and administrative (in millions):

			Aonths Ende aber 30,	d					Nine Mo Septem	onths Ended ber 30,			
	 2021		2020		(Change	2021			2020		(Change
Selling, general and administrative	\$ 428.4		\$ 312.5		\$	115.9	\$ 1,257.4		\$	852.4		\$	405.1
% of net revenues	42.2	%	42.6	%			43.0	%		52.1	%		

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 September 30, 2021, selling, general and administrative expense increased, compared to the same period in 2020, primarily due to higher compensation related costs of \$41.5 million from higher salaries, fringe benefits, commissions, incentive bonuses and stock-based compensation mainly due to increased headcount. Additionally, we also incurred higher advertising and marketing costs of \$53.4 million during the three months ended September 30, 2021.

For the nine months ended September 30, 2021, selling, general and administrative expense increased, compared to the same period in 2020, primarily due to higher compensation related costs of \$191.5 million from higher salaries, fringe benefits, commissions, incentive bonuses and stock-based compensation due to increased headcount as we continue to invest in sales and marketing to penetrate into new markets. We also incurred higher advertising and marketing costs of \$147.2 million during the nine months ended September 30, 2021.

Research and development (in millions):

				Ionths Endo ber 30,	ed		Nine Months Ended September 30,									
	 2021			2020		Change		2021			2020			Change		
Research and development	\$ 65.6		\$	44.5		\$	21.1	\$ 177.8		\$	126.4		\$	51.4		
% of net revenues	6.5	%		6.1	%			6.1	%		7.7	%				

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, outside service costs associated with the research and development of new products and enhancements to existing products, software, equipment, material and maintenance costs, depreciation and amortization expense and allocations of corporate overhead expenses including facilities and IT.

For the three and nine months ended September 30, 2021, research and development expense increased, compared to the same periods in 2020, primarily due to higher compensation costs including higher salaries, fringe benefits, and incentive bonuses mainly from increased headcount as we continue to focus our investments in innovation and research.

Income from operations (in millions):

				Ionths Ende ber 30,	d	Nine Months Ended September 30,											
20		2021		2020		C	hange		2021			2020		(Change		
<u>Clear</u> <u>Aligner</u>																	
Income from operations	\$	347.0		\$ 261.8		\$	85.2	\$	1,022.0		\$	467.1		\$	555.0		
Operating margin %		41.4	%	42.2	%				42.0	%		33.3	%				
Systems and Services																	
Income from operations	\$	65.8		\$ 34.9		\$	30.9	\$	177.7		\$	52.2		\$	125.5		
Operating margin %		36.9	%	30.8	%				36.3	%		22.1	%				
Total income from operations ¹	\$	261.2		\$ 177.1		\$	84.1	\$	<i>7</i> 55 . 5		\$	174.0		\$	581.5		
Operating margin %		25. <i>7</i>	%	24.1	%				25.9	%		10.6	%				

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

Clear Aligner

For the three months ended September 30, 2021, our operating margin decreased slightly, compared to the same period in 2020, due to higher operating expenses which were partially offset by higher gross margins.

For the nine months ended September 30, 2021, our operating margin increased, compared to the same period in 2020, due to higher gross margins and operating leverage on higher net revenues.

Systems and Services

For the three and nine months ended September 30, 2021, our operating margin percentage increased, compared to the same periods in 2020, due to operating leverage on higher net revenues and higher gross margins due to a favorable mix shift towards higher priced scanners.

Interest income (in millions):

			Septem	ontns Ena ber 30,	ea			Nine Months Ended September 30,								
	2021			2020			hange	2021			2020			Change		
Interest income	\$ 0.4		\$	0.3		\$	0.1	\$	2.4		\$	2.8		\$	(0.4)	
% of net revenues	_	%		_	%				0.1	%		0.2	%			

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 September 30, 2021, there was no significant change to interest income compared to the same period in 2020.

For the nine months ended September 30, 2021, interest income decreased slightly, compared to the same period in 2020, mainly due to the divestiture of our marketable securities portfolio during the first quarter of 2020 offset by interest income recognized during the nine months ended September 30, 2021 from the SDC arbitration award regarding the value of Align's capital account balance.

¹ Refer to *Note 13 "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.

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

			Three M Septem	lonths End ber 30,	led					lonths Ended ıber 30,	!									
	 2021			2020		C	hange	2021		2020		C	Change							
Other income (expense), net	\$ 0.4		\$	7.1		\$	(6.7)	\$ 34.5		\$ (12.4)		\$	46.8							
% of net revenues	_	%		1.0	%			1.2	%	(0.8)	%									

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 September 30, 2021, other income (expense), net decreased, compared to the same period in 2020, primarily due to net foreign exchange losses in the three months ended September 30, 2021 as compared to net foreign exchange gains in the same period in 2020. This was partially offset by an unrealized gain on investment held in a private company recognized in the three months ended September 30, 2021.

For the nine months ended September 30, 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 recognized in the first quarter of 2021, a \$10.2 million loss on a foreign currency forward contract related to the exocad acquisition recognized in 2020 and an increase due to fair value changes relating to an investment held in a private company recognized in the nine months ended September 30, 2021 compared to 2020. These increases were partially offset by net foreign exchange losses in the nine months ended September 30, 2021 as compared to net foreign exchange gains in the same period in 2020.

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

			Three M Septem	Ionths End ber 30,	ed			Nine Months Ended September 30,									
	 2021			2020		(Change		2021			2020			Change		
Provision for (benefit from) income taxes	\$ 81.0		\$	45.2		\$	35.8	\$	211.4		\$	(1,452.5)		\$	1,663.8		
Effective tax rates	30.9	%		24.5	%				26.7	%		(883.5)	%				

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

Our effective tax rate differs from the statutory federal income tax rate of 21% for the three and nine months ended September 30, 2021 primarily due to foreign income taxed at different rates, state income taxes, and non-deductible expenses in the U.S., 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 September 30, 2020 primarily due to state income taxes and non-deductible expenses in the U.S., partially offset by tax benefit resulting from settlement of an income tax audit. Our effective tax rate differs from the statutory federal income tax rate of 21% for the nine months ended September 30, 2020 mainly as a result of the recognition of tax benefits associated with the intra-entity transfer of certain intellectual property rights and fixed assets completed last year.

The increase in our effective tax rate for the three months ended September 30, 2021, compared to the same period in 2020, is primarily attributable to foreign income taxed at different rates and a tax benefit recognized last year resulting from settlement of an income tax audit. The increase in our effective tax rate for the nine months ended September 30, 2021, compared to the same period in 2020, is primarily attributable to the recognition of tax benefits associated with the intra-entity transfer of certain intellectual property rights and fixed assets during the nine months ended September 30, 2020.

During the nine months ended September 30, 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 nine months ended September 30, 2020, which is the net impact of the deferred tax asset recognized as a result of the additional Swiss tax deductible basis in the transferred assets and certain costs related to the transfer of fixed assets and inventory. 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 September 30, 2021 and December 31, 2020, we had cash and cash equivalents, which are comprised of money market funds, of \$1.2 billion and \$960.8 million, respectively.

As of September 30, 2021 and December 31, 2020, approximately \$630.3 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 \$400.0 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, we also expect to invest significantly in sales, marketing and innovation to meet the growing demand for our solutions.

As of September 30, 2021, we have \$825.0 million available for repurchase under the stock repurchase program authorized by our Board of Directors in May 2021. Subsequent to the third quarter, on October 29, 2021, we entered into an accelerated stock repurchase agreement to repurchase \$100.0 million under the program.

Additional information regarding the impact of COVID-19 on our liquidity and capital resources may be found in *Part II*, *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 nine months ended September 30, 2021 and 2020 (in thousands):

		nded),		
	20	021		2020
Net cash flow provided by (used in):			-	
Operating activities	\$	899,695	\$	280,756
Investing activities		(255,719)		(186,840)
Financing activities		(356,759)		(28,360)
Effect of exchange rate changes on cash, cash equivalents, and restricted cash		(10,241)		(568)
Net increase in cash, cash equivalents, and restricted cash	\$	276,976	\$	64,988

Operating Activities

For the nine months ended September 30, 2021, cash flows from operations of \$899.7 million resulted primarily from our net income of approximately \$581.1 million as well as the following:

Adjustments to net income

- Stock-based compensation of \$84.5 million related to equity awards granted to employees and directors;
- Depreciation and amortization of \$79.1 million related to our investments in property, plant and equipment and intangible assets;
- Gain related to our SDC arbitration award of \$43.4 million; and
- Changes in deferred taxes of \$48.1 million primarily related to current year amortization and adjustments to our deferred tax assets of our Swiss entity.

Significant changes in working capital

Increase of \$348.4 million in deferred revenues primarily related to increased sales volume in both our Clear Aligner and Systems and Services segments and timing of revenue recognition;

- Increase of \$216.1 million in accounts receivable which is primarily a result of the increase in sales; and
- Increase of \$74.7 million in prepaid expenses and other assets and an increase of \$107.2 million in accrued and other long-term liabilities due to the timing of payment and activities.

Investing Activities

Net cash used in investing activities was \$255.7 million for the nine months ended September 30, 2021 which primarily consisted of purchases of property and plant and equipment of \$292.0 million, which was partially offset by \$43.4 million of proceeds from our SDC arbitration award in addition to \$4.6 million received on an unsecured promissory note.

Financing Activities

Net cash used in financing activities was \$356.8 million for the nine months ended September 30, 2021 which consisted of payments related to our accelerated stock repurchase agreements of \$275.0 million and payroll taxes paid for equity awards through share withholdings of \$107.3 million which were partially offset by \$25.6 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 September 30, 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 nine months ended September 30, 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 September 30, 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 SEC rules and forms.

Changes in internal control over financial reporting.

There were no changes in our internal control over financial reporting during the quarter ended September 30, 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 Operations and Strategy," 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 alone or with others create aligners or retainers or other products or services that
 compete with us.

- 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 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.
- Our products and information technology systems are critical to our business. Issues with product development or enhancements, IT system integration, implementation, updates and upgrades along with security and data protection risks have previously and could again in the future disrupt our operations, which could have a material adverse impact on our business and operating results.
- If we are unable to protect our customer or patient information or if we are unable to comply with applicable privacy, security and data protection laws, our operations may be severely adversely impacted, patient care could suffer, we could be liable for related damages, and our business, operations and reputation could be harmed.
- 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, higher shipping costs or shipping delays 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.
- 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 is 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 those related to personal healthcare information, financial
 information and data privacy, 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 services 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 are highly dependent on third party suppliers, some of whom are sole source suppliers for certain key machines, components 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 found 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.
- The requirements to comply with current or future environmental, health and safety and workforce laws may materially increase our costs, expose us to potential liability and otherwise materially impact our business.

General Risk Factors

- We rely on highly skilled personnel and, if we fail to attract, motivate or retain personnel, or if our growth harms our corporate culture, it may be more difficult to grow effectively and pursue our strategic priorities.
- 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 have in the past and may again in the future acquire other businesses, products or technologies which could require significant management attention, disrupt our business, dilute stockholder value and adversely affect our results of operations.
- Historically, the market price for our common stock has been volatile.
- We cannot guarantee that we will continue to repurchase our common stock in the future, and any repurchases that we may make may not achieve our desired objectives.
- Future sales of significant amounts of our common stock may depress our stock price.
- Increased scrutiny of our environmental, social or governance responsibilities have and will likely continue to result in additional costs and risks, and may adversely impact our reputation, employee retention, and willingness of customers and suppliers to do business with us.

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 set forth 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 for the reporting periods of 2021 to the same reporting periods of 2020 may not be a useful means by which to evaluate the health of our business and our results of operations because of the broad and significant global impact to our business and the businesses of our customers from the pandemic followed by variances and inconsistencies in regional and local economies as they recover.

COVID-19 has 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. In the quarters that have followed, practices across all regions have largely reopened, although many continue to operate at less than pre-pandemic capacities.

The pandemic also increased demand for digital solutions such as the products and solutions we offer in the dental field. As restrictions continue to ease or are removed entirely, employees return to office work environments, and the availability of travel, dining, entertainment and other similar purchases and activities rebound, it is uncertain whether 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 have been highly disruptive to our business and may continue to be disruptive. As physical offices are allowed to reopen, the rules and regulations for reopening will likely increase in

complexity, making compliance more difficult. Furthermore, if employees perceive the protocols and requirements we implement to create a safe and effective work environment to be inadequate, overly burdensome or no longer necessary, employees may choose to leave, 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 have been and may in the future 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 or any of its variants, 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;
- disruptions and shortages impacting the cost, availability and timing of the procurement, delivery, manufacturing and overall supply chain for raw materials, components, parts and products, including semiconductor chips;
- delays and cancellations as a result of port congestion and intermittent supplier shutdowns;
- 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, servers, software or software applications, 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 Officer and Chief Financial Officer, 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 effects of the pandemic continue to linger and evolve and we cannot predict the future direct and ancillary impacts of the pandemic on our business or results of operations, although they 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, suppliers 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 remain 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 have become a material percentage of our overall revenues and we expect our 2020 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 or increase as rapidly as anticipated; 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 (including the timing of orders for additional clear aligners under certain Invisalign products), 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 we introduce new or change existing products or services, or modify how we market or sell any of our new or existing products or services; 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, products and services have been unsuccessful or driven demand in unexpected and material ways and this may happen again in the future. If any of the foregoing were 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 alone or with others create aligners, or retainers or other products or services that compete with us.

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 and dental service organizations ("DSOs") 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 and DSOs 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 improperly performed or 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, there has been a shift away from traditional practices that may impact our primary selling channels. We also believe doctors and DSOs 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 such as our recently announced facility in Poland. 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, including shipping delays and cost increases, 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, manufacturing 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 U.S., 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 customers, 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;
- delays, disruptions and increasing costs to us and our suppliers for raw materials or components, manufacturing, and transportation, including as a
 result of customs clearance, port congestion, workforce unrest or labor shortages, slowdowns or stoppages, unionization efforts, or disasters,
 whether 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") are 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 and timely 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, inflation, consumer confidence and consumer perception of current and future economic conditions. Declines in, or uncertain economic outlooks for, the U.S. or certain international economies could adversely affect consumer spending habits which may, among other things, result in a decrease in the number of overall orthodontic and dental case starts, reduce patient traffic in dentists' offices, reduce or shift spending away from elective, non-urgent, or higher value procedures or reduce demand for dental services generally, any of which could materially adversely affect our sales and operating results. Conversely, the pandemic may have temporarily limited options for consumer spending and demand for our products may decline once travel and other restrictions are eased. Weakness in the global economy can result 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/or market new and existing products and services offerings to effectively meet customer demand and compete in evolving target markets; and
- encourage customers to adopt new technologies and provide the needed technical, sales and marketing support to make new product and services 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 net revenues and cause our operating results to decline.

We may not achieve the anticipated benefits from our 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 has presented and continues to pose 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 must continue implementing and improving our operational, financial and management information systems, hire, train, motivate, manage and retain employees, and ensure our suppliers remain diverse and capable of meeting 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 while balancing near-term efforts to meet existing demand, including adding personnel, creating scalable, secure 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 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, 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, any 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 facilities 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 required, any of which may take time to accomplish, lower our gross margin, inhibit sales or harm our reputation. Additionally, if we are required to implement new or modify existing health and safety protocols to safeguard our employees, customers or their patients, productivity could decline. Production of our clear aligners and intraoral scanners are also limited by capacity constraints due to a variety of factors, including labor shortages, shipping delays, our dependency on third party vendors for key materials, parts, components and equipment, and 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.

Our products and information technology systems are critical to our business. Issues with product development or enhancements, IT system integration, implementation, updates and upgrades along with security and data protection risks have previously and could again in the future disrupt our operations, which could have a material adverse impact on our business and operating results.

We rely on the efficient, uninterrupted and secure operation of our own complex information technology systems ("IT systems") and are dependent on key software of third parties embedded in our products and IT systems as well as third party hosted IT systems to support our operations. All software and IT systems are vulnerable to damage, attack or interruption from a variety of sources. As our business has grown in size and complexity, including through the integration of acquired businesses, which to date have been smaller organizations with less-mature or less sophisticated systems, securities practices or training, the growth has placed, and will continue to place, significant demands on our operations and such systems and have increased the risk of security incidents. To effectively manage our existing operations and continue to grow, our IT systems and applications require an ongoing commitment of significant resources to maintain, protect, enhance and restore 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 usage of online and hosted 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"), product development, manufacturing, and other software and IT systems which entails certain risks, including disruption of our operations, such as our ability to develop and update products that are safe and secure, track orders and timely ship products, manage our supply chain and aggregate financial and operational data.

System upgrades, development of 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 products and customer facing software applications, such as our iTero intraoral scanners, exocad CAD/CAM solutions, 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 and products containing software 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 products, 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 products or primary IT systems may cause adverse consequences, including: delay or loss of revenues, delay in market acceptance, loss of data, disclosure of financial, health or other personal information of our customers or their patients, product recalls, 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. Failures 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, malware or ransomware attacks, product or

system vulnerabilities or defects, or a system outage for any reason have harmed our operations previously and in the future could affect materially and adversely 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, secure or restore our IT systems, if the integrity of our products or IT systems is compromised or questioned or data is lost, 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, accurate or complete 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 recall or repair products, 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 the security features of our products, IT systems or our cloud-based software servers hosted by third parties and misappropriate, destroy or damage our confidential information or that of third parties, expose health, financial data, or other personal information 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 products, networks or data. The costs to eliminate, mitigate or recover from 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, decreased product sales, or data

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

If we are unable to protect our customer or patient information or if we are unable to comply with applicable privacy, security and data protection laws, our operations may be severely adversely impacted, patient care could suffer, we could be liable for related damages, and our business, operations and reputation could be harmed.

We retain confidential customer financial as well as patient health information in addition to our own proprietary information and data essential to our business operations. Therefore, it is critical that the facilities and infrastructure on which we depend to run our business and the products we develop remain secure and are also perceived by the marketplace and our customers to be secure. Despite the implementation of security features in our products and security measures in our IT systems, our products as well as the infrastructure and IT systems on which we depend are vulnerable to physical break-ins, computer viruses, programming errors or other technical malfunctions, hacking or phishing attacks by third parties, malware and ransomware, employee error or malfeasance or similar disruptive problems. For example, we have experienced cybersecurity incidents and may again in the future. Further, the frequency of third-party cyber attacks has increased since the onset of the COVID-19 pandemic. Significant service disruptions, breaches in our infrastructure and IT systems or other cybersecurity incidents could expose us to litigation or regulatory investigations and could impair our reputation and competitive position. 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, patients and partners from using our products. In addition, patient care could suffer, and we could be liable if our products or IT systems fail to deliver accurate and complete 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, damages 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 security and protection, content regulation, and consumer protection among others. We are subject to various national and regional 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 and other countries are considering enacting similar data localization or data residency laws. We have and likely will again in the future 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 are also subject to data export restrictions and 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 privacy and data security 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, and in the U.S., we must comply with data privacy and data security provisions of the U.S. Health Insurance Portability and Accountability Act ("HIPAA") regulations. Moreover, the number of local and national governments enacting data privacy laws continues to increase and we expect this trend to continue. 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 privacy and data security requirements.

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 have historically and in the future could cause our operating results to fluctuate include:

- limited visibility into and difficulty predicting from quarter to quarter, the types of procedures and level of activities 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;
- new programs or business models, new product or services introductions or changes or modifications to existing products and services offerings, including any impacts related to the timing of orders, product mix or market cannibalization;
- changes in relationships with our dental service 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 the seasonality of teen treatments 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, parts or components, shortages or turnover in the labor force or the introduction of new production

processes, power outages or insufficient power, 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 or disruptions 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, higher shipping costs or shipping delays 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 frames our customers expect. Such delays 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 and financial results.

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 take actions in support of, make or publish statements in support of 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 or individuals 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 has released mobile operating systems that include 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. Asserting or defending these types of proceedings can be unpredictable, protracted, time consuming, 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, an injunction prohibiting us from selling our products, or an exclusion order preventing us from importing our products in one or more countries. Moreover, independent actions by competitors, customers or others have been 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 U.S. and other jurisdictions and investigations and additional litigation based on the same or similar claims may be brought in the future. Any of these litigation efforts or adverse litigation results could adversely affect our results of operations and stock price.

Obtaining approvals and complying with governmental regulations, particularly those related to personal healthcare information, financial information and data privacy, 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 our 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 applicable to healthcare providers and

their business associates, such as 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, customers, advertisers and influencers 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.

Consequently, if we cannot successfully obtain approval for our products or services or timely and cost-effectively maintain compliance with laws regulating our products and services, our results of operations and financial condition could be harmed.

If we or any vendors on whose products or services we rely for our products and services 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, optical scanner, 3D printing and other technologies and industries on which our products and services are based. We have been sued for infringement of third party's patents in the past and we are currently defending patent infringement suits and other legal claims. In addition, 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 in any legal 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 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 are highly dependent on third party suppliers, some of whom are sole source suppliers, for certain key machines, components 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 our supply chain, particularly 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. Our relationships with one or more of our suppliers could change. For instance, our suppliers could encounter financial, operating or other difficulties, be unable to hire or maintain personnel, or fail to timely obtain supplies, maintain manufacturing standards or controls, or timely deliver materials, parts or components. Further, the effects of climate change on regional and global economies could change the supply, demand or availability of sources of energy or other resources material to our products and operations, and affect the availability or cost of natural resources and goods and services on which we rely.

Additionally, our relationship or the terms by which we contract with any of our suppliers could change. Because of our dependence on our suppliers, changes in one or more of our relationships with them can materially impact our business. For instance, 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, labor stoppages or shortages, or shortages of, or increases in price for, these items, our sales may slow and 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 segregated 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 personnel 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 support our products. Our agreements with these distributors are generally 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 found 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, how we package, bundle or sell them to customers who may be private individuals or companies or public entities such as hospitals and clinics and how we train and support doctors, their staffs and patients who administer or use our products. 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 research and technology that we deem promising, 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.

The requirements to comply with current or future environmental, health and safety and workforce laws may materially increase our costs, expose us to potential liability and otherwise materially impact our business.

Our operations are subject to a variety of existing local, regional and global environmental, health and safety and workforce laws and regulations, and we will likely be required to comply with new, broader, more complex and costly laws and regulations that focus on societal and environmental matters in the future. Our compliance obligations will likely span all aspects of our business and operations, including product design and development, materials sourcing and other procurement activities, energy and natural resources usage, facilities design and utilization, recycling and collection, transportation, and disposal activities. For instance, many U.S. and foreign regulators have enacted or are considering enacting new or additional limits on the emissions of greenhouse gases, including, but not limited to, carbon dioxide and methane, from power generation units using fossil fuels like coal and natural gas. The effects of greenhouse gas emission limits on power generation that have been enacted already or that may be enacted in the future are subject to significant uncertainties, including the timing of any

new requirements and levels of emissions reductions. Moreover, alternative energy sources that supply the power to meet current and future demands of Align, our suppliers and the global and regional economies in general, coupled with reduced investments in traditional energy sources and infrastructure, may fail to provide the predictable, reliable, and consistent energy that Align, its suppliers and other businesses need for operations. Meeting our obligations under existing laws, rules, or regulations is already costly, and we expect those costs to increase in the future, possibly materially. Additionally, we expect regulators to perform investigations, inspections and periodically audit our compliance with these laws and regulations, and we cannot provide assurance that our compliance efforts or operations will be compliant or adequate. If we fail to comply with applicable laws, rules and regulations, we could be subject to significant penalties or liabilities and we may be required to implement new and significantly more costly processes and procedures to come into compliance.

In addition to us, our suppliers are also subject to environmental, health and safety and workforce laws and regulations, that may impact their businesses. For instance, 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. Although we do not believe that we or our suppliers source minerals from this region, 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, leading customers to potentially choose competitive goods and services. 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 which may negatively impact our revenues and results of operations.

General Risk Factors

We rely on highly skilled personnel and, if we fail to attract, motivate or retain personnel, or if our growth harms our corporate culture, it may be more difficult to grow effectively and pursue our strategic priorities.

To be successful, we must effectively manage our growth which depends on our ability to identify, hire, develop, motivate, and retain personnel throughout our organization. We are highly dependent on the talent and effort of highly skilled employees, including orthodontists and production technicians in our treatment planning facilities and employees in our clinical engineering, technology development, manufacturing, sales, and management teams. The loss of the services provided by these employees may significantly delay or prevent the achievement of our development and business objectives and could harm our business.

Moreover, competition for qualified employees in our industry is intense, and our employees are targeted by other employers. Our compensation and benefit arrangements, such as our equity award programs, may not always be successful in attracting new employees and retaining and motivating our existing employees. Furthermore, other internal and external factors can impact our ability to hire and retain talent, including insufficient advancement or career opportunities, restrictive immigration policy and regulatory changes, and, more recently, an increase in employees choosing to retire or quit with no immediate intentions to continue working.

We also believe a key factor in our success has been the culture we have created that emphasizes a shared vision and values focusing on agility, customer success and accountability. We believe this culture fosters an environment of integrity, innovation, creativity, and teamwork but we have also experienced in the past and expect to experience in the future, difficulties attracting and retaining employees that meet the qualifications, experience, compliance mindset and values we expect.

Additionally, many of our employees have worked remotely during the COVID-19 pandemic, which makes it difficult to maintain or enhance our culture, especially for employees onboarded remotely. As we evaluate when and how to return employees to our offices globally, we continue to assess the impact various return-to-office plans may have on our culture, morale, and hiring and retention, particularly considering tight labor markets and generous or broad remote working policies being adopted by companies against whom we compete for talent. Should we choose to require employees to return to the office, implement or modify a remote working policy, and/or allow or modify a hybrid approach in which employees can continue to work from home or other remote locations on a limited or part time basis only, it may materially increase our costs or create unforeseen challenges or complications, including:

- difficulties maintaining our corporate culture, disruption of morale or decreased loyalty;
- negative impacts to collaboration, performance and productivity;
- · increased employee stress, fatigue or "burn out" by employees unable to disengage their work life from the home life;
- increased operational, governance, compliance, and tax risks;
- increased attrition or limits to our ability to attract employees who prefer to continue working remotely full time, in the office or in geographies different from where they were hired to work or are expected to work;
- problems managing office space requirements;

- greater risk of breaches of data protection and cybersecurity protocols, inadvertent or unauthorized use or dissemination of our confidential information, including information that may be deemed material;
- concerns regarding favoritism or discrimination;
- · strains to our business continuity plans and difficulties achieving our strategic objectives; and
- increased labor and employment claims and litigation.

If we are unable to attract and retain personnel that meet our selection criteria or relax our standards in order to meet the demands of our growth or if our growth is not managed effectively, our corporate culture, ability to achieve our strategic objectives, and our compliance with obligations under our internal controls and other requirements may be harmed.

Business disruptions could seriously harm our financial condition.

Our global operations have been disrupted by natural or human induced disasters in the past and will likely be disrupted and harmed again in the future, including as a result of earthquakes, tsunamis, floods, droughts, hurricanes, typhoons, wildfires, extreme weather conditions, power outages, restrictions and shortages, telecommunications failures, materials scarcity and price volatility, and medical epidemics or health pandemics. For instance, the COVID-19 pandemic and subsequent recovery materially impacted our sales and business operations in 2020, the operations of our customers and the global economy overall. Further, initiatives and legislation designed to reduce, restrict or eliminate greenhouse gas emissions from power generation may have the effect of increasing our costs and those of our suppliers and could result in manufacturing, transportation and supply chain disruptions and delays if clean energy alternatives are not readily available in adequate supply when required. When such events occur, they may, individually or in the aggregate, affect our ability to provide products, services and solutions to our customers, and could cause production delays or limitations, create adverse effects on distributors, disrupt supply chains, result in shipping and distribution disruptions and reduce the availability of or access to one or more facilities. Climate change is likely to increase both the frequency and severity of natural disasters and, consequently, risks to our operations and growth. The occurrence of any material or prolonged 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, power shortages 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, often substantially, fluctuating 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.

Additionally, in July 2017, the United Kingdom Financial Conduct Authority announced that it intends to stop compelling banks to submit interest rates for the calculation of the London Interbank Offered Rate ("LIBOR") after 2021. Although we do not have any outstanding debt under our 2020 Credit Facility, were we to draw on it, the outstanding amounts would bear interest at fluctuating interest rates, primarily based on LIBOR or an approved replacement benchmark. We also have other contracts that may be indexed to LIBOR. We are monitoring this matter and evaluating the related risks and potential impact of the expiration of LIBOR. If LIBOR is discontinued, reformed or replaced, any indebtedness that we incur may be indexed to a replacement benchmark, such as the Secured Overnight Financing Rate ("SOFR"). Any such change could cause the effective interest rate under an agreement, including our 2020 Credit Facility, and our overall interest expense to increase, adversely affecting our cash flows and results of operations.

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. Goodwill and purchased assets require periodic fair value assessments 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.

New tax laws, or changes in existing tax laws or tax rulings, or the way they are applied to our business could negatively impact our income tax provision and net income or subject us to new or greater tax burdens that may harm our sales or results of operations.

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.

Moreover, the application of indirect taxes (such as sales and use tax ("SUT"), value-added tax ("VAT"), goods and services tax ("GST"), and other indirect taxes) to our operations is complex and evolving. U.S. states, local and foreign taxing jurisdictions have differing rules and regulations governing differing types of taxes, and these rules and regulations are subject to varying interpretations that may change over time. We collect and remit SUT, VAT, GST and other taxes in many jurisdictions and we are routinely subject to audits. The positions we take regarding taxes as well as the amounts we collect or remit may be challenged and we may be liable for failing to collect or remit all or any portion of taxes deemed owed or the taxes could exceed our estimates. We may also be subject to audits in U.S. states, local and foreign jurisdictions for which we have not accrued tax liabilities. One or more U.S. states or countries may seek to impose incremental or new sales, use, or other tax collection obligations on us or may determine that such taxes should have but have not been paid by us. The application of existing, new, or future tax laws, and results of audits, whether in the U.S. or internationally, could harm our business. Furthermore there have been and will continue to be substantial ongoing costs associated with complying with the various tax requirements in the numerous markets in which we conduct or will conduct business.

We have in the past and may again in the future acquire other businesses, products or technologies which could require significant management attention, disrupt our business, dilute stockholder 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 make investments or complete acquisitions, we may not ultimately strengthen our competitive position or achieve our goals or desired synergies, and any investments that we make or acquisitions we complete could be viewed negatively by our customers, securities analysts and investors. Moreover, to the extent we make strategic investments, the companies in which we invest may fail or we may ultimately own less than a majority of the outstanding shares of the company and be outvoted on critical matters or issues that could harm us or the value of our investment.

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 an acquisition, 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 stockholders. 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 to objections by one or more stockholders or result in stockholder 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, new, additional or revised programs, business models, 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 are often unrelated to or disproportionate to the operating performance of those companies. These broad market and industry factors may include market expectations of, or actual changes in, monetary policies that have the goal of easing or tightening interest rates such as the federal funds rate in the U.S. and austerity measures of governments intended to control budget deficits. Historically, our stock has fluctuated materially based on broad economic and industry factors unrelated to our actual performance and future changes in monetary policies, austerity, and other market 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 that we will continue to repurchase our common stock in the future, and any repurchases that we may make may not achieve our desired objectives.

We have a history of recurring stock repurchase programs intended to return capital to our investors. Although repurchases were suspended in 2020 primarily as a result of uncertainties regarding the pandemic, we ended the suspension in the second quarter of 2021 with two accelerated stock repurchase programs in the aggregate amount of \$200 million which also included the announcement of a \$1 billion stock repurchase authorization by our Board of Directors. Any further authorizations or continuance of existing stock repurchase programs is contingent on a variety of factors, including our financial condition, results of operations, business requirements, and our Board of Directors' continuing determination that stock repurchases are in the best interests of our stockholders and in compliance with all applicable laws and agreements. There is no assurance that we will continue repurchasing our common stock in the future, 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.

Increased scrutiny of our environmental, social or governance responsibilities have and will likely continue to result in additional costs and risks, and may adversely impact our reputation, employee retention, and willingness of customers and suppliers to do business with us.

Investor advocacy groups, institutional investors, investment funds, proxy advisory services, stockholders, and customers are increasingly focused on environmental, social and governance ("ESG") practices of companies. Additionally, public interest

and legislative pressure related to public companies' ESG practices continues to grow. If our ESG practices fail to meet regulatory requirements or investor or other industry stakeholders' evolving expectations and standards for responsible corporate citizenship in areas including environmental stewardship, support for local communities, Board of Director and employee diversity, human capital management, employee health and safety practices, product quality, supply chain management, corporate governance and transparency and employing ESG strategies in our operations, our brand, reputation and employee retention may be negatively impacted and customers and suppliers may be unwilling to do business with us. In addition, as we work to align our ESG practices with industry standards, we have expanded and, in the future, will likely continue to expand our disclosures in these areas. We also expect to incur additional costs and require additional resources to monitor, report, and comply with our various ESG practices. If we fail to adopt ESG standards or practices as quickly as stakeholders desire, report on our ESG efforts or practices accurately, or satisfy the expectations of stakeholders, our reputation, business, financial performance and growth may be adversely impacted.

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

Unregistered Sales of Equity Securities

None.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

The following table summarizes the stock repurchase activity for the three months ended September 30, 2021:

Period	Total Number of Shares Repurchased	Total Number of Shares Repurchased as Part of Average Price Publicly Announced Programs		Approximate Dollar Value of Shares that May Yet Be Repurchased Under the Programs ^{(1),(2)}	
July 1, 2021 through July 31, 2021	36,988	\$ 540.72	36,988	\$	900,000,000
August 1, 2021 through August 31, 2021	104,959	\$ 762.56	104,959	\$	824,962,500
September 1, 2021 through September 30, 2021	23,007	\$ 651.97	23,007	\$	824,962,500
Total	164,954		164,954		

¹ May 2018 Repurchase Program. On May 23, 2018, we announced that our Board of Directors authorized a \$600 million share repurchase program. As of September 30, 2021, the authorization under the May 2018 Repurchase Program was completed.

See Note 9 "Common Stock Repurchase Programs" of the Notes to Condensed Consolidated Financial Statements for details on the repurchase programs.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None

² May 2021 Repurchase Program. On May 13, 2021, we announced that our Board of Directors had authorized a plan to repurchase up to \$1.0 billion of our common stock. The program does not have an expiration date. Subsequent to the third quarter, on October 29, 2021, we entered into an ASR to repurchase \$100.0 million of our common stock. We paid \$100.0 million 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 ASR, less an agreed upon discount.

ITEM 6. EXHIBITS

(a) Exhibits:

Exhibit <u>Number</u>	<u>Description</u>	<u>Filing</u>	<u>Date</u>	<u>Exhibit</u> <u>Number</u>	<u>Filed</u> herewith
<u>10.1</u>	Fixed Dollar Accelerated Share Repurchase Confirmation between Goldman Sachs & Co. LLC and Align Technology, Inc. dated July 30, 2021.				*
<u>31.1</u>	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.			*	
<u>31.2</u>	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.				*
<u>32.1†</u>	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				*
101.INS			*		
101.SCH	Inline XBRL Taxonomy Extension Schema Document				*
101.CAL	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)				*

[†] The certifications attached as Exhibit 32.1 that accompany this Quarterly Report on Form 10-Q are not deemed filed with the SEC and are not to be incorporated by reference into any filing of the Registrant under the Securities Act or the Exchange Act, whether made before or after the date of this Quarterly Report on Form 10-Q, irrespective of any general incorporation language contained in such filing.

November 2, 2021

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.

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

GOLDMAN SACHS & CO. LLC | 200 WEST STREET | NEW YORK, NEW YORK 10282-2198 | TEL: 212-902-1000

Opening Transaction

To:

Align Technology, Inc.

410 N. Scottsdale Road, Suite 1300

Tempe, Arizona 85281

A/C: provided

From: Goldman Sachs & Co. LLC

Re: Fixed Dollar Accelerated Share Repurchase Transaction

Date:

July 30, 2021

Dear Sir/Madam:

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

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

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

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

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

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

GENERAL TERMS:

Trade Date:

Buyer:	Issuer
Seller:	Dealer
Shares:	Common Stock, par value USD 0.0001 per share, of Issuer (Ticker: ALGN)
Forward Price:	A price per Share (as determined by the Calculation Agent) equal to the greater of (A) (i) the arithmetic mean (not a weighted average, subject to "Market Disruption Event" below) of the 10b-18 VWAP on each Observation Date that is a Trading Day during the Calculation Period minus (ii) the Discount and (B) \$5.00.
Discount:	As specified in Schedule I
10b-18 VWAP:	On any Trading Day, a price per Share equal to the volume- weighted average price of the Rule 10b-18 eligible trades in the Shares for the entirety of such Trading Day as determined by the Calculation Agent by reference to the screen entitled "ALGN <equity> AQR SEC" or any successor page as reported by Bloomberg L.P. or any successor (excluding (i) trades that do not settle regular way, (ii) opening (regular way) reported trades in the consolidated system on such Scheduled Trading Day (including, for the avoidance of doubt, the first reported trade on the Exchange following the scheduled open of trading on the Exchange), (iii) trades that occur in the last ten minutes before the scheduled close of trading on the Exchange on such Scheduled Trading Day and ten minutes before the scheduled close of the primary trading in the market where the trade is effected, and (iv) trades on such Scheduled Trading Day that do not satisfy the requirements of Rule 10b-18(b)(3) of the Securities</equity>

As specified in Schedule I

Observation Dates:

Calculation Period:

Final Termination Date:

Trading Day:

As specified in Schedule I

The period from, and including, the first Observation Date that is a Trading Day that occurs on or after the Prepayment Date to, but excluding, the relevant Valuation Date; <u>provided</u>, <u>however</u>, that if the Valuation Date is the Scheduled Valuation Date, then the Valuation Date shall be included in the Calculation Period; <u>provided further</u> that in no event shall any Scheduled Valuation Date be postponed to a date later than the Final Termination Date.

Exchange Act of 1934, as amended (the "Exchange Act") on such Trading Day) or, if the price displayed on such screen is clearly erroneous, as determined by the Calculation Agent

As specified in Schedule I; <u>provided</u> that if a Market Disruption Event has occurred pursuant to Section 7 of this Confirmation, such Final Termination Date shall be postponed by one Trading Day for every Trading Day that is a Disrupted Day as a result of such Merger Transaction during the Calculation Period

Any Exchange Business Day that is not a Disrupted Day in whole

in good faith and in a commercially reasonable manner.

Initial Shares:

Initial Share Delivery Date:

Prepayment:

Prepayment Amount:

Prepayment Date:

Exchange:

Related Exchange:

As specified in Schedule I; <u>provided</u> that if Dealer is unable to borrow or otherwise acquire a number of Shares equal to the Initial Shares for delivery to Issuer on the Initial Share Delivery Date, the Initial Shares delivered on the Initial Share Delivery Date shall be reduced to such number of Shares that Dealer is able to so borrow or otherwise acquire, and thereafter Dealer shall continue to use commercially reasonable efforts to borrow or otherwise acquire a number of Shares, at a stock borrow cost no greater than the Initial Stock Loan Rate, equal to the shortfall in the Initial Shares and to deliver such additional Shares as soon as reasonably practicable. For the avoidance of doubt, the aggregate of all shares delivered to Dealer in respect of the Transaction pursuant to this paragraph shall be the "Initial Shares" for purposes of determining the "Settlement Amount" below.

One Exchange Business Day following the Trade Date. On the Initial Share Delivery Date, Seller shall deliver to Buyer a number of Shares equal to the Initial Shares in accordance with Section 9.4 of the Equity Definitions, with the Initial Share Delivery Date being deemed to be a "Settlement Date" for purposes of such Section 9.4.

Applicable

As specified in Schedule I

One Exchange Business Day following the Trade Date. On the Prepayment Date, Buyer shall pay to Seller the Prepayment Amount.

The Nasdaq Global Select Market

All Exchanges; <u>provided</u> that Section 1.26 of the Equity Definitions shall be amended to add the words "United States" before the word "exchange" in the tenth line of such Section.

Market Disruption Event:

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

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

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

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

If a Disrupted Day occurs during the Calculation Period or the Buyer Settlement Valuation Period and each of the nine immediately following Scheduled Trading Days is a Disrupted Day, then the Calculation Agent may, in its good faith and commercially reasonable discretion, deem such ninth Scheduled Trading Day to be an Exchange Business Day that is not a Disrupted Day and determine the 10b-18 VWAP for such ninth Scheduled Trading Day using its good faith and commercially reasonable estimate of the value of the Shares on such ninth Scheduled Trading Day based on the volume, historical trading patterns and trading price of the Shares.

VALUATION:

Valuation Date:

Scheduled Valuation Date:

Lock-Out Date:

SETTLEMENT TERMS:

Physical Settlement:

Settlement Currency:

Settlement Date:
Other Applicable Provisions:

SHARE ADJUSTMENTS:

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

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

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

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

As specified in Schedule I, subject to postponement in accordance with "Market Disruption Event" above

As specified in Schedule I

Applicable.

On the Settlement Date, Seller shall deliver to Buyer a number of Shares equal to (a) (i) the Prepayment Amount <u>divided by</u> (ii) the Forward Price <u>minus</u> (b) the Initial Shares (such number of Shares, the "**Settlement Amount**"), rounded to the nearest whole number of Shares; <u>provided</u>, <u>however</u>, that if the Settlement Amount is less than zero, then the Buyer Settlement Provisions in Annex A hereto shall apply.

USD

The date that falls one Settlement Cycle after the relevant Valuation Date.

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

Potential Adjustment Event:

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

It shall constitute a Potential Adjustment Event if a Disrupted Day occurs or, pursuant to Section 9 below, is deemed to occur (in whole or in part) on any Trading Day on or prior to the Valuation Date.

Extraordinary Dividend:

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

Method of Adjustment:

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

EXTRAORDINARY EVENTS:

Consequences of Merger Events:

Share-for-Share: Share-for-Other:

Share-for-Combined:

Tender Offer:

Consequences of Tender Offers:

Share-for-Share: Share-for-Other: Share-for-Combined:

New Shares:

Modified Calculation Agent Adjustment

Cancellation and Payment on that portion of the Other Consideration that consists of cash; Modified Calculation Agent Adjustment on the remainder of the Other Consideration

Component Adjustment

Applicable; <u>provided</u> that the definition of "Tender Offer" in Section 12.1 of the Equity Definitions will be amended by replacing the phrase "greater than 10% and less than 100% of the outstanding voting shares of the Issuer" in the third and fourth line thereof with "(a) greater than 15% and less than 100% of the outstanding Shares of the Issuer in the event that such Tender Offer is being made by any entity or person other than the Issuer or any subsidiary thereof or (b) greater than 20% and less than 100% of the outstanding Shares of the Issuer in the event that such Tender Offer is being made by the Issuer or any subsidiary thereof".

Modified Calculation Agent Adjustment Modified Calculation Agent Adjustment Modified Calculation Agent Adjustment

In the definition of New Shares in Section 12.1(i) of the Equity Definitions, the text in clause (i) thereof shall be deleted in its entirety and replaced with "publicly quoted, traded or listed on any of the New York Stock Exchange, The NASDAQ Global Select Market or The NASDAQ Global Market (or their respective successors)".

For purposes of the Transaction,

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

Composition of Combined Consideration: Not Applicable

Nationalization, Insolvency or Delisting:

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

Additional Disruption Events:

Change in Law:

Failure to Deliver:
Insolvency Filing:
Hedging Disruption:
Increased Cost of Hedging:
Loss of Stock Borrow:

Maximum Stock Loan Rate:

Increased Cost of Stock Borrow: Initial Stock Loan Rate:

Determining Party:

Hedging Party: Non-Reliance: Applicable; provided that (i) any determination as to whether (A) the adoption of or any change in any applicable law or regulation (including, for the avoidance of doubt and without limitation, (x) any tax law or (y) adoption or promulgation of new regulations authorized or mandated by existing statute) or (B) the promulgation of or any change in the interpretation by any court, tribunal or regulatory authority with competent jurisdiction of any applicable law or regulation (including any action taken by a taxing authority), in each case, constitutes a "Change in Law" shall be made without regard to Section 739 of the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 or any similar legal certainty provision in any legislation enacted, or rule or regulation promulgated, on or after the Trade Date, (ii) Section 12.9(a)(ii) of the Equity Definitions is hereby amended by replacing the parenthetical beginning after the word "regulation" in the second line thereof the words "(including, for the avoidance of doubt and without limitation, (x) any tax law or (y) adoption or promulgation of new regulations authorized or mandated by existing statute)" and (iii) by, immediately following the word "Transaction" in clause (x) thereof, adding the phrase "in the manner contemplated by the Hedging Party on the Trade Date".

Applicable
Applicable
Applicable
Not Applicable
Applicable
200 bps

Applicable 25 bps

For all applicable events, Dealer; *provided* that, when making any determination or calculation as "Determining Party," Dealer shall be bound by the same obligations relating to required acts of the Calculation Agent as set forth in Section 1.40 of the Equity Definitions and this Confirmation as if Determining Party were the Calculation Agent. All calculations and determinations made by the Determining Party shall be made in good faith and in a commercially reasonable manner.

Following any determination or calculation by Determining Party hereunder, upon a written request by Issuer, Determining Party will promptly (but in any event within five Scheduled Trading Days) provide to Issuer in writing a report (in a commonly used file format for the storage and manipulation of financial data) displaying in reasonable detail the basis for such determination or calculation (including any assumptions used in the making of such determination or calculation), it being understood that in no event will Determining Party be obligated to share with Issuer any proprietary or confidential data or information or any proprietary or confidential models used by it in making such determination or calculation or any information that is subject to an obligation not to disclose such information.

For all applicable events, Dealer Applicable

Agreements and Acknowledgements Regarding Hedging Activities:

Additional Acknowledgments:

Calculation Agent:

Applicable Applicable

Dealer; <u>provided</u> that following the occurrence of an Event of Default of the type described in Section 5(a)(vii) of the Agreement with respect to which Dealer is the sole Defaulting Party, if the Calculation Agent fails to timely make any calculation, adjustment or determination required to be made by the Calculation Agent hereunder or to perform any obligation of the Calculation Agent hereunder and such failure continues for five (5) Exchange Business Days following notice to the Calculation Agent by Issuer of such failure the Issuer shall have the right to designate a nationally recognized third-party dealer in overthe-counter corporate equity derivatives to act, during the period commencing on the date such Event of Default occurred and ending on the Early Termination Date with respect to such Event of Default, as the Calculation Agent.

All calculations and determinations by the Calculation Agent shall be made in good faith and in a commercially reasonable manner. Following any calculation made by the Calculation Agent hereunder, upon a prior written request by the Issuer, the Calculation Agent will provide to the Issuer by email to the email address provided by the Issuer in such prior written request a report (in a commonly used file format for the storage and manipulation of financial data) displaying in reasonable detail the basis for such calculation and specifying the particular section of the Confirmation pursuant to which such calculation or determination is being made (and in the event that more than one section of the Confirmation would permit the Calculation Agent to make an adjustment upon the occurrence of a specific event, then the Calculation Agent shall specify the particular section number pursuant to which the Calculation Agent is making the adjustment hereunder); provided, however, that in no event will the Calculation Agent be obligated to share with the Issuer any proprietary or confidential data or information or any proprietary models used by it.

4. Account Details and Notices:

(a) Account for delivery of Shares to Issuer:

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

(b) Account for payments to Issuer:

Bank of America Acct: provided ABA: provided

(c) Account for payments to Dealer:

Chase Manhattan Bank New York For A/C Goldman Sachs & Co. LLC A/C #: provided

ABA: provided

For purposes of this Confirmation:

(i) Address for notices or communications to Issuer:

Align Technology, Inc. 410 N. Scottsdale Road, Suite 1300 Tempe, Arizona 85281 Attn: Legal Department

(ii) Address for notices or communications to Dealer:

Goldman Sachs & Co. LLC 200 West Street New York, NY 10282-2198

Attention: Michael Voris, Equity Capital Markets

Telephone: provided Facsimile: provided Email: provided

With a copy to:

Attention: Blair Seideman, Equity Capital Markets

Telephone: provided Facsimile: provided Email: provided

And email notification to the following address:

provided

5. <u>Amendments to the Equity Definitions and Agreement</u>.

- (a) Section 9.2(a)(iii) of the Equity Definitions is hereby amended by deleting the words "the Excess Dividend Amount, if any, and".
- (b) Section 11.2(a) of the Equity Definitions is hereby amended by deleting the words "a diluting or concentrative effect on the theoretical value of the relevant Shares" and replacing them with the words "a material economic effect on the relevant Transaction".
- (c) The first sentence of Section 11.2(c) of the Equity Definitions, prior to clause (A) thereof, is hereby amended to read as follows: '(c) If "Calculation Agent Adjustment" is specified as the Method of Adjustment in the related Confirmation of a Share Option Transaction or Share Forward Transaction, then, following the announcement or occurrence of any Potential Adjustment Event, the Calculation Agent will determine in its commercially reasonable judgment whether such Potential Adjustment Event has a material economic effect on the Transaction and, if so, will (i) make appropriate adjustment(s), if any, to any one or more of:' and the portion of such sentence immediately preceding clause (ii) thereof is hereby amended by replacing the words "diluting or concentrative" with the words "material economic".
- (d) Section 11.2(e)(vii) of the Equity Definitions is hereby amended by deleting the words "diluting or concentrative effect on the theoretical value of the relevant Shares" and replacing them with the words "any other corporate event involving the Issuer that in the commercially reasonable judgment of the Calculation Agent has a material economic effect on the relevant Transaction".

- (e) Section 12.6(c)(ii) of the Equity Definitions is hereby amended by replacing the words "the Transaction will be cancelled," in the first line with the words "Dealer will have the right to cancel the Transaction,".
- (f) Section 12.9(b)(iv) of the Equity Definitions is hereby amended by (A) deleting (1) subsection (A) in its entirety, (2) the phrase "or (B)" following subsection (A) and (3) the phrase "in each case" in subsection (B); and (B) deleting the phrase "neither the Non-Hedging Party nor the Lending Party lends Shares in the amount of the Hedging Shares or" in the penultimate sentence.
- (g) Section 12.9(b)(v) of the Equity Definitions is hereby amended by (A) adding the word "or" immediately before subsection "(B)" and deleting the comma at the end of subsection (A); and (B)(1) deleting subsection (C) in its entirety, (2) deleting the word "or" immediately preceding subsection (C) and (3) replacing in the penultimate sentence the words "either party" with "the Hedging Party" and (4) deleting clause (X) in the final sentence.
- (h) Section 2(a)(iii) of the Agreement is hereby amended by deleting the words "or Potential Event of Default" in clause (1) of such Section and deleting the word "and" immediately before subsection (3) and deleting clause "(3)" in its entirety.

6. <u>Alternative Termination Settlement</u>.

Notwithstanding anything to the contrary herein, or in the Equity Definitions, if at any time (i) an Early Termination Date occurs or (ii) the Transaction is cancelled or terminated upon the occurrence of an Extraordinary Event (other than (i) an Insolvency, a Nationalization, a Merger Event or a Tender Offer, in each case, in which the consideration or proceeds to be paid to holders of Shares consists solely of cash or (ii) an Event of Default in which Issuer is the Defaulting Party or a Termination Event in which Issuer is an Affected Party, which Event of Default or Termination Event resulted from an event or events within Issuer's control), if either party would owe any amount to the other party pursuant to Section 6(d)(ii) of the Agreement or any Cancellation Amount pursuant to Article 12 of the Equity Definitions (any such amount, a "Payment Amount"), then such payment shall be paid as set forth under the Agreement or Equity Definitions, as the case may be, unless Issuer makes an election to the contrary no later than the Early Termination Date or the date on which such Transaction is terminated or cancelled, in which case Issuer or Dealer, as the case may be, shall deliver to the other party a number of Shares (or a number of units, each comprising the number or amount of the securities or property that a hypothetical holder of one Share would receive in the case of a Nationalization, Insolvency or Merger Event, as the case may be (each such unit, an "Alternative Delivery Unit")), with a value equal to the Payment Amount, as determined by the Calculation Agent. In determining the number of Shares (or Alternative Delivery Units) required to be delivered under this provision, the Calculation Agent may take into account a number of factors, including, without limitation, the market price of the Shares (or Alternative Delivery Units) on the Early Termination Date or the date of early cancellation or termination, as the case may be. Additionally, if such delivery is made by Dealer, the Calculation Agent shall take into account the prices at which Dealer purchases Shares (or Alternative Delivery Units) to fulfill its delivery obligations under this Section 6; provided that in determining the composition of any Alternative Delivery Unit, if the relevant Merger Event involves a choice of consideration to be received by holders, such holder shall be deemed to have elected to receive the maximum possible amount of cash. If delivery of Shares or Alternative Delivery Units, as the case may be, pursuant to this Section 6 is to be made by Issuer, paragraphs 2 through 8 of Annex A hereto shall apply as if (A) such delivery were a settlement of the Transaction to which Net Share Settlement applied, (B) the Buyer Cash Settlement Payment Date were the Early Termination Date or the date of early cancellation or termination, as the case may be, and (C) the Forward Cash Settlement Amount were equal to (x) zero *minus* (y) the Payment Amount owed by Issuer.

- 7. Special Provisions for Merger Transactions. Notwithstanding anything to the contrary herein or in the Equity Definitions:
 - (a) Issuer agrees that:
- (i) Issuer will use its commercially reasonable efforts such that Issuer will not during the term of the Transaction make, or, to the extent within its control, permit to be made, any public announcement (as defined in Rule 165(f) under the Securities Act of 1933, as amended (the "Securities Act")) of any Merger Transaction or potential Merger Transaction unless such public announcement is made prior to the open or after the close of the regular trading session on the Exchange for the Shares.
- (ii) To the extent that an announcement of a potential Merger Transaction occurs during the term of the Transaction and Dealer has not provided notice to Issuer as promptly as reasonably practicable following such announcement that Dealer will cause the Transaction to be cancelled or terminated in whole pursuant to "Extraordinary Events" in Section 2 above, then as soon as practicable following such announcement (but in any event prior to the next opening of the regular trading session on the Exchange), Issuer shall provide Dealer with written notice specifying (x) Issuer's average daily "Rule 10b-18 purchases" (as defined in Rule 10b-18) during the three full calendar months immediately preceding the Announcement Date that were not effected through Dealer or its affiliates and (y) the number of Shares purchased pursuant to the block purchase proviso in Rule 10b-18(b)(4) under the Exchange Act for the three full calendar months preceding the Announcement Date. Such written notice shall be deemed to be a certification by Issuer to Dealer that such information is true and correct. Issuer understands that Dealer will use this information in calculating the trading volume for purposes of Rule 10b-18. In addition, Issuer shall promptly notify Dealer of the earlier to occur of the completion of such transaction and the completion of the vote by target shareholders. Issuer acknowledges that any such public announcement may trigger the provision set forth in Section 9 below.

Accordingly, Issuer acknowledges that its actions in relation to any such announcement or transaction must comply with the standards set forth in Section 11(b) below.

(b) Upon the occurrence of any public announcement of a Merger Transaction, Dealer may in a good faith and commercially reasonable manner elect either to (i) apply the provisions of Section 9 below or (ii) treat the occurrence of such announcement as an Additional Termination Event with respect to which the Transaction shall be the sole Affected Transaction, Issuer shall be the sole Affected Party and Dealer shall be the party entitled to designate an Early Termination Date pursuant to Section 6(b) of the Agreement (a "Merger Termination Event"). In the event that the Dealer elects to treat the Merger Transaction as a Merger Termination Event under this Section 7(b), then neither the provisions of "Extraordinary Events: Consequences of Merger Events" set forth above in this Confirmation nor the provisions of Section 8 below shall apply.

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

- 8. <u>Special Provisions for Acquisition Transaction Announcements.</u>
- (a) If an Acquisition Transaction Announcement occurs on or prior to the final Valuation Date, then the Forward Price shall be determined as if the words "minus (ii) the Discount" were deleted from the definition thereof. If an Acquisition Transaction Announcement occurs after the Trade Date but prior to the Lock-Out Date, the Lock-Out Date shall be deemed to be the date of such Acquisition Transaction Announcement.
- (b) "Acquisition Transaction Announcement" means (i) the announcement of an Acquisition Transaction, (ii) an announcement that Issuer or any of its subsidiaries has entered into an agreement, a letter of intent or an understanding designed to result in an Acquisition Transaction, (iii) the announcement of the intention to solicit or enter into, or to explore strategic alternatives or other similar undertaking that may include, an Acquisition Transaction, or (iv) any announcement subsequent to an Acquisition Transaction Announcement relating to a material amendment, a material extension, withdrawal

or other material change to the subject matter of the previous Acquisition Transaction Announcement. For the avoidance of doubt, the term "announcement" as used in the definition of Acquisition Transaction Announcement refers to any public announcement whether made by Issuer or any subsidiary or agent thereof or by a bona fide third party that is reasonably likely to be a party to the Acquisition Transaction.

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

9. Dealer Adjustments.

In the event that Dealer determines, in a good faith and commercially reasonable manner that, based on advice of legal counsel, it is appropriate with regard to any legal, regulatory or self-regulatory requirements or related policies and procedures (whether or not such requirements, policies or procedures are imposed by law or have been voluntarily adopted by Dealer, and including, without limitation, Rule 10b-18, Rule 10b-5, Regulations 13D-G and Regulations 14 D-E under the Exchange Act; provided that such requirements, policies and procedures relate to legal and regulatory issues and are generally applicable in similar situations and applied in a consistent manner in similar transactions), for Dealer to refrain from purchasing Shares or engaging in other market activity or to purchase fewer than the number of Shares or to engage in fewer or smaller other market transactions Dealer would otherwise purchase or engage in on any Trading Day on or prior to the last day of the Potential Purchase Period, then Dealer may, in its reasonable discretion, elect that a Market Disruption Event shall be deemed to have occurred on such Trading Day. Dealer shall notify Issuer upon the exercise of Dealer's rights pursuant to this Section 9 and the Trading Days affected by it and shall subsequently notify Issuer on the day Dealer believes that the circumstances giving rise to such exercise have changed.

10. Covenants.

Issuer covenants and agrees that:

(a) Until the end of the Potential Purchase Period (as defined below), neither it nor any of its affiliated purchasers (as defined in Rule 10b-18 under the Exchange Act) shall directly or indirectly (which shall be deemed to include the writing or purchase of any cash-settled or other derivative or structured Share repurchase transaction with a hedging period, calculation period or settlement valuation period or similar period that overlaps with the Transaction) purchase, offer to purchase, place any bid or limit order relating to a purchase of or commence any tender offer relating to Shares (or any security convertible into or exchangeable for Shares) without the prior written approval of Dealer or take any other action that would cause the purchase by Dealer of any Shares in connection with this Confirmation not to qualify for the safe harbor provided in Rule 10b-18 under the Exchange Act (assuming for the purposes of this paragraph that such safe harbor were otherwise available for such purchases); provided that this Section 10(a) shall not (i) limit the Issuer's ability, pursuant to its employee incentive plan or dividend reinvestment program to re-acquire Shares in connection with the related equity transactions, (ii) limit the Issuer's ability to withhold shares to cover tax liabilities associated with such equity transactions, (iii) limit the Issuer's ability to grant stock and options to "affiliated purchasers" (as defined in Rule 10b-18) or the ability of such affiliated purchasers to acquire such stock or options, provided that in connection with any such purchase Issuer will be deemed to represent to Dealer that such purchase does not constitute a "Rule 10b-18 Purchase" (as defined in Rule 10b-18) (any such incentive or compensatory plan, program or policy of Issuer, a "Compensatory Plan"), (iv) limit any purchases by affiliated purchasers (as defined in Rule 10b-18) of the Issuer in an amount, in aggregate, not to exceed 5% of ADTV (as defined in Rule 10b-18) for such

Exchange Business Day, which purchases shall be executed by Dealer (or its affiliate) and made pursuant to documentation and terms reasonably acceptable to Dealer and Issuer or (v) limit the Issuer's ability to fulfill its obligations to Dealer under the letter agreement entered into between Dealer and the Issuer on May 17, 2021 (the "Existing Agreement"). "Potential Purchase Period" means the period from, and including, the Trade Date to, and including, the latest of (i) the last day of any Buyer Settlement Valuation Period, (ii) the earlier of (A) the date ten Exchange Business Days immediately following the last day of the Calculation Period and (B) the Scheduled Valuation Date and (iii) if an Early Termination Date occurs or the Transaction is cancelled pursuant to Article 12 of the Equity Definitions, a date determined by Dealer in its commercially reasonable discretion and communicated to Issuer no later than the Exchange Business Day immediately following such date.

- (b) Without limiting the generality of Section 13.1 of the Equity Definitions, it is not relying, and has not relied, upon Dealer or any of its representatives or advisors with respect to the legal, accounting, tax or other implications of this Agreement and that it has conducted its own analyses of the legal, accounting, tax and other implications of this Agreement, and that Dealer and its affiliates may from time to time effect transactions for their own account or the account of customers and hold positions in securities or options on securities of Issuer and that Dealer and its affiliates may continue to conduct such transactions during the term of this Agreement. Without limiting the generality of the foregoing, Issuer acknowledges that Dealer is not making any representations or warranties or taking any position or expressing any view with respect to the treatment of the Transaction under any accounting standards including ASC Topic 260, Earnings Per Share, ASC Topic 815, Derivatives and Hedging, or ASC Topic 480, Distinguishing Liabilities from Equity and ASC 815-40, Derivatives and Hedging Contracts in Entity's Own Equity (or any successor issue statements) or under FASB's Liabilities & Equity Project.
- (c) Neither it nor any affiliates shall take any action that would cause a restricted period (as defined in Regulation M under the Exchange Act ("**Regulation M**")) to be applicable to any purchases of Shares, or of any security for which Shares is a reference security (as defined in Regulation M), by Issuer or any affiliated purchasers (as defined in Regulation M) of Issuer during the Potential Purchase Period.
- (d) It will not make any election or take any other action in connection with the Transaction while aware of any material nonpublic information regarding Issuer or the Shares.
- (e) It shall not declare or pay any Extraordinary Dividend until the Exchange Business Day immediately following the last day of the Potential Purchase Period.
- (f) Counterparty represents and warrants that it and any of its subsidiaries has not applied, and shall not, until after the first date on which no portion of the Transaction remains outstanding following any final exercise and settlement, cancellation or early termination of the Transaction, apply, for a loan, loan guarantee, direct loan (as that term is defined in the Coronavirus Aid, Relief and Economic Security Act (the "CARES Act")) or other investment, or to receive any financial assistance or relief under any program or facility (collectively "Financial Assistance") that (a) is established under applicable law (whether in existence as of the Trade Date or subsequently enacted, adopted or amended), including without limitation the CARES Act and the Federal Reserve Act, as amended, and (b) (i) requires under applicable law (or any regulation, guidance, interpretation or other pronouncement of a governmental authority with jurisdiction for such program or facility) as a condition of such Financial Assistance, that the Counterparty comply with any requirement not to repurchase, or otherwise agree, attest, certify or warrant that it has not, as of the date specified in such condition, repurchased, or will not repurchase, any equity security of Counterparty, and that Counterparty has not, as of the date specified in the condition, made a capital distribution or will not make a capital distribution, or (ii) where the terms of the Transaction would cause Counterparty to fail to satisfy any condition for application for or receipt or retention of the Financial Assistance (collectively "Restricted Financial Assistance"); provided, that Counterparty or any of its subsidiaries may apply for Restricted Financial Assistance if Counterparty or any of its subsidiaries to fail to satisfy any condition for application for or receipt or retention of such Financial Assistance based on the terms of the program or facility as of the date of such advice or (b) delivers to Dealer evidence or other guidance from a governmental a

specific reference to the Transaction or by general reference to transactions with the attributes of the Transaction in all relevant respects).

11. Representations, Warranties and Acknowledgments.

- (a) Issuer hereby represents and warrants to Dealer on the date hereof and on and as of the Initial Share Delivery Date that:
- (i) (A) None of Issuer and its officers and directors is aware of any material nonpublic information regarding Issuer or the Shares, and is entering into the Transaction in good faith and not as part of a plan or scheme to evade the prohibitions of federal securities laws, including, without limitation, Rule 10b-5 under the Exchange Act and (B) Issuer agrees not to alter or deviate from the terms of this Confirmation or enter into or alter a corresponding or hedging transaction or position with respect to the Shares (including, without limitation, with respect to any securities convertible or exchangeable into the Shares) during the term of this Confirmation. Without limiting the generality of the foregoing, all reports and other documents filed by Issuer with the Securities and Exchange Commission pursuant to the Exchange Act when considered as a whole (with the more recent such reports and documents deemed to amend inconsistent statements contained in any earlier such reports and documents) do not contain any untrue statement of a material fact or any omission of a material fact required to be stated therein or necessary to make the statements therein, in the light of the circumstances in which they were made, not misleading.
- (ii) The transactions contemplated by this Confirmation have been authorized under Issuer's publicly announced program to repurchase Shares.
- (iii) Issuer is not entering into this Confirmation to facilitate a distribution of the Shares (or any security convertible into or exchangeable for Shares) or in connection with a future issuance of securities.
- (iv) Issuer is not entering into this Confirmation to create actual or apparent trading activity in the Shares (or any security convertible into or exchangeable for Shares) or to manipulate the price of the Shares (or any security convertible into or exchangeable for Shares) in violation of the federal securities laws.
- (v) There have been no purchases of Shares in Rule 10b-18 purchases of blocks pursuant to the once-a-week block exception contained in Rule 10b-18(b)(4) by or for Issuer or any of its affiliated purchasers during each of the four calendar weeks preceding the Trade Date and during the calendar week in which the Trade Date occurs ("Rule 10b-18 purchase", "blocks" and "affiliated purchaser" each being used as defined in Rule 10b-18).
- (vi) Issuer is as of the date hereof and after giving effect to the transactions contemplated hereby will be, Solvent. As used in this paragraph, the term "Solvent" means, with respect to a particular date, that on such date (A) the present fair market value (or present fair saleable value) of the assets of Issuer is not less than the total amount required to pay the liabilities of Issuer on its total existing debts and liabilities (including contingent liabilities) as they become absolute and matured, (B) Issuer is able to realize upon its assets and pay its debts and other liabilities, contingent obligations and commitments as they mature and become due in the normal course of business, (C) assuming consummation of the transactions as contemplated by this Confirmation, Issuer is not incurring debts or liabilities beyond its ability to pay as such debts and liabilities mature, (D) Issuer is not engaged in any business or transaction, and does not propose to engage in any business or transaction, for which its property would constitute unreasonably small capital after giving due consideration to the prevailing practice in the industry in which Issuer is engaged, (E) Issuer is not a defendant in any civil action that could reasonably be expected to result in a judgment that Issuer is or would become unable to satisfy, (F) Issuer is not "insolvent" (as such term is defined under Section 101(32) of the U.S. Bankruptcy Code (Title 11 of the United States Code) (the "Bankruptcy Code")) and (G) Issuer would be able to purchase Shares with an aggregate purchase price equal to the Prepayment Amount in compliance with the corporate laws of the jurisdiction of its incorporation.

- (vii) Issuer is not, and after giving effect to the transactions contemplated hereby will not be, required to register as an "investment company" as such term is defined in the Investment Company Act of 1940, as amended.
- (viii) No state or local (including non-U.S. jurisdictions) law, rule, regulation or regulatory order applicable to the Shares would give rise to any reporting, consent, registration or other requirement (including without limitation a requirement to obtain prior approval from any person or entity) as a result of Dealer or its affiliates owning or holding (however defined) Shares other than any such law, rule, regulation or regulatory order that applies (A) to the beneficial ownership of Shares under the Exchange Act or (B) solely as a result of the business, identity, place of business or jurisdiction of organization of Dealer or any such affiliate.
- (b) Issuer acknowledges and agrees that the Initial Shares may be sold short to Issuer. Issuer further acknowledges and agrees that Dealer may purchase Shares in connection with the Transaction, which Shares may be used to cover all or a portion of such short sale or may be delivered to Issuer. Such purchases and any other market activity by Dealer will be conducted independently of Issuer by Dealer as principal for its own account. All of the actions to be taken by Dealer in connection with the Transaction shall be taken by Dealer independently and without any advance or subsequent consultation with Issuer. It is the intent of the parties that the Transaction comply with the requirements of Rule 10b5-1(c)(1)(i)(B) of the Exchange Act, and the parties agree that this Confirmation shall be interpreted to comply with the requirements of such Rule, and Issuer shall not take any action that results in the Transaction not so complying with such requirements. Without limiting the generality of the preceding sentence, Issuer acknowledges and agrees that (A) Issuer does not have, and shall not attempt to exercise, any influence over how, when or whether Dealer effects any market transactions in connection with the Transaction and (B) neither Issuer nor its officers or employees shall, directly or indirectly, communicate any information regarding Issuer or the Shares to any employee of Dealer or its Affiliates that have been identified by Dealer to Issuer in writing as employees responsible for executing market transactions in connection with the Transaction. Issuer also acknowledges and agrees that any amendment, modification, waiver or termination of this Confirmation must be effected in accordance with the requirements for the amendment or termination of a "plan" as defined in Rule 10b5-1(c) under the Exchange Act. Without limiting the generality of the foregoing, any such amendment, modification, waiver or termination shall be made in good faith and not as part of a plan or scheme to evade the prohibitions of Rule 10b-5 under the Exchange Act, and no such amendment, modification or waiver shall be made at any time at which Issuer or any officer or director of Issuer is aware of any material nonpublic information regarding Issuer or the Shares.
- (c) Each of Issuer and Dealer represents and warrants to the other that it is an "eligible contract participant" as defined in Section 1a(12) of the U.S. Commodity Exchange Act, as amended.
- (d) Each of Issuer and Dealer acknowledges that the offer and sale of the Transaction to it is intended to be exempt from registration under the Securities Act by virtue of Section 4(2) thereof. Accordingly, it represents and warrants to the other party that (i) it has the financial ability to bear the economic risk of its investment in the Transaction and is able to bear a total loss of its investment, (ii) it is an "accredited investor" as that term is defined in Regulation D as promulgated under the Securities Act, (iii) it is entering into the Transaction for its own account and without a view to the distribution or resale thereof and (iv) the assignment, transfer or other disposition of the Transaction has not been and will not be registered under the Securities Act and is restricted under this Confirmation, the Securities Act and state securities laws.
 - (e) In addition to the representations, warranties and covenants in the Agreement, Dealer represents warrants and covenants to Issuer that:
 - (i) In addition to the covenants in the Agreement and herein, Dealer agrees to use commercially reasonable efforts, during the Calculation Period and any Buyer Settlement Valuation Period for the Transaction, to make all purchases of Shares in connection with such Transaction in a manner that would comply with the limitations set forth in clauses (b)(1), (b)(2), (b)(3) and (b)(4) and (c) of Rule 10b-18, as if such rule were applicable to such purchases and taking into account any applicable Securities and Exchange

Commission no-action letters as appropriate, and subject to any delays between the execution and reporting of a trade of the Shares on the Exchange and other circumstances beyond Dealer's control; *provided* that, during the Calculation Period, the foregoing agreement shall not apply to purchases made to dynamically hedge for Dealer's own account or the account of its affiliate(s) the optionality arising under the Transaction or the Transaction (as defined in the Existing Agreement) (including, for the avoidance of doubt, timing optionality); *provided further* that, without limiting the generality of this Section, Dealer shall not be responsible for any failure to comply with Rule 10b-18(b)(3) to the extent any transaction that was executed (or deemed to be executed) by or on behalf of Issuer or an "affiliated purchaser" (as defined under Rule 10b-18) pursuant to a separate agreement is not deemed to be an "independent bid" or an "independent transaction" for purposes of Rule 10b-18(b)(3).

- (ii) Dealer hereby represents and covenants to Issuer that it has implemented policies and procedures, taking into consideration the nature of its business, reasonably designed to ensure that (A) individuals making investment decisions related to the Transaction do not have access to material nonpublic information regarding Issuer or the Shares and (B) individuals of Dealer that are in possession of material nonpublic information regarding the Issuer or the Shares have not, while in possession of such material nonpublic information, participated in any offsetting transaction(s) in respect of such Transaction.
- (iii) Within one Exchange Business Day of purchasing any Shares on behalf of Issuer pursuant to the once-a-week block exception set forth in paragraph (b)(4) of Rule 10b-18, Dealer shall notify Issuer of the total number of Shares so purchased.
- (iv) On the first Exchange Business Day of each week, Dealer shall provide weekly reports (the "Weekly Reports") in connection with the Transaction to the Issuer and to such other persons or agents of the Issuer as the Issuer shall reasonably designate in writing, by electronic mail to the Issuer or its designee. Each Weekly Report shall include the ADTV (as defined in Rule 10b-18) in the Shares for each Scheduled Trading Day during the immediately preceding week (as defined and determined in accordance with Rule 10b-18, as defined herein), the 10b-18 VWAP for each such Scheduled Trading Day and the high and low price on each such Scheduled Trading Day. For the avoidance of doubt and notwithstanding anything to the contrary in the two immediately preceding sentences, the 10b-18 VWAP for purposes of this Master Confirmation shall be determined pursuant the language opposite the caption "10b-18 VWAP" in Section 1 of this Confirmation and not on the basis of, or by reference to, the 10b-18 VWAP set forth in any Weekly Report.

12. Acknowledgements of Issuer.

- (a) Issuer agrees, understands and acknowledges that:
- (i) during the period from (and including) the Trade Date to (and including) the Settlement Date, Dealer and its Affiliates may buy or sell Shares or other securities or buy or sell options or futures contracts or enter into swaps or other derivative transactions in order to adjust its Hedge Position with respect to the Transaction;
- (ii) Dealer and its Affiliates also may be active in the market for the Shares or options, futures contracts, swaps or other derivative transactions relating to the Shares other than in connection with hedging activities in relation to the Transaction;
- (iii) Dealer shall make its own determination as to whether, when and in what manner any hedging or market activities in Issuer's securities or other securities or transactions shall be conducted and shall do so in a manner that it deems appropriate to hedge its price and market risk with respect to the Transaction; and

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

(b) Issuer:

- (i) is an "institutional account" as defined in FINRA Rule 4512(c);
- (ii) is capable of evaluating investment risks independently, both in general and with regard to all transactions and investment strategies involving a security or securities, and will exercise independent judgment in evaluating the recommendations of Dealer or its associated persons, unless it has otherwise notified Dealer in writing; and
 - (iii) will notify Dealer if any of the statements contained in clause (i) or (ii) of this Section 12(b) ceases to be true.

13. Delivery of Cash.

For the avoidance of doubt, other than payment of the Prepayment Amount by Issuer, nothing in this Confirmation shall be interpreted as requiring Issuer to cash settle the Transaction hereunder, except in circumstances where cash settlement is within Issuer's control or in those circumstances in which holders of the Shares would also receive cash.

14. Other Provisions.

- (a) Issuer agrees and acknowledges that Dealer is a "financial institution" and "financial participant" within the meaning of Sections 101(22) and 101(22A) of the Bankruptcy Code. The parties hereto further agree and acknowledge that it is the intent of the parties that (A) this Confirmation is a "securities contract," as such term is defined in Section 741(7) of the Bankruptcy Code, with respect to which each payment and delivery hereunder or in connection herewith is a "termination value," "payment amount" or "other transfer obligation" within the meaning of Section 362 of the Bankruptcy Code and a "settlement payment," within the meaning of Section 546 of the Bankruptcy Code, and (B) Dealer is entitled to the protections afforded by, among other sections, Sections 362(b)(6), 362(b)(17), 362(o), 546(e), 555 and 561 of the Bankruptcy Code.
- (b) Dealer and Issuer hereby agree and acknowledge that Dealer has authorized Issuer to disclose the Transaction to any and all persons, and there are no express or implied agreements, arrangements or understandings to the contrary, and authorizes Issuer to use any information that Issuer receives or has received with respect to the Transaction in any manner.
- (c) In the event Issuer becomes the subject of proceedings ("Bankruptcy Proceedings") under the Bankruptcy Code or any other applicable bankruptcy or insolvency statute, any rights or claims of Dealer hereunder in respect of the Transaction shall rank for all purposes no higher than, but on a parity with, the rights or claims of holders of Shares, and Dealer hereby agrees that its rights and claims hereunder shall be subordinated to those of all parties with claims or rights against Issuer (other than common stockholders) to the extent necessary to assure such ranking. Without limiting the generality of the foregoing, after the commencement of Bankruptcy Proceedings, the claims of Dealer hereunder shall for all purposes have rights equivalent to the rights of a holder of a percentage of the Shares equal to the aggregate amount of such claims (the "Claim Amount") taken as a percentage of the sum of (i) the Claim Amount and (ii) the aggregate fair market value of all outstanding Shares on the record date for distributions made to the holders of such Shares in the related Bankruptcy Proceedings. Notwithstanding any right it might otherwise have to assert a higher priority claim in any such Bankruptcy Proceedings, Dealer shall be entitled to receive a distribution solely to the extent and only in the form that a holder of such percentage of the Shares would be entitled to receive in such Bankruptcy Proceedings, and, from and after the commencement of such Bankruptcy Proceedings, Dealer expressly waives (i) any other rights or distributions to which it might otherwise be entitled in such Bankruptcy Proceedings in respect of its rights

and claims hereunder and (ii) any rights of setoff it might otherwise be entitled to assert in respect of such rights and claims.

- (d) Notwithstanding any provision of this Confirmation or any other agreement between the parties to the contrary, neither the obligations of Issuer nor the obligations of Dealer hereunder are secured by any collateral, security interest, pledge or lien.
- (e) Each party waives any and all rights it may have to set off obligations arising under the Agreement and the Transaction against other obligations between the parties, whether arising under any other agreement, applicable law or otherwise.
- (f) Notwithstanding anything to the contrary herein, Dealer may, by prior notice to Issuer, satisfy its obligation to deliver any Shares or other securities on any date due (an "**Original Delivery Date**") by making separate deliveries of Shares or such securities, as the case may be, at more than one time on or prior to such Original Delivery Date, so long as the aggregate number of Shares and other securities so delivered on or prior to such Original Delivery Date is equal to the number required to be delivered on such Original Delivery Date.
- (g) It shall constitute an Additional Termination Event with respect to which the Transaction is the sole Affected Transaction and Issuer is the sole Affected Party and Dealer shall be the party entitled to designate an Early Termination Date pursuant to Section 6(b) of the Agreement if, at any time on or prior to the Valuation Date, the price per Share on the Exchange, as determined by the Calculation Agent, is at or below the Threshold Price (as specified in Schedule I).
- (h) Notwithstanding any other provision in this Confirmation to the contrary requiring or allowing Dealer to purchase, sell, receive or deliver any Shares or other securities to or from Issuer, Dealer may designate any of its affiliates (a "Designated Affiliate") to purchase, sell, receive or deliver such Shares or other securities and otherwise to perform Dealer's obligations in respect of the Transaction and any such designee may assume such obligations. Dealer shall be discharged of its obligations to Issuer to the extent that such Designated Affiliate performs in full all of the obligations of Dealer designated by Dealer to such Designated Affiliate under this Transaction.
- (i) The parties hereto agree that (i) this Confirmation shall serve as evidence of Dealer's prior written agreement to permit entry into this Transaction notwithstanding Section 10(a) of the Existing Agreement, (ii) Section 11(e)(i) shall be amended by replacing the phrase ("optionality arising under the Transaction" with the phrase "optionality arising under the Transaction or under the transaction pursuant to the letter agreement entered into between Dealer and the Issuer on July 30, 2021 (the "New Agreement")", and (iii) the definition for Buyer Cash Settlement Payment Date shall add the following proviso, "; provided, if Net Share Settlement is applicable Dealer may postpone the Buyer Cash Settlement Payment Date to a date following the end of the Calculation Period in the New Agreement to extent advisable in light of any legal, regulatory, or self-regulatory issues and to avoid any interruption in the Calculation Period for the New Agreement". For the avoidance of doubt, the consent provided in this Section 14(i)(i) shall not be considered a waiver of any other rights the Dealer may have under the Existing Agreement.

15. <u>Transfer and Assignment</u>.

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

16. <u>US Resolution Stay.</u>

(a) Recognition of the U.S. Special Resolution Regimes.

- (i) In the event that Dealer becomes subject to a proceeding under (i) the Federal Deposit Insurance Act and the regulations promulgated thereunder or (ii) Title II of the Dodd-Frank Wall Street Reform and Consumer Protection Act and the regulations promulgated thereunder (a "U.S. Special Resolution Regime") the transfer from Dealer of this Confirmation, and any interest and obligation in or under, and any property securing, this Confirmation, will be effective to the same extent as the transfer would be effective under the U.S. Special Resolution Regime if this Confirmation, and any interest and obligation in or under, and any property securing, this Confirmation were governed by the laws of the United States or a state of the United States.
- (ii) In the event that Dealer or an Affiliate becomes subject to a proceeding under a U.S. Special Resolution Regime, any Default Rights (as defined in 12 C.F.R. §§ 252.81, 47.2 or 382.1, as applicable ("**Default Right**")) under this Confirmation that may be exercised against Dealer are permitted to be exercised to no greater extent than such Default Rights could be exercised under the U.S. Special Resolution Regime if this Confirmation were governed by the laws of the United States or a state of the United States.
- (b) Limitation on Exercise of Certain Default Rights Related to an Affiliate's Entry Into Insolvency Proceedings. Notwithstanding anything to the contrary in this Confirmation, the parties expressly acknowledge and agree that:
- (i) Counterparty shall not be permitted to exercise any Default Right with respect to this Confirmation or any Affiliate Credit Enhancement that is related, directly or indirectly, to an Affiliate of Dealer becoming subject to receivership, insolvency, liquidation, resolution, or similar proceeding (an "Insolvency Proceeding"), except to the extent that the exercise of such Default Right would be permitted under the provisions of 12 C.F.R. 252.84, 12 C.F.R. 47.5 or 12 C.F.R. 382.4, as applicable; and
- (ii) Nothing in this Confirmation shall prohibit the transfer of any Affiliate Credit Enhancement, any interest or obligation in or under such Affiliate Credit Enhancement, or any property securing such Affiliate Credit Enhancement, to a transferee upon or following an Affiliate of Dealer becoming subject to an Insolvency Proceeding, unless the transfer would result in the Counterparty being the beneficiary of such Affiliate Credit Enhancement in violation of any law applicable to the Counterparty.
 - (iii) For the purpose of this paragraph:
 - (A) "Affiliate" is defined in, and shall be interpreted in accordance with, 12 U.S.C. § 1841(k).
 - (B) "Credit Enhancement" means any credit enhancement or credit support arrangement in support of the obligations of Dealer under or with respect to this Confirmation, including any guarantee, collateral arrangement (including any pledge, charge, mortgage or other security interest in collateral or title transfer arrangement), trust or similar arrangement, letter of credit, transfer of margin or any similar arrangement.
- (c) U.S. Protocol. If Counterparty has previously adhered to, or subsequently adheres to, the ISDA 2018 U.S. Resolution Stay Protocol as published by the International Swaps and Derivatives Association, Inc. as of July 31, 2018 (the "ISDA U.S. Protocol"), the terms of the ISDA U.S. Protocol shall be incorporated into and form a part of this Confirmation and the terms of the ISDA U.S. Protocol shall supersede and replace the terms of this section. For purposes of incorporating the ISDA U.S. Protocol, Dealer shall be deemed to be a Regulated Entity, Counterparty shall be deemed to be an Adhering Party, and this Confirmation shall be deemed to be a Protocol Covered Agreement. Capitalized terms used but not defined in this paragraph shall have the meanings given to them in the ISDA U.S. Protocol.
- (d) Pre-existing In-Scope Agreements. Dealer and Counterparty agree that to the extent there are any outstanding "in-scope QFCs," as defined in 12 C.F.R. § 252.82(d), that are not excluded under 12 C.F.R. § 252.88, between Dealer and Counterparty that do not otherwise comply with the requirements of 12 C.F.R. § 252.2, 252.81–8 (each such agreement, a "**Preexisting In-Scope Agreement**"), then each such

Preexisting In-Scope Agreement is hereby amended to include the foregoing provisions in this section, with references to "this Confirmation" being understood to be references to the applicable Preexisting In-Scope Agreement.

17. Governing Law; Jurisdiction; Waiver.

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

EACH PARTY HEREBY IRREVOCABLY WAIVES (ON ITS OWN BEHALF AND, TO THE EXTENT PERMITTED BY APPLICABLE LAW, ON BEHALF OF ITS STOCKHOLDERS) ALL RIGHT TO TRIAL BY JURY IN ANY ACTION, PROCEEDING OR COUNTERCLAIM (WHETHER BASED ON CONTRACT, TORT OR OTHERWISE) ARISING OUT OF OR RELATING TO THE TRANSACTION OR THE ACTIONS OF THE OTHER PARTY OR THE OTHER PARTY'S AFFILIATES IN THE NEGOTIATION, PERFORMANCE OR ENFORCEMENT HEREOF.

Remainder of Page Intentionally Blank

Please confirm that the foregoing correctly sets forth the terms of our agreement by executing this Confirmation and returning an original or electronic copy in accordance with the notice provisions set forth in Section 4.

Confirmed as of the date first written above:

ALIGN TECHNOLOGY, INC

By: /s/ John Morici

Name: John Morici

Title: CFO and SVP, Global Finance

GOLDMAN SACHS & CO. LLC

By: /s/ Ashley Everett

Name: Ashley Everett Title: Managing Director

BUYER SETTLEMENT PROVISIONS

1. The following Buyer Settlement Provisions shall apply to the Transaction to the extent indicated under the Confirmation:

Settlement Currency: USD

Settlement Method Election: Applicable; provided that (i) Section 7.1 of the Equity Definitions is hereby amended by deleting the word

"Physical" in the sixth line thereof and replacing it with the words "Net Share" and (ii) the Electing Party may make a settlement method election only if the Electing Party represents and warrants to Dealer in writing on the date it notifies Dealer of its election that, as of such date, the Electing Party is not aware of any material nonpublic information concerning Issuer or the Shares and is electing the settlement method in good faith and not as part of a plan or scheme to evade compliance with the federal securities laws.

Electing Party: Buyer

Settlement Method

Election Date: In respect of any Valuation Date, the earlier of (i) the Scheduled Valuation Date and (ii) the third Exchange Business

Day immediately following the Valuation Date designated in an Acceleration (if any) (in which case the election under Section 7.1 of the Equity Definitions shall be made no later than 10 minutes prior to the

open of trading on the Exchange on such second Exchange Business Day), as the case may be.

Default Settlement Method: Cash Settlement

Forward Cash Settlement

Amount: The Settlement Amount *multiplied by* the Buyer Settlement Price.

Buyer Settlement Price: The average of the 10b-18 VWAPs for the Observation Dates that are Trading Days in the Buyer Settlement

Valuation Period, subject to the provisions opposite the caption "Market Disruption Event" in the Confirmation, <u>plus</u> USD 0.05 (in each case, <u>plus</u> interest on such amount during the Buyer Settlement Valuation Period at the rate of interest for Issuer's long term, unsecured and unsubordinated indebtedness,

as determined in good faith and in a commercially reasonable manner by the Calculation Agent).

Buyer Settlement

Valuation Period: A number of Scheduled Trading Days selected by Dealer in its commercially reasonable discretion, beginning on the

Scheduled Trading Day immediately following the earlier of (i) the Scheduled Valuation Date or (ii) the

Exchange Business Day immediately following the Valuation Date.

Cash Settlement: If Cash Settlement is applicable, then Buyer shall pay to Seller the absolute value of the Forward Cash Settlement

Amount on the Buyer Cash Settlement Payment Date.

Buyer Cash Settlement

Payment Date: The date one Settlement Cycle following the last day of the Buyer Settlement Valuation Period.

Net Share Settlement

Procedures: If Net Share Settlement is applicable, Net Share Settlement shall be made in accordance with paragraphs 2 through 8

below.

2. Net Share Settlement shall be made by delivery on the Buyer Cash Settlement Payment Date of a number of Shares satisfying the conditions set forth in paragraph 3 below (the "Registered Settlement Shares"), or a number of Shares not satisfying such conditions (the "Unregistered Settlement Shares"), in either case with a value equal to the absolute value of the Forward Cash Settlement Amount, with such Shares' value based on the value thereof to Dealer (which value shall, in the case of Unregistered Settlement Shares, take into account a commercially reasonable illiquidity discount), in each case, as determined by the Calculation Agent in good faith and in a commercially reasonable manner.

- 3. Buyer may deliver Registered Settlement Shares pursuant to paragraph 2 above only if:
- (a) a registration statement covering public resale of the Registered Settlement Shares by Dealer (the "Registration Statement") shall have been filed with the Securities and Exchange Commission under the Securities Act and been declared or otherwise become effective on or prior to the date of delivery, and no stop order shall be in effect with respect to the Registration Statement; and a printed prospectus relating to the Registered Settlement Shares (including any prospectus supplement thereto, the "Prospectus") shall have been delivered to Dealer, in such quantities as Dealer shall reasonably have requested, on or prior to the date of delivery;
- (b) the form and content of the Registration Statement and the Prospectus (including, without limitation, any sections describing the plan of distribution) shall be reasonably satisfactory to Dealer;
- (c) as of or prior to the date of delivery, Dealer and its agents shall have been afforded a reasonable opportunity to conduct a due diligence investigation with respect to Buyer customary in scope for underwritten offerings of equity securities for companies of a similar size and in a similar industry and the results of such investigation are satisfactory to Dealer, in its discretion; and

- (d) as of the date of delivery, an agreement (the "**Underwriting Agreement**") shall have been entered into with Dealer in connection with the public resale of the Registered Settlement Shares by Dealer substantially similar to underwriting agreements customary for underwritten offerings of equity securities for companies of a similar size and in a similar industry, in form and substance commercially reasonably satisfactory to Dealer, which Underwriting Agreement shall include, without limitation, provisions substantially similar to those contained in such underwriting agreements relating, without limitation, to the indemnification of, and contribution in connection with the liability of, Dealer and its affiliates and the provision of customary opinions, accountants' comfort letters and lawyers' negative assurance letters.
 - 4. If Buyer delivers Unregistered Settlement Shares pursuant to paragraph 2 above:
- (a) all Unregistered Settlement Shares shall be delivered to Dealer (or any affiliate of Dealer designated by Dealer) pursuant to the exemption from the registration requirements of the Securities Act provided by Section 4(a)(2) thereof;
- (b) as of or prior to the date of delivery, Dealer and any potential purchaser of any such shares from Dealer (or any affiliate of Dealer designated by Dealer) identified by Dealer shall be afforded a commercially reasonable opportunity to conduct a due diligence investigation with respect to Buyer customary in scope for private placements of equity securities for companies of a similar size and in a similar industry (including, without limitation, the right to have made available to them for inspection all financial and other records, pertinent corporate documents and other information reasonably requested by them subject to customary confidentiality agreements);
- (c) as of the date of delivery, Buyer shall enter into an agreement (a "**Private Placement Agreement**") with Dealer (or any affiliate of Dealer designated by Dealer) in connection with the private placement of such shares by Buyer to Dealer (or any such affiliate) and the private resale of such shares by Dealer (or any such affiliate), substantially similar to private placement purchase agreements customary for private placements of equity securities for companies of a similar size and in a similar industry, in form and substance commercially reasonably satisfactory to Dealer, which Private Placement Agreement shall include, without limitation, provisions substantially similar to those contained in such private placement purchase agreements for companies of a similar size and in a similar industry relating, without limitation, to the indemnification of, and contribution in connection with the liability of, Dealer and its affiliates and the provision of customary opinions, accountants' comfort letters and lawyers' negative assurance letters, and shall provide for the payment by Buyer of all reasonable fees and expenses in connection with such resale, including all reasonable fees and expenses of counsel for Dealer, and shall contain representations, warranties, covenants and agreements of Buyer reasonably necessary or advisable to establish and maintain the availability of an exemption from the registration requirements of the Securities Act for such resales; and
- (d) in connection with the private placement of such shares by Buyer to Dealer (or any such affiliate) and the private resale of such shares by Dealer (or any such affiliate), Buyer shall, if so requested by Dealer, prepare, in cooperation with Dealer, a private placement memorandum in form and substance reasonably satisfactory to Dealer.
- 5. Dealer, itself or through an affiliate (the "Selling Agent") or any underwriter(s), will sell all, or such lesser portion as may be required hereunder, of the Registered Settlement Shares or Unregistered Settlement Shares and any Makewhole Shares (as defined below) (together, the "Settlement Shares") delivered by Buyer to Dealer pursuant to paragraph 6 below commencing on the Buyer Cash

Settlement Payment Date and continuing until the date on which the aggregate Net Proceeds (as such term is defined below) of such sales, as determined by Dealer, is equal to the absolute value of the Forward Cash Settlement Amount (such date, the "Final Resale Date"). If the proceeds of any sale(s) made by Dealer, the Selling Agent or any underwriter(s), net of any fees and commissions (including, without limitation, underwriting or placement fees) customary for similar transactions under the circumstances at the time of the offering, together with carrying charges and expenses incurred in connection with the offer and sale of the Shares (including, but without limitation to, the covering of any over-allotment or short position (syndicate or otherwise)) (the "Net Proceeds") exceed the absolute value of the Forward Cash Settlement Amount, Dealer will refund, in USD, such excess to Buyer on the date that is two (2) Currency Business Days following the Final Resale Date, and, if any portion of the Settlement Shares remains unsold, Dealer shall return to Buyer on that date such unsold Shares.

- 6. If the Calculation Agent determines that the Net Proceeds received from the sale of the Registered Settlement Shares or Unregistered Settlement Shares or any Makewhole Shares, if any, pursuant to this paragraph 6 are less than the absolute value of the Forward Cash Settlement Amount (the amount in USD by which the Net Proceeds are less than the absolute value of the Forward Cash Settlement Amount being the "Shortfall" and the date on which such determination is made, the "Deficiency Determination Date"), Buyer shall, on the Exchange Business Day next succeeding the Deficiency Determination Date (the "Makewhole Notice Date"), deliver to Dealer, through the Selling Agent, a notice of Buyer's election that Buyer shall either (i) pay an amount in cash equal to the Shortfall on the day that is one (1) Currency Business Day after the Makewhole Notice Date, or (ii) deliver additional Shares. If Buyer elects to deliver to Dealer additional Shares, then Buyer shall deliver additional Shares in compliance with the terms and conditions of paragraph 3 or paragraph 4 above, as the case may be (the "Makewhole Shares"), on the first Clearance System Business Day that is also an Exchange Business Day following the Makewhole Notice Date in such number as the Calculation Agent reasonably believes would have a market value on that Exchange Business Day equal to the Shortfall. Such Makewhole Shares shall be sold by Dealer in accordance with the provisions above; provided that if the sum of the Net Proceeds from the sale of the originally delivered Shares and the Net Proceeds from the sale of any Makewhole Shares is less than the absolute value of the Forward Cash Settlement Amount then Buyer shall, at its election, either make such cash payment or deliver to Dealer further Makewhole Shares until such Shortfall has been reduced to zero.
- 7. Notwithstanding the foregoing, in no event shall the aggregate number of Settlement Shares for the Transaction be greater than the Share Cap (as specified in Schedule I). Buyer represents and warrants (which shall be deemed to be repeated on each day that the Transaction is outstanding) that the Share Cap is equal to or less than the number of Shares determined according to the following formula:

A - B

Where A = the number of authorized but unissued shares of Buyer that are not reserved for future issuance on the date hereof; and

B = the maximum number of Shares required to be delivered to third parties if Buyer elected Net Share Settlement of all transactions in the Shares (other than the Transaction) with all third parties that are then currently outstanding and unexercised.

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: November 2, 2021

/s/ JOSEPH M. HOGAN

Joseph M. Hogan President and Chief Executive Officer

CERTIFICATION

I, John F. Morici, certify that:

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

Date: November 2, 2021

/s/ JOHN F. MORICI

John F. Morici

Chief Financial Officer and Senior Vice President, Global Finance

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

In connection with the Quarterly Report of Align Technology, Inc. (the "Company") on Form 10-Q for the period ending September 30, 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 results of operations of the Company.

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

Date: November 2, 2021

In connection with the Quarterly Report of Align Technology, Inc. (the "Company") on Form 10-Q for the period ending September 30, 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 results 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: November 2, 2021