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

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2022

or

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

For the transition period from to

Commission file number: 000-32259

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

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

410 North Scottsdale Road, Suite 1300
Tempe, Arizona 85281
(Address of principal executive offices)
(602) 742-2000
(Registrant's telephone number, including area code)

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

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

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

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

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

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

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

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

The number of shares outstanding of the registrant's Common Stock, $0.0001 par value, as of July 29, 2022 was 78,108,185.

ALIGN TECHNOLOGY, INC.

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PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Net revenues	$ 969,553	$ 1,010,808	$ 1,942,772	$ 1,905,579
Cost of net revenues	281,994	252,270	545,867	469,943
Gross profit	687,559	758,538	1,396,905	1,435,636
Operating expenses:				
Selling, general and administrative	426,398	431,921	865,855	829,036
Research and development	72,965	57,715	144,772	112,252
Total operating expenses	499,363	489,636	1,010,627	941,288
Income from operations	188,196	268,902	386,278	494,348
Interest income and other income (expense), net:				
Interest income	245	383	922	2,026
Other income (expense), net	(14,832)	(483)	(26,105)	34,049
Total interest income and other income (expense), net	(14,587)	(100)	(25,183)	36,075
Net income before provision for income taxes	173,609	268,802	361,095	530,423
Provision for income taxes	60,809	69,088	113,997	130,333
Net income	$ 112,800	$ 199,714	$ 247,098	$ 400,090
Net income per share:				
Basic	$ 1.44	$ 2.53	$ 3.15	$ 5.06
Diluted	$ 1.44	$ 2.51	$ 3.13	$ 5.02
Shares used in computing net income per share:				
Basic	78,395	79,008	78,568	79,004
Diluted	78,545	79,638	78,840	79,737

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Net income	$ 112,800	$ 199,714	$ 247,098	$ 400,090
Other comprehensive income (loss):				
Change in foreign currency translation adjustment, net of tax	(13,756)	586	(21,067)	(13,865)
Change in unrealized gains (losses) on investments, net of tax	(301)	—	(3,029)	(20)
Other comprehensive income (loss)	(14,057)	586	(24,096)	(13,885)
Comprehensive income	$ 98,743	$ 200,300	$ 223,002	$ 386,205

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

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

	June 30, 2022	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 877,501	$ 1,099,370
Marketable securities, short-term	22,138	71,972
Accounts receivable, net of allowance for doubtful accounts of $9,520 and $9,245, respectively	931,854	897,198
Inventories	310,046	230,230
Prepaid expenses and other current assets	235,265	195,305
Total current assets	2,376,804	2,494,075
Marketable securities, long-term	77,551	125,320
Property, plant and equipment, net	1,182,444	1,081,926
Operating lease right-of-use assets, net	117,912	121,257
Goodwill	390,100	418,547
Intangible assets, net	93,817	109,709
Deferred tax assets	1,518,648	1,533,767
Other assets	52,843	57,509
Total assets	$ 5,810,119	$ 5,942,110
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 145,607	$ 163,886
Accrued liabilities	416,459	607,315
Deferred revenues	1,242,348	1,152,870
Total current liabilities	1,804,414	1,924,071
Income tax payable	116,414	118,072
Operating lease liabilities	98,332	102,656
Other long-term liabilities	191,878	174,597
Total liabilities	2,211,038	2,319,396
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; 78,059 and 78,710 issued and outstanding, respectively)	8	8
Additional paid-in capital	1,016,882	999,006
Accumulated other comprehensive income (loss), net	(19,770)	4,326
Retained earnings	2,601,961	2,619,374
Total stockholders' equity	3,599,081	3,622,714
Total liabilities and stockholders' equity	$ 5,810,119	$ 5,942,110

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

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

Three Months Ended June 30, 2022	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss), Net	Retained Earnings	Total
Balance as of March 31, 2022	78,805	$ 8	$ 992,287	$ (5,713)	$ 2,680,270	$ 3,666,852
Net income	—	—	—	—	112,800	112,800
Net change in unrealized gains (losses) from investments	—	—	—	(301)	—	(301)
Net change in foreign currency translation adjustment	—	—	—	(13,756)	—	(13,756)
Issuance of common stock relating to employee equity compensation plans	11	—	—	—	—	—
Tax withholdings related to net share settlements of equity awards	—	—	(654)	—	—	(654)
Common stock repurchased and retired	(757)	—	(8,891)	—	(191,109)	(200,000)
Stock-based compensation	—	—	34,140	—	—	34,140
Balance as of June 30, 2022	78,059	$ 8	$ 1,016,882	$ (19,770)	$ 2,601,961	$ 3,599,081

Six Months Ended June 30, 2022	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss), Net	Retained Earnings	Total
Balance as of December 31, 2021	78,710	$ 8	$ 999,006	$ 4,326	$ 2,619,374	$ 3,622,714
Net income	—	—	—	—	247,098	247,098
Net change in unrealized gains (losses) from investments	—	—	—	(3,029)	—	(3,029)
Net change in foreign currency translation adjustment	—	—	—	(21,067)	—	(21,067)
Issuance of common stock relating to employee equity compensation plans	250	—	14,827	—	—	14,827
Tax withholdings related to net share settlements of equity awards	—	—	(52,187)	—	—	(52,187)
Common stock repurchased and retired	(901)	—	(10,525)	—	(264,511)	(275,036)
Stock-based compensation	—	—	65,761	—	—	65,761
Balance as of June 30, 2022	78,059	$ 8	$ 1,016,882	$ (19,770)	$ 2,601,961	$ 3,599,081

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

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

	Common Stock				
Three Months Ended June 30, 2021	**Shares**	**Amount**	**Additional Paid-In Capital**	**Accumulated Other Comprehensive Income (Loss), Net**	**Retained Earnings**	**Total**
Balance as of March 31, 2021	79,136	$ 8	$ 948,362	$ 29,030	$ 2,416,176	$ 3,393,576
Net income	—	—	—	—	199,714	199,714
Net change in foreign currency translation adjustment	—	—	—	586	—	586
Issuance of common stock relating to employee equity compensation plans	89	—	—	—	—	—
Tax withholdings related to net share settlements of equity awards	—	—	(38,321)	—	—	(38,321)
Common stock repurchased and retired	(277)	—	(3,065)	—	(156,935)	(160,000)
Equity forward contract related to accelerated stock repurchase	—	—	(40,000)	—	—	(40,000)
Stock-based compensation	—	—	28,855	—	—	28,855
Balance as of June 30, 2021	78,948	$ 8	$ 895,831	$ 29,616	$ 2,458,955	$ 3,384,410

	Common Stock					
Six Months Ended June 30, 2021	**Shares**	**Amount**	**Additional Paid-In Capital**	**Accumulated Other Comprehensive Income (Loss), Net**	**Retained Earnings**	**Total**
Balance as of December 31, 2020	78,860	$ 8	$ 974,556	$ 43,501	$ 2,215,800	$ 3,233,865
Net income	—	—	—	—	400,090	400,090
Net change in unrealized gains (losses) from investments	—	—		(20)	—	(20)
Net change in foreign currency translation adjustment	—	—	—	(13,865)	—	(13,865)
Issuance of common stock relating to employee equity compensation plans	365	—	13,133	—	—	13,133
Tax withholdings related to net share settlements of equity awards	—	—	(104,889)	—	—	(104,889)
Common stock repurchased and retired	(277)	—	(3,065)	—	(156,935)	(160,000)
Equity forward contract related to accelerated stock repurchase	—	—	(40,000)	—	—	(40,000)
Stock-based compensation	—	—	56,096	—	—	56,096
Balance as of June 30, 2021	78,948	$ 8	$ 895,831	$ 29,616	$ 2,458,955	$ 3,384,410

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

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

	Six Months Ended June 30, 2022	Six Months Ended June 30, 2021
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net income	$ 247,098	$ 400,090
Adjustments to reconcile net income to net cash provided by operating activities:		
Deferred taxes	14,747	39,961
Depreciation and amortization	59,907	51,527
Stock-based compensation	65,761	56,096
Non-cash operating lease cost	15,075	12,413
Arbitration award gain	—	(43,403)
Other non-cash operating activities	16,172	13,174
Changes in assets and liabilities:		
Accounts receivable	(53,462)	(164,822)
Inventories	(91,060)	(49,070)
Prepaid expenses and other assets	(14,219)	(70,132)
Accounts payable	(23,944)	(5,736)
Accrued and other long-term liabilities	(212,896)	65,650
Long-term income tax payable	(1,657)	7,535
Deferred revenues	136,021	231,408
Net cash provided by operating activities	157,543	544,691
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property, plant and equipment	(163,348)	(167,668)
Purchase of marketable securities	(20,466)	—
Proceeds from maturities of marketable securities	21,690	—
Proceeds from sales of marketable securities	92,235	—
Repayment on unsecured promissory note	—	4,594
Proceeds from arbitration award	—	43,403
Other investing activities	(2,189)	(4,249)
Net cash used in investing activities	(72,078)	(123,920)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock	14,827	13,133
Common stock repurchases	(275,036)	(160,000)
Payments for equity forward contracts related to accelerated share repurchase agreements	—	(40,000)
Payroll taxes paid upon the vesting of equity awards	(52,187)	(104,889)
Net cash used in financing activities	(312,396)	(291,756)
Effect of foreign exchange rate changes on cash, cash equivalents, and restricted cash	4,978	(3,511)
Net (decrease) increase in cash, cash equivalents, and restricted cash	(221,953)	125,504
Cash, cash equivalents, and restricted cash at beginning of the period	1,100,139	961,474
Cash, cash equivalents, and restricted cash at end of the period	$ 878,186	$ 1,086,978

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

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

Note 1. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying unaudited Condensed Consolidated Financial Statements have been prepared by Align Technology, Inc. (“we”, “our”, "Company", or “Align”) on a consistent basis with the audited Consolidated Financial Statements for the year ended December 31, 2021, and contains all adjustments, including normal recurring adjustments, necessary to state fairly state the information set forth herein. The unaudited Condensed Consolidated Financial Statements have been prepared in accordance with the rules and regulations of the Securities and Exchange Commission (“SEC”), and, therefore, omit certain information and footnote disclosures necessary to present the unaudited Condensed Consolidated Financial Statements in accordance with accounting principles generally accepted in the United States of America (“U.S.”).

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, 2021. The results of operations for the three and six months ended June 30, 2022 are not necessarily indicative of the results that may be expected for the year ending December 31, 2022 or any other future period, and we make no representations related thereto.

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, contingent liabilities, the fair values of financial instruments, stock-based compensation and the valuation of investments in privately held companies among others. We base our estimates on historical experience and on various other assumptions that are believed to be reasonable, the results of which form the basis for making judgments about the carrying values of assets and liabilities.

Certain Risks and Uncertainties

The military conflict between Russia and Ukraine and its impact on the economy has caused significant worldwide challenges. While the situation is highly uncertain and evolving, its impact on the economy, including inflation, volatilities in the financial market, supply chain challenges, impacts on consumer confidence, purchasing power, sanctions and retaliatory sanctions among others, have impacted and could potentially subject our business to materially adverse consequences should any portion of its impacts become prolonged or escalate beyond its current scope.

Further, as the COVID-19 pandemic continues and new variants of the virus emerge, we are continuing to see fluctuations in the numbers of patients seeking treatment for dental services and the number of doctors providing services and treatments globally. The full extent to which the pandemic, including as a result of any new variants, 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. Additionally, we could also be materially adversely affected by 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.

Revenue Recognition

Our revenues are derived primarily from the sale of aligners, scanners, and services from our Clear Aligner and Systems and Services segments. We enter into sales contracts that may consist of multiple distinct performance obligations where certain performance obligations of the sales contract are not delivered in one reporting period. We measure and allocate revenues according to ASC 606-10, “Revenues from Contracts with Customers.”

We identify a performance obligation as distinct if both of the following criteria are met: the customer can benefit from the good or service either on its own or together with other resources that are readily available to the customer and the entity’s promise to transfer the good or service to the customer is separately identifiable from other promises in the contract.

Determining the standalone selling price ("SSP") in order to allocate consideration from the contract to the individual performance obligations is the result of various factors, such as changing trends and market conditions, historical prices, costs, and gross margins. While changes in the allocation of the SSP between performance obligations will not affect the amount of total revenues recognized for a particular contract, any material changes could impact the timing of revenue recognition, which would have a material effect on our financial position and result of operations. This is because the contract consideration is allocated to each performance obligation, delivered or undelivered, at the inception of the contract based on the SSP of each distinct performance obligation.

Clear Aligner

We enter into contracts ("treatment plan(s)") that involve multiple future performance obligations. Invisalign Comprehensive, Invisalign First, Invisalign Moderate, and Lite and Express Packages include optional additional aligners at no charge for a certain period of time ranging from six months to five years after initial shipment, and Invisalign Go and Invisalign Go Plus includes optional additional aligners at no charge for a period of up to two years after initial shipment.

Our treatment plans comprise the following performance obligations that also represent distinct deliverables: initial aligners, the option of additional aligners, case refinement, and replacement aligners. We take the practical expedient to consider shipping and handling costs as activities to fulfill the performance obligation. We allocate revenues for each treatment plan based on each unit's SSP. Management considers a variety of factors such as same or similar product historical sales, costs, and gross margin, which may vary over time depending upon the unique facts and circumstances related to each performance obligation in making these estimates. In addition to historical data, we take into consideration changing trends and market conditions. For treatment plans with multiple future performance obligations, we also consider usage rates, which is the number of times a customer is expected to order additional aligners. Our process for estimating usage rates requires significant judgment and evaluation of inputs, including historical usage data by region, country and channel. We recognize the revenues upon shipment, as the customers obtain physical possession, and we have enforceable rights to payment. As we collect most consideration upfront, we consider whether a significant financing component exists; however, as the delivery of the performance obligations are at the customer's discretion, we conclude that no significant financing component exists.

Systems and Services

We sell intraoral scanners and CAD/CAM services through both our direct sales force and distribution partners. The intraoral scanner sales price includes one year of warranty and unlimited scanning services. The customer may also select, for additional fees, extended warranty and unlimited scanning services for periods beyond the initial year. When intraoral scanners are sold with an unlimited scanning service agreement and/or extended warranty, we allocate revenues based on the respective SSP of the scanner and the subscription service. We estimate the SSP of each element, taking into account factors such as same or similar historical prices and discounting strategies. Revenues are then recognized over time as the monthly services are rendered and upon shipment of the scanner, as that is when we deem the customer to have obtained control. CAD/CAM services, where sold separately, include the initial software license and maintenance and support. We allocate revenues based upon the respective SSPs of the software license and the maintenance and support. We estimate the SSP of each element using data such as historical prices. Revenues related to the software license are recognized upfront and revenues related to the maintenance and support are recognized over time. For both scanner and service sales, most consideration is collected upfront and in cases where there are payment plans, consideration is collected within one year and, therefore, there are no significant financing components.

Recent Accounting Pronouncements Not Yet Effective

We continue to monitor new accounting pronouncements issued by the Financial Accounting Standards Board and do not believe any of the recently issued accounting pronouncements will have a material impact on our consolidated financial statements or related disclosures.

Note 2. Financial Instruments

Cash, Cash Equivalents and Marketable Securities

The following tables summarize our cash and cash equivalents, and marketable securities on our Consolidated Balance Sheets as of June 30, 2022 and December 31, 2021 (in thousands):

					Reported as:		
June 30, 2022	**Amortized Cost**	**Gross Unrealized Gains**	**Gross Unrealized Losses**	**Fair Value**	**Cash and Cash Equivalents**	**Marketable securities, short-term**	**Marketable securities, long-term**
Cash	$ 758,365	$ —	$ —	$ 758,365	$ 758,365	$ —	$ —
Money market funds	119,148	—	(12)	119,136	119,136	—	—
Corporate bonds	70,808	—	(2,812)	67,996	—	8,488	59,508
U.S. government treasury bonds	18,609	—	(495)	18,114	—	6,490	11,624
Asset-backed securities	7,042	—	(59)	6,983	—	3,113	3,870
Municipal bonds	5,541	—	(100)	5,441	—	4,047	1,394
U.S. government agency bonds	1,201	—	(46)	1,155	—	—	1,155
Total	$ 980,714	$ —	$ (3,524)	$ 977,190	$ 877,501	$ 22,138	$ 77,551

					Reported as:		
December 31, 2021	**Amortized Cost**	**Gross Unrealized Gains**	**Gross Unrealized Losses**	**Fair Value**	**Cash and Cash Equivalents**	**Marketable securities, short-term**	**Marketable securities, long-term**
Cash	$ 754,802	$ —	$ —	$ 754,802	$ 754,802	$ —	$ —
Money market funds	343,012	—	(2)	343,010	343,010	—	—
Corporate bonds	115,507	9	(398)	115,118	1,042	35,065	79,011
U.S. government treasury bonds	42,976	—	(48)	42,928	—	22,251	20,677
Asset-backed securities	32,031	—	(40)	31,991	—	10,999	20,992
Municipal bonds	7,628	—	(15)	7,613	516	3,657	3,440
U.S. government agency bonds	1,201	—	(1)	1,200	—	—	1,200
Total	$ 1,297,157	$ 9	$ (504)	$ 1,296,662	$ 1,099,370	$ 71,972	$ 125,320

The following table summarizes the fair value of our available-for-sale marketable securities classified by contractual maturity as of June 30, 2022 and December 31, 2021 (in thousands):

	June 30, 2022	**December 31, 2021**
Due in 1 year or less	$ 17,185	$ 59,737
Due in 1 year through 5 years	82,504	139,113
Total	$ 99,689	$ 198,850

The securities that we invest in are generally deemed to be low risk based on their credit ratings from the major rating agencies. The longer the duration of these securities, the more susceptible they are to changes in market interest rates and bond yields. As interest rates increase, those securities purchased at a lower yield show a mark-to-market unrealized loss. Our unrealized losses as of June 30, 2022 and December 31, 2021 are primarily due to changes in interest rates and credit spreads.

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 as of June 30, 2022 and December 31, 2021 (in thousands):

Description	Balance as of June 30, 2022	Level 1	Level 2	Level 3
Cash equivalents:				
Money market funds	$ 119,136	$ 119,136	$ —	$ —
Short-term investments:				
U.S. government treasury bonds	6,490	6,490	—	—
Corporate bonds	8,488	—	8,488	—
Municipal bonds	4,047	—	4,047	—
Asset-backed securities	3,113	—	3,113	—
Long-term investments:				
U.S. government treasury bonds	11,624	11,624	—	—
Corporate bonds	59,508	—	59,508	—
Municipal bonds	1,394	—	1,394	—
U.S. government agency bonds	1,155	—	1,155	—
Asset-backed securities	3,870	—	3,870	—
Other assets:				
Investments in privately held companies	11,793	—	—	11,793
	$ 230,618	$ 137,250	$ 81,575	$ 11,793

Description	Balance as of December 31, 2021	Level 1	Level 2	Level 3
Cash equivalents:				
Money market funds	$ 343,010	$ 343,010	$ —	$ —
Corporate bonds	1,042	—	1,042	—
Municipal bonds	516	—	516	—
Short-term investments:				
U.S. government treasury bonds	22,251	22,251	—	—
Corporate bonds	35,065	—	35,065	—
Municipal bonds	3,657	—	3,657	—
Asset-backed securities	10,999	—	10,999	—
Long-term investments:				
U.S. government treasury bonds	20,677	20,677	—	—
Corporate bonds	79,011	—	79,011	—
Municipal bonds	3,440	—	3,440	—
U.S. government agency bonds	1,200	—	1,200	—
Asset-backed securities	20,992	—	20,992	—
Prepaid expenses and other current assets:				
Israeli funds	3,841	—	3,841	—
Other assets:				
Investments in privately held companies	8,621	—	—	8,621
	$ 554,322	$ 385,938	$ 159,763	$ 8,621

Derivatives Not Designated as Hedging Instruments

We enter into foreign currency forward contracts to minimize the short-term impact of foreign currency exchange rate fluctuations on certain trade and intercompany receivables and payables. These forward contracts are classified within Level 2 of the fair value hierarchy. As a result of the settlement of foreign currency forward contracts, during the three months ended June 30, 2022 and 2021, we recognized a net gain of $10.8 million and a net loss of $13.0 million, respectively, and during the six months ended June 30, 2022 we recognized a net gain of $9.2 million. The net loss recognized during the six months ended June 30, 2021 was not material. As of June 30, 2022 and December 31, 2021, the fair value of foreign exchange forward contracts outstanding was not material.

The following tables present the gross notional value of all our foreign exchange forward contracts outstanding as of June 30, 2022 and December 31, 2021 (in thousands):

	June 30, 2022	
	Local Currency Amount	Notional Contract Amount (USD)
Euro	€147,830	$ 154,164
Chinese Yuan	¥719,300	107,297
Polish Zloty	PLN351,500	77,556
Canadian Dollar	C$95,200	73,748
Brazilian Real	R$317,000	59,913
Japanese Yen	¥6,081,000	44,744
British Pound	£34,097	41,333
Swiss Franc	CHF22,500	23,536
Mexican Peso	M$282,700	13,988
Israeli Shekel	ILS43,160	12,380
Australian Dollar	A$4,600	3,170
		$ 611,829

	December 31, 2021	
	Local Currency Amount	Notional Contract Amount (USD)
Euro	€165,110	$ 186,358
Canadian Dollar	C$99,800	78,018
Chinese Yuan	¥494,500	77,358
Polish Zloty	PLN219,800	54,014
Brazilian Real	R$286,500	50,894
Japanese Yen	¥5,548,700	48,206
British Pound	£34,740	46,881
Israeli Shekel	ILS54,110	17,416
Mexican Peso	M$311,500	15,133
Swiss Franc	CHF9,950	10,883
Australian Dollar	A$6,900	5,009
		$ 590,170

Note 3. Balance Sheet Components

Inventories consist of the following (in thousands):

	June 30, 2022	December 31, 2021
Raw materials	$ 159,037	$ 123,234
Work in process	82,292	51,706
Finished goods	68,717	55,290
Total inventories	$ 310,046	$ 230,230

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

	June 30, 2022	December 31, 2021
Value added tax receivables	$ 110,988	$ 93,610
Prepaid expenses	61,628	70,218
Other current assets	62,649	31,477
Total prepaid expenses and other current assets	$ 235,265	$ 195,305

Accrued liabilities consist of the following (in thousands):

	June 30, 2022	December 31, 2021
Accrued payroll and benefits	$ 152,849	$ 288,355
Accrued expenses	74,281	67,169
Accrued sales and marketing expenses	37,250	41,387
Accrued property, plant and equipment	35,563	46,561
Current operating lease liabilities	24,613	22,719
Accrued professional fees	18,433	31,457
Other accrued liabilities	73,470	109,667
Total accrued liabilities	$ 416,459	$ 607,315

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

	Six Months Ended June 30,	
	2022	2021
Balance at beginning of period	$ 16,169	$ 12,615
Charged to cost of net revenues	7,660	8,936
Actual warranty expenditures	(7,334)	(7,105)
Balance at end of period	$ 16,495	$ 14,446

Deferred revenues consist of the following (in thousands):

	June 30, 2022	December 31, 2021
Deferred revenues - current	$ 1,242,348	$ 1,152,870
Deferred revenues - long-term [1]	$ 155,510	$ 136,684

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

During the three months ended June 30, 2022 and 2021, we recognized $969.6 million and $1,010.8 million of net revenues, respectively, of which $178.4 million and $134.4 million was included in the deferred revenues balance at December 31, 2021 and 2020, respectively.

During the six months ended June 30, 2022 and 2021, we recognized $1,942.8 million and $1,905.6 million of net revenues, respectively, of which $363.3 million and $260.2 million was included in the deferred revenues balance at December 31, 2021 and 2020, respectively.

Our unfulfilled performance obligations, including deferred revenues and backlog, as of June 30, 2022 were $1,409.4 million. These performance obligations are expected to be fulfilled over six months to five years.

Note 4. Goodwill and Intangible Assets

Goodwill

The change in the carrying value of goodwill for the six months ended June 30, 2022, categorized by reportable segments, is as follows (in thousands):

	Clear Aligner	Systems and Services	Total
Balance as of December 31, 2021	$ 112,208	$ 306,339	$ 418,547
Foreign currency translation adjustments	(3,804)	(24,643)	(28,447)
Balance as of June 30, 2022	$ 108,404	$ 281,696	$ 390,100

Intangible Long-Lived Assets

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

	Weighted Average Amortization Period (in years)	Gross Carrying Amount as of June 30, 2022	Accumulated Amortization	Accumulated Impairment Loss	Net Carrying Value as of June 30, 2022
Existing technology	10	$ 104,531	$ (27,640)	$ (4,328)	$ 72,563
Customer relationships	10	21,500	(4,838)	—	16,662
Trademarks and tradenames	10	17,200	(5,466)	(4,179)	7,555
Patents	8	6,511	(4,891)	—	1,620
		$ 149,742	$ (42,835)	$ (8,507)	98,400
Foreign currency translation adjustments					(4,583)
Total intangible assets, net [1]					$ 93,817

[1] Also includes $33.5 million of fully amortized intangible assets related to customer relationships.

	Weighted Average Amortization Period (in years)	Gross Carrying Amount as of December 31, 2021	Accumulated Amortization	Accumulated Impairment Loss	Net Carrying Value as of December 31, 2021
Existing technology	10	$ 104,531	$ (22,495)	$ (4,328)	$ 77,708
Customer relationships	11	55,000	(25,891)	(10,751)	18,358
Trademarks and tradenames	10	17,200	(4,547)	(4,179)	8,474
Patents	8	6,511	(4,495)	—	2,016
		$ 183,242	$ (57,428)	$ (19,258)	106,556
Foreign currency translation adjustments					3,153
Total intangible assets, net					$ 109,709

The total estimated annual future amortization expense for these acquired intangible assets as of June 30, 2022 is as follows (in thousands):

Fiscal Year Ending December 31,	Amortization
Remainder of 2022	$ 7,536
2023	14,997
2024	13,831
2025	13,455
2026	12,849
Thereafter	35,732
Total	$ 98,400

Amortization expense for both the three months ended June 30, 2022 and 2021 was $3.9 million and amortization expense for the six months ended June 30, 2022 and 2021 was $8.2 million and $7.8 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”). 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 June 30, 2022, we had no outstanding borrowings under the 2020 Credit Facility and were in compliance with the conditions and performance requirements in all material respects.

Note 6. Legal Proceedings

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 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 was stayed until April 28, 2022. Defendants have not yet responded to the complaints.

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 was similarly stayed until April 28, 2022. Defendants have not yet responded to the complaint.

Align believes these claims are without merit. 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. The defendants-appellees filed their answering brief on November 22, 2021. The lead plaintiff-appellant’s reply brief was filed on January 12, 2022. Oral argument was held on March 10, 2022. On July 8, 2022, a panel of the Ninth Circuit affirmed the district court order dismissing the complaint. On July 21, 2022, plaintiff-appellant filed a petition for rehearing or hearing en banc, which is pending. 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 believes these claims are without merit. 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.

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 June 29, 2024. 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. Plaintiffs filed a second amended complaint on October 21, 2021. On March 2, 2022, Plaintiffs filed a third amended complaint. A jury trial is scheduled to begin in this matter on June 29, 2024. 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.

On August 27, 2020, Align initiated a confidential arbitration proceeding against SmileDirectClub LLC ("SDC") 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 SDC 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. On May 3, 2022, SDC filed an additional counterclaim alleging that Align breached the Supply Agreement. Align denies SDC's allegations in the counterclaims and will vigorously defend itself against them. The arbitration hearing on Align's claims and SDC's first counterclaim was held on July 18-27, 2022 in Chicago, Illinois. The arbitration hearing on SDC's second counterclaim is set for February 20-24, 2023.

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

Off-Balance Sheet Arrangements

As of June 30, 2022, 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 for the year ended December 31, 2021.

Indemnification Provisions

In the normal course of business to facilitate transactions in our services and products, we indemnify certain parties: customers, vendors, lessors, and other parties with respect to certain matters, including, but not limited to, services to be provided by us and intellectual property infringement claims made by third parties. In addition, we have entered into indemnification agreements with our directors and our executive officers that will require us, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. Several of these agreements limit the time within which an indemnification claim can be made and the amount of the claim.

It is not possible to make a reasonable estimate of the maximum potential amount under these indemnification agreements due to the unique facts and circumstances involved in each particular agreement. Additionally, we have a limited history of prior indemnification claims and the payments we have made under such agreements have not had a material adverse effect on our results of operations, cash flows or financial position. However, to the extent that valid indemnification claims arise in the future, future payments by us could be significant and could have a material adverse effect on our results of operations or cash flows in a particular period. As of June 30, 2022, we did not have any material indemnification claims that were probable or reasonably possible.

Note 8. Stockholders' Equity

As of June 30, 2022, the 2005 Incentive Plan, as amended, has a total reserve of 27,783,379 shares of which 3,744,033 shares are available for issuance.

Summary of Stock-Based Compensation Expense

The stock-based compensation related to our stock-based awards and employee stock purchase plan for the three and six months ended June 30, 2022 and 2021 is as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Cost of net revenues	$ 1,614	$ 1,418	$ 3,128	$ 2,724
Selling, general and administrative	26,491	23,058	51,216	44,902
Research and development	6,035	4,379	11,417	8,470
Total stock-based compensation	$ 34,140	$ 28,855	$ 65,761	$ 56,096

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 six months ended June 30, 2022 is as follows:

	Number of Shares Underlying RSUs (in thousands)	Weighted Average Grant Date Fair Value	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Unvested as of December 31, 2021	492	$ 369.17		
Granted	232	485.01		
Vested and released	(189)	333.28		
Forfeited	(22)	429.13		
Unvested as of June 30, 2022	513	$ 432.28	1.6	$ 121,475

As of June 30, 2022, we expect to recognize $174.7 million of total unamortized compensation costs, net of estimated forfeitures, related to RSUs over a weighted average period of 2.6 years.

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

We grant MSUs to members of senior management. 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.

The following table summarizes the MSU performance for the six months ended June 30, 2022:

	Number of Shares Underlying MSUs (in thousands)	Weighted Average Grant Date Fair Value	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Unvested as of December 31, 2021	174	$ 551.57		
Granted [1]	101	607.96		
Vested and released	(128)	396.10		
Forfeited	(3)	744.39		
Unvested as of June 30, 2022	144	$ 725.73	1.5	$ 34,097

[1] Includes MSUs vested during the period above 100% of the grant as actual shares released is based on Align's stock performance over the vesting period.

As of June 30, 2022, we expect to recognize $55.2 million of total unamortized compensation costs, net of estimated forfeitures, related to MSUs over a weighted average period of 1.5 years.

Employee Stock Purchase Plan

As of June 30, 2022, we have 2,156,295 shares available for future issuance under our Amended and Restated 2010 Employee Stock Purchase Plan (the "2010 Purchase Plan").

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

	Six Months Ended June 30,	
	2022	2021
Expected term (in years)	1.5	1.0
Expected volatility	48.6 %	58.8 %
Risk-free interest rate	1.0 %	0.1 %
Expected dividends	—	—
Weighted average fair value at grant date	$ 196.97	$ 202.74

As of June 30, 2022, we expect to recognize $14.3 million of total unamortized compensation costs related to future employee stock purchases over a weighted average period of 0.8 year.

Note 9. Common Stock Repurchase Program

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 December 31, 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 June 30, 2022, we have $449.9 million available for repurchases under the May 2021 Repurchase Program.

Accelerated Share Repurchase Agreements (“ASRs”)

During the six months ended June 30, 2022 and 2021, we entered into 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 following table summarizes the information regarding repurchases of our common stock under ASRs:

Agreement Date	Repurchase Program	Amount Paid (in millions)	Completion Date	Total Shares Received	Average Price per Share
Q2 2021	May 2018	$ 100.0	Q3 2021	171,322	$ 583.70
Q2 2021	May 2021	$ 100.0	Q3 2021	161,707	$ 618.40
Q2 2022	May 2021	$ 200.0	Q2 2022	756,502	$ 264.37

Open Market Common Stock Repurchases

During the six months ended June 30, 2022, we repurchased on the open market approximately 0.1 million shares of our common stock at an average price of $522.61 per share, including commissions and fees, for an aggregate purchase price of $75.0 million.

Note 10. Accounting for Income Taxes

Our provision for income taxes was $60.8 million and $69.1 million for the three months ended June 30, 2022 and 2021, respectively, representing effective tax rates of 35.0% and 25.7%, respectively. Our provision for income taxes was $114.0 million and $130.3 million for the six months ended June 30, 2022 and 2021, respectively, representing effective tax rates of 31.6% and 24.6%, respectively. Our effective tax rate differs from the statutory federal income tax rate of 21% for the three and six months ended June 30, 2022 and 2021 primarily due to the recognition of additional tax expense resulting from 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. Additionally, a change in U.S. tax laws effective January 1, 2022 which requires capitalization and amortization of research and development expenses incurred after December 31, 2021 has increased our effective tax rate for the three and six months ended June 30, 2022.

We exercise significant judgment in regards to estimates of future market growth, forecasted earnings and projected taxable income in determining the provision for income taxes and for purposes of assessing our ability to utilize any future benefit from deferred tax assets. We continue to assess the realizability of the deferred tax assets as we take into account new information.

We file U.S. federal, U.S. state, and non-U.S. income tax returns. Our major tax jurisdictions include U.S. federal, the State of California and Switzerland. For U.S. federal and state tax returns, we are no longer subject to tax examinations for years before 2018 and 2017, respectively. Our Israeli subsidiary is under tax audit for years 2016 through 2019. During the fourth quarter of 2021, the Israel Tax Authority issued a tax assessment in connection with a 2016 transaction to which our Israeli subsidiary was a party. We filed an administrative appeal challenging the assessment during the first quarter of 2022 and, by doing so, proceeded to the next administrative stage of the audit. We will continue to vigorously defend our Israeli subsidiary’s tax return position. Based on our assessment of the information currently available, we have not derecognized or remeasured our tax positions with respect to this matter during the six months ended June 30, 2022. With few exceptions, we are no longer subject to examination by foreign tax authorities for years before 2015.

Our total gross unrecognized tax benefits, excluding interest and penalties, were $73.2 million and $63.3 million as of June 30, 2022 and December 31, 2021, respectively, a material amount of which would impact our effective tax rate if recognized. We have elected to recognize interest and penalties related to unrecognized tax benefits as a component of income taxes. Total interest and penalties accrued as of June 30, 2022 was not material. While we defend income tax audits in various jurisdictions and the results of such audits may differ materially from the amounts accrued for each year, we cannot currently ascertain the bases on which any given audit will be ultimately resolved. Accordingly, we are unable to estimate the range of possible adjustments to our balance of gross unrecognized tax benefits in the next 12 months.

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):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Numerator:				
Net income	$ 112,800	$ 199,714	$ 247,098	$ 400,090
Denominator:				
Weighted average common shares outstanding, basic	78,395	79,008	78,568	79,004
Dilutive effect of potential common stock	150	630	272	733
Total shares, diluted	78,545	79,638	78,840	79,737
Net income per share, basic	$ 1.44	$ 2.53	$ 3.15	$ 5.06
Net income per share, diluted	$ 1.44	$ 2.51	$ 3.13	$ 5.02
Anti-dilutive potential common shares [1]	361	49	314	38

[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):

	Six Months Ended June 30,	
	2022	2021
Non-cash investing and financing activities:		
Acquisition of property, plant and equipment in accounts payable and accrued liabilities	$ 60,115	$ 133,530
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	$ 15,048	$ 14,030
Right-of-use assets obtained in exchange for lease obligations:		
Operating leases	$ 16,351	$ 24,338

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.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Net revenues				
Clear Aligner	$ 798,398	$ 840,959	$ 1,608,094	$ 1,594,228
Systems and Services	171,155	169,849	334,678	311,351
Total net revenues	$ 969,553	$ 1,010,808	$ 1,942,772	$ 1,905,579
Gross profit				
Clear Aligner	$ 585,245	$ 646,665	$ 1,190,941	$ 1,231,199
Systems and Services	102,314	111,873	205,964	204,437
Total gross profit	$ 687,559	$ 758,538	$ 1,396,905	$ 1,435,636
Income from operations				
Clear Aligner	$ 307,209	$ 347,626	$ 619,928	$ 675,091
Systems and Services	45,599	64,675	96,398	111,903
Unallocated corporate expenses	(164,612)	(143,399)	(330,048)	(292,646)
Total income from operations	$ 188,196	$ 268,902	$ 386,278	$ 494,348
Stock-based compensation				
Clear Aligner	$ 3,001	$ 2,632	$ 5,855	$ 4,926
Systems and Services	236	174	450	345
Unallocated corporate expenses	30,903	26,049	59,456	50,825
Total stock-based compensation	$ 34,140	$ 28,855	$ 65,761	$ 56,096
Depreciation and amortization				
Clear Aligner	$ 14,029	$ 12,170	$ 27,796	$ 23,290
Systems and Services	6,776	4,622	13,698	9,167
Unallocated corporate expenses	9,476	9,100	18,413	19,070
Total depreciation and amortization	$ 30,281	$ 25,892	$ 59,907	$ 51,527

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Total segment income from operations	$ 352,808	$ 412,301	$ 716,326	$ 786,994
Unallocated corporate expenses	(164,612)	(143,399)	(330,048)	(292,646)
Total income from operations	188,196	268,902	386,278	494,348
Interest income	245	383	922	2,026
Other income (expense), net	(14,832)	(483)	(26,105)	34,049
Net income before provision for income taxes	$ 173,609	$ 268,802	$ 361,095	$ 530,423

Geographical Information

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

	Three Months Ended June 30, 2022	Three Months Ended June 30, 2021	Six Months Ended June 30, 2022	Six Months Ended June 30, 2021
Net revenues [1]:				
U.S.	$ 430,053	$ 434,398	$ 850,973	$ 817,400
Switzerland	330,351	366,334	662,090	681,784
Other International	209,149	210,076	429,709	406,395
Total net revenues	$ 969,553	$ 1,010,808	$ 1,942,772	$ 1,905,579

[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):

	June 30, 2022	December 31, 2021
Long-lived assets [1]:		
Switzerland	$ 499,626	$ 444,205
U.S.	212,071	210,582
China	123,180	125,346
Other International	465,479	423,050
Total long-lived assets	$ 1,300,356	$ 1,203,183

[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 and expectations regarding macroeconomic conditions, including inflation, fluctuations in currency exchange rates, consumer confidence and demand, weakness in general economic conditions and recessions, our expectations regarding the near and long-term implications of the COVID-19 pandemic on the global and regional economies, our expectations regarding the impact of the military conflict in Ukraine generally and specifically regarding our operations and assets in Russia, including the potential ramifications of sanctions and regarding relations with other countries and impact on our workforce located in Russia, our marketing and efforts to build our brand awareness, 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 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, 2021 as filed with the Securities and Exchange Commission (the "SEC").

Executive Overview of Results

Trends and Uncertainties

Our business strategic priorities remain focused on four principal pillars of growth: (i) international expansion; (ii) general practitioner dentists ("GPs") adoption; (iii) patient demand and conversion; and (iv) orthodontic utilization. Below is a discussion of the significant trends and uncertainties that could impact to our operations:

Macroeconomic Challenges and Military Conflict in Ukraine

Our revenues and costs are susceptible to fluctuations in macroeconomic conditions, in line with inflation and slowing global and regional economic activity and contractions, changes in customer and consumer sentiment and demand, seasonality, increasing prices for commodities, services and transportation and disruptions in our manufacturing, supply and distribution operations and also those of our suppliers. These factors can be further exacerbated by the anticipation of, or actual, global and regional economic recessions which compound the impacts of existing macroeconomic challenges. Moreover, many of our international operations are denominated in currencies other than the U.S. dollar and the weakening of the foreign currencies against the U.S. dollar has caused a negative impact on our financial condition and results of operations which we expect to continue into the future. Specifically, during the first half of 2022, primarily due to the military conflict between Russia and Ukraine and the significant sanctions that followed, Russia's currency, the ruble, weakened against the U.S. dollar. The nature and extent of the impact of these factors varies by time and region and remain uncertain and unpredictable.

The military conflict between Russia and Ukraine has increased the unpredictability of the already uncertain macroeconomic conditions. We remain deeply concerned about the devastating events that have and continue to unfold in Ukraine and the significant humanitarian, economic and societal tragedy unfolding there. Our top priority remains the safety and security of our employees and their families, particularly those most directly impacted by the hostilities and the resulting sanctions and retaliatory sanctions. We continue to employ a significant number of research and development personnel in Russia as well as sales, marketing and administrative personnel. We do not have employees in Ukraine. We have taken extraordinary efforts to support our team members in the region, including helping them financially and working to maintain their safety and security. We furthermore accelerated programs underway before the conflict began aimed at maintaining and growing our research and development operations over the long run that includes diversifying the facilities at which our personnel are located. Our Board of Directors and its applicable committees receive regular updates from management and have and continue to provide oversight of the risks associated with the military conflict between Russia and Ukraine and other areas of strategic importance related to the conflict. Our management continues to closely monitor the situation and evaluate additional ways in which we can support our employees.

Although immaterial to our consolidated financial statements, our commercial business operations in Russia have been significantly impacted by the conflict. In February 2022, after the military conflict commenced, our primary shipping vendor, UPS, ceased deliveries into Russia and shortly thereafter, we suspended all commercial activities. Our current focus is on providing continuity of care consistent with our values and ethical responsibility to patients, who are in treatment. In doing so, we are also focused on managing compliance with global sanctions applicable to our business, including significant restrictions imposed by countries on both sides of the conflict targeting business entities, persons and certain activities. The pace at which sanctions are being imposed and the expanding number and breadth of the sanctions enacted continue to create global and regional economic challenges that have caused and are expected to continue to cause significant uncertainty and unpredictability to our operations.

COVID-19 Pandemic Update

The COVID-19 pandemic continues to cause significant volatility and uncertainty in the global and regional economies, leading to changes in consumer and business behavior, market fluctuations, materials and product shortages and restrictions on business and individual activities, all of which are materially impacting supply and demand in broad sectors of the world markets. As new variants of the virus emerge, there has been a patchwork response to prevent its spread and, consequently, continuing fluctuations in the numbers of patients seeking treatment for dental services and the number of doctors providing services and treatments in other markets. The emergence of new variants, vaccinations and public health measures are driving the pace of economic recovery unevenly in various regions. These factors and ongoing consumer concerns regarding the virus have continued to impact our results of operations, sometimes materially, and may continue to impact our results in future periods. Therefore, comparing our financial results for the reporting periods of 2022 to the same reporting periods of 2021 or earlier may not be a useful means by which to evaluate the health of our business and our results of operations.

Our top priority remains the health and safety of our employees and their families, our customers and their staff, and we are taking prudent measures to safeguard them while remaining flexible in our operational efforts. Concerns regarding the spread and impact of the virus have lessened in many countries in which we operate, including the U.S. Consequently, efforts to reopen many of our offices in 2022 are continuing but remain in fluctuation as certain parts of the world at certain periods of time continue to respond to outbreaks of COVID-19 and new variants of the virus. Where our offices have reopened, we have adopted a flexible hybrid schedule that will allow many of our employees the opportunity to collaborate and connect with others in our offices three days per week while having the option to work remotely other days. We believe that this added flexibility benefits employees and Align overall.

Overall, we expect the challenges and risks discussed above to persist, creating uncertainty and unpredictability for consumers, global and regional economies as well as our business and the businesses of our customers and suppliers. We strive to manage the challenges by focusing on improving our operations, building flexibility and efficiencies in our processes, and adjusting our business models to changing circumstances. Specifically, we are managing cost impacts through pricing actions, implementing cost saving measures, and averting supply chain shortages and delays. We do this by proactively communicating with our suppliers and distributors and modifying our purchase order commitments to mitigate the risks of production interruptions and maintaining inventory levels as required. We have also increased our cybersecurity measures to detect, protect against potential incidents and recover from actual incidents and events.

Further discussion of the impact of the unpredictable macroeconomic conditions, the military conflict in Ukraine, and the ramifications from the impacts of COVID-19 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

We measure our performance against these strategic priorities by the achievement of key financial and operating metrics.

For the three months ended June 30, 2022, our business operations reflect the following:

- Revenues of $969.6 million, a decrease of 4.1% year-over-year;
- Clear Aligner revenues of $798.4 million, a decrease of 5.1% year-over-year;
  - Americas Clear Aligner revenues of $385.2 million, a decrease of 3.8% year-over-year;
  - International Clear Aligner revenues of $346.2 million, a decrease of 11.2% year-over-year;
  - Clear Aligner case volume decrease of 10.0% year-over-year and Clear Aligner case volume decrease for teenage patients of 2.1% year-over-year;
- Imaging Systems and CAD/CAM Services revenues of $171.2 million, an increase of 0.8% year-over-year;
- Income from operations of $188.2 million and operating margin of 19.4%;
- Effective tax rate of 35.0%;
- Net income of $112.8 million with diluted net income per share of $1.44;
- Cash, cash equivalents and marketable securities of $977.2 million as of June 30, 2022;
- Operating cash flow of $127.0 million;
- Capital expenditures of $76.0 million, predominantly related to increases in our manufacturing capacity and facilities; and
- Number of employees was 24,020 as of June 30, 2022, an increase of 17.8% year-over-year.

Other Statistical Data and Trends

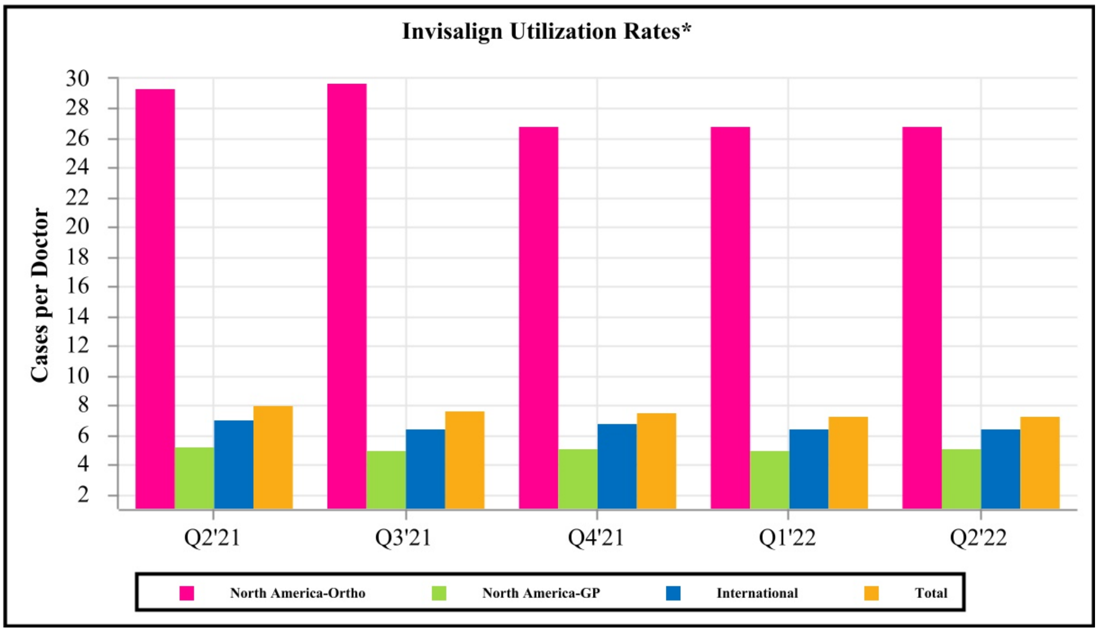
- As of June 30, 2022, approximately 13.4 million people worldwide have been treated with our Invisalign system, approximately 77,000 iTero scanners have been sold and approximately 51,000 exocad software licenses have been installed. Management measures these results by comparing to the millions of people who can benefit from straighter teeth and dental practices that could use intraoral scanners and uses this data to target opportunities to expand the market for orthodontics by educating consumers about the benefits of straighter teeth using the Invisalign system, dental professionals and/or labs and service providers to use iTero intraoral scanners, and dental labs and practitioners to install exocad CAD/CAM software.

- For the second quarter of 2022, total Invisalign cases submitted with a digital scanner in the Americas increased to 91.4%, up from 86.6% in the second quarter of 2021 and international scans increased to 84.4%, up from 76.2% in the second quarter of 2021. For the second quarter of 2022, 97.1% of Invisalign cases submitted by North American orthodontists were submitted digitally.

- Total utilization rate in the second quarter of 2022 decreased to 7.3 cases per doctor compared to 8.0 cases per doctor in the second quarter of 2021. Utilization rates in North America and our International locations were as follows:

  - *North America:* Utilization rate among our North American orthodontist customers decreased to 26.8 cases per doctor in the second quarter of 2022 compared to 29.4 cases per doctor in the second quarter of 2021 and the utilization rate among our North American GP customers decreased to 5.1 cases per doctor in the second quarter of 2022 compared to 5.3 cases per doctor in the second quarter of 2021.

  - *International:* International doctor utilization rate was 6.4 cases per doctor in the second quarter of 2022 compared to 7.1 cases per doctor in the second quarter of 2021.



* 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.

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 and Invisalign Go Plus.
  - Non-Case products include, but are not limited to, retention products, Invisalign training, adjusting tools used by dental professionals during the course of treatment and, more recently, Consumer Products that are complementary to our doctor-prescribed principal products such as aligner cases (clamshells), teeth whitening products, cleaning solutions (crystals, foam and other material) and other oral health products available in certain e-commerce channels in select markets. We also offer in the U.S. and Canada, a Doctor Subscription Program which is a monthly subscription program based on the doctor's monthly need for retention or limited treatment. The program allows doctors the flexibility to order both "touch-up" or retention aligners within their subscribed tier and is designed for a segment of experienced Invisalign doctors who are currently not regularly using our retainers or low-stage aligners.
- Our Systems and Services segment consists of our iTero intraoral scanning systems, which includes a single hardware platform and restorative or orthodontic software options. Our services include subscription software, disposables, rentals, pay per scan services, as well as exocad's CAD/CAM software solutions that integrate workflows to dental labs and dental practices.

Net revenues for our Clear Aligner and Systems and Services segments by region for the three and six months ended June 30, 2022 and 2021 are as follows (in millions):

	Three Months Ended June 30,				Six Months Ended June 30,			
Net Revenues	2022	2021	Change		2022	2021	Change	
Clear Aligner net revenues:								
Americas	$ 385.2	$ 400.5	$ (15.3)	(3.8)%	$ 761.4	$ 757.9	$ 3.5	0.5 %
International	346.2	389.7	(43.5)	(11.2)%	717.3	743.0	(25.7)	(3.5)%
Non-case	67.0	50.8	16.2	31.9 %	129.4	93.3	36.1	38.7 %
Total Clear Aligner net revenues	$ 798.4	$ 841.0	$ (42.6)	(5.1)%	$ 1,608.1	$ 1,594.2	$ 13.9	0.9 %
Systems and Services net revenues	171.2	169.8	1.3	0.8 %	334.7	311.4	23.3	7.5 %
Total net revenues	$ 969.6	$ 1,010.8	$ (41.3)	(4.1)%	$ 1,942.8	$ 1,905.6	$ 37.2	2.0 %

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

Case volume data which represents Clear Aligner case shipments for the three and six months ended June 30, 2022 and 2021 is as follows (in thousands):

	Three Months Ended June 30,				Six Months Ended June 30,			
	2022	2021	Change		2022	2021	Change	
Total case volume	599.0	665.6	(66.6)	(10.0)%	1,197.8	1,261.4	(63.6)	(5.0)%

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

For the three months ended June 30, 2022, total net revenues decreased $41.3 million as compared to the same period in 2021 primarily due to a decrease in Clear Aligner case volume partially offset by increases in Clear Aligner ASP, Clear Aligner non-case revenues and service revenues.

For the six months ended June 30, 2022, total net revenues increased $37.2 million as compared to the same period in 2021 primarily due to increases in Clear Aligner ASP, Clear Aligner non-case revenues and service revenues partially offset by a decrease in Clear Aligner case volume.

Clear Aligner - Americas

For the three months ended June 30, 2022, Americas net revenues decreased by $15.3 million as compared to the same period in 2021 primarily due to a 9.9% decrease in case volume which reduced net revenues by $39.7 million which was partially offset by an increase in ASP which increased net revenues by $24.4 million. Higher ASP was mainly due to processing fees charged on most clear aligner shipments and price increases in certain markets which increased revenues by $12.7 million along with lower net deferrals which increased net revenues by $11.4 million.

For the six months ended June 30, 2022, Americas net revenues increased by $3.5 million as compared to the same period in 2021 primarily due to an increase in ASP which increased net revenues by $48.5 million. Higher ASP was mainly due to processing fees charged on most clear aligner shipments and price increases in certain markets which increased revenues by $25.5 million along with lower net deferrals which increased net revenues by $20.2 million. Higher ASP was partially offset by a 5.9% decrease in case volume which reduced net revenues by $45.0 million.

Clear Aligner - International

For the three months ended June 30, 2022, International net revenues decreased by $43.5 million as compared to the same period in 2021 primarily due to a 10.1% decrease in case volume which reduced net revenues by $39.5 million. Lower ASP also decreased net revenues by $4.0 million largely due to unfavorable foreign exchange rates which decreased net revenues by $33.4 million and a product mix shift to lower priced products which decreased net revenues by $10.0 million. The decrease in ASP was partially offset by lower net deferrals which increased net revenues by $29.2 million and processing fees charged on most clear aligner shipments which increased net revenues by $12.1 million.

For the six months ended June 30, 2022, International net revenues decreased by $25.7 million as compared to the same period in 2021 primarily due to a 3.9% decrease in case volume which resulted in lower net revenues of $29.3 million. Higher

ASP increased net revenues by $3.6 million largely due to lower net deferrals which increased net revenues by $47.4 million and processing fees charged on most clear aligner shipments which increased net revenues by $36.9 million. The increase in ASP was mostly offset by unfavorable foreign exchange rates which decreased net revenues by $56.3 million, unfavorable promotional discounts which decreased net revenues $14.6 million, and a product mix shift to lower priced products which decreased net revenues by $11.5 million.

Clear Aligner - Non-Case

For the three and six months ended June 30, 2022, non-case net revenues increased by $16.2 million and $36.1 million as compared to the same periods in 2021 due to increased volume for retention products across all regions primarily driven by Vivera retainers.

Systems and Services

For the three months ended June 30, 2022, Systems and Services net revenues increased by $1.3 million as compared to the same period in 2021 primarily due to higher service and other revenues which increased $18.7 million mostly due to a larger installed base. These increases were mostly offset by a lower number of scanners sold which decreased net revenues $13.1 million in addition to a lower scanner ASP.

For the six months ended June 30, 2022, Systems and Services net revenues increased by $23.3 million as compared to the same period in 2021 primarily due to higher service and other revenues which increased $36.4 million mostly due to a larger installed base partially offset by a lower number of scanners sold which decreased net revenues by $9.5 million and lower scanner ASP.

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

	Three Months Ended June 30,			Six Months Ended June 30,		
	2022	2021	Change	2022	2021	Change
Clear Aligner						
Cost of net revenues	$ 213.2	$ 194.3	$ 18.9	$ 417.2	$ 363.0	$ 54.1
% of net segment revenues	*26.7 %*	*23.1 %*		*25.9 %*	*22.8 %*	
Gross profit	$ 585.2	$ 646.7	$ (61.4)	$ 1,190.9	$ 1,231.2	$ (40.3)
Gross margin %	*73.3 %*	*76.9 %*		*74.1 %*	*77.2 %*	
Systems and Services						
Cost of net revenues	$ 68.8	$ 58.0	$ 10.9	$ 128.7	$ 106.9	$ 21.8
% of net segment revenues	*40.2 %*	*34.1 %*		*38.5 %*	*34.3 %*	
Gross profit	$ 102.3	$ 111.9	$ (9.6)	$ 206.0	$ 204.4	$ 1.5
Gross margin %	*59.8 %*	*65.9 %*		*61.5 %*	*65.7 %*	
Total cost of net revenues	$ 282.0	$ 252.3	$ 29.7	$ 545.9	$ 469.9	$ 75.9
% of net revenues	*29.1 %*	*25.0 %*		*28.1 %*	*24.7 %*	
Gross profit	$ 687.6	$ 758.5	$ (71.0)	$ 1,396.9	$ 1,435.6	$ (38.7)
Gross margin %	*70.9 %*	*75.0 %*		*71.9 %*	*75.3 %*	

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, freight and shipping related costs, depreciation on capital equipment and facilities used in the production process, amortization of acquired intangible assets and training costs.

Clear Aligner

For the three and six months ended June 30, 2022, our gross margin percentage decreased as compared to the same periods in 2021 primarily due to a higher mix of additional aligners along with increased costs from freight and manufacturing spend. These factors were offset in part by higher ASP.

Systems and Services

For the three and six months ended June 30, 2022, our gross margin percentage decreased as compared to the same period in 2021 primarily due to lower ASP, manufacturing inefficiencies from lower production volumes and higher component costs partially offset by higher service revenues.

Selling, general and administrative (in millions):

	Three Months Ended June 30,			Six Months Ended June 30,		
	2022	2021	Change	2022	2021	Change
Selling, general and administrative	$ 426.4	$ 431.9	$ (5.5)	$ 865.9	$ 829.0	$ 36.8
% of net revenues	*44.0 %*	*42.7 %*		*44.6 %*	*43.5 %*	

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, market research, 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 June 30, 2022, selling, general and administrative expense decreased compared to the same period in 2021 primarily due to lower advertising and marketing costs, and lower incentive compensation. These decreases were partially offset by higher salaries expense, fringe benefits and stock-based compensation from increased headcount along with higher equipment, software and material costs.

For the six months ended June 30, 2022, selling, general and administrative expense increased compared to the same period in 2021 primarily due to higher salaries expense, fringe benefits and stock-based compensation from increased headcount, higher expense related to advertising and marketing, equipment, software and maintenance in addition to increased travel and expense related costs. These increases were partially offset by lower incentive compensation.

Research and development (in millions):

	Three Months Ended June 30,			Six Months Ended June 30,		
	2022	2021	Change	2022	2021	Change
Research and development	$ 73.0	$ 57.7	$ 15.3	$ 144.8	$ 112.3	$ 32.5
% of net revenues	*7.5 %*	*5.7 %*		*7.5 %*	*5.9 %*	

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 six months ended June 30, 2022, research and development expense increased compared to the same periods in 2021 primarily due to higher compensation costs from higher salaries and fringe benefits driven mainly by increased headcount as we continue to focus our investments in innovation and research.

Income from operations (in millions):

	Three Months Ended June 30, 2022		Three Months Ended June 30, 2021		Change	Six Months Ended June 30, 2022		Six Months Ended June 30, 2021		Change
Clear Aligner										
Income from operations	$ 307.2		$ 347.6		$ (40.4)	$ 619.9		$ 675.1		$ (55.2)
Operating margin %	*38.5*	*%*	*41.3*	*%*		*38.6*	*%*	*42.3*	*%*	
Systems and Services										
Income from operations	$ 45.6		$ 64.7		$ (19.1)	$ 96.4		$ 111.9		$ (15.5)
Operating margin %	*26.6*	*%*	*38.1*	*%*		*28.8*	*%*	*35.9*	*%*	
Total income from operations [1]	$ 188.2		$ 268.9		$ (80.7)	$ 386.3		$ 494.3		$ (108.1)
Operating margin %	*19.4*	*%*	*26.6*	*%*		*19.9*	*%*	*25.9*	*%*	

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

[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.

Clear Aligner

For the three months ended June 30, 2022, our operating margin percentage decreased compared to the same period in 2021 primarily due to lower gross margin which was partially offset by lower operating expenses as a percentage of net revenues.

For the six months ended June 30, 2022, our operating margin percentage decreased compared to the same period in 2021 primarily due to lower gross margin as well as higher operating expenses as a percentage of net revenues.

Systems and Services

For the three and six months ended June 30, 2022, our operating margin percentage decreased compared to the same periods in 2021 primarily due to lower gross margin as well as higher operating expenses as a percentage of net revenues.

Interest income (in millions):

	Three Months Ended June 30, 2022		Three Months Ended June 30, 2021		Change	Six Months Ended June 30, 2022		Six Months Ended June 30, 2021		Change
Interest income	$ 0.2		$ 0.4		$ (0.1)	$ 0.9		$ 2.0		$ (1.1)
% of net revenues	*—*	*%*	*—*	*%*		*—*	*%*	*0.1*	*%*	

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 June 30, 2022, there was no significant change to interest income compared to the same period in 2021.

For the six months ended June 30, 2022, interest income decreased compared to the same period in 2021 mainly due to interest earned from the arbitration award related to our investment in SmileDirectClub in the first quarter of 2021.

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

	Three Months Ended June 30, 2022	Three Months Ended June 30, 2021	Change	Six Months Ended June 30, 2022	Six Months Ended June 30, 2021	Change
Other income (expense), net	$ (14.8)	$ (0.5)	$ (14.3)	$ (26.1)	$ 34.0	$ (60.2)
% of net revenues	*(1.5) %*	*— %*		*(1.3) %*	*1.8 %*	

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 June 30, 2022, other income (expense), net decreased compared to the same period in 2021 primarily due to larger net foreign exchange losses in the three months ended June 30, 2022 as compared to the same period in 2021.

For the six months ended June 30, 2022, other income (expense), net decreased compared to the same period in 2021 primarily due to a $43.4 million gain related to the arbitration award related to our investment in SmileDirectClub recognized in the first quarter of 2021 as well as larger net foreign exchange losses in the six months ended June 30, 2022 as compared to the same period in 2021.

Provision for income taxes (in millions):

	Three Months Ended June 30, 2022	Three Months Ended June 30, 2021	Change	Six Months Ended June 30, 2022	Six Months Ended June 30, 2021	Change
Provision for income taxes	$ 60.8	$ 69.1	$ (8.3)	$ 114.0	$ 130.3	$ (16.3)
Effective tax rates	*35.0 %*	*25.7 %*		*31.6 %*	*24.6 %*	

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 both the three and six months ended June 30, 2022 and 2021 primarily due to the recognition of additional tax expense resulting from 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. Additionally, a change in U.S. tax laws effective January 1, 2022 which requires capitalization and amortization of research and development expenses incurred after December 31, 2021 increased our effective tax rate for the three and six months ended June 30, 2022.

The increase in our effective tax rate for the three and six months ended June 30, 2022 compared to the same periods in 2021 is primarily attributable to foreign income taxed at different rates, capitalization and amortization of research and development expenses in 2022 and lower excess tax benefits from stock-based compensation.

Liquidity and Capital Resources

Liquidity and Trends

As of June 30, 2022 and December 31, 2021, we had the following cash and cash equivalents and short-term and long-term marketable securities (in thousands):

	June 30, 2022	December 31, 2021
Cash and cash equivalents	$ 877,501	$ 1,099,370
Marketable securities, short-term	22,138	71,972
Marketable securities, long-term	77,551	125,320
Total	$ 977,190	$ 1,296,662

As of June 30, 2022 and December 31, 2021, approximately $725.8 million and $713.8 million, respectively, of cash, cash equivalents and marketable securities held by our foreign subsidiaries. Our intent is to permanently reinvest our earnings from our international operations going forward, and our current plans do not require us to repatriate them to fund our U.S.

operations as we generate sufficient domestic operating cash flow and have access to external funding under our $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.

The sanctions against Russian banks or international bank messaging systems due to the military conflict between Ukraine and Russia could impact our ability to access our cash in Russia but would not materially impact our liquidity position. As of June 30, 2022, cash and cash equivalents domiciled in Russia represent approximately 7.0% of our total cash, cash equivalents and marketable securities which is required to fund their current operating requirements.

Our material cash requirements are as follows:

- For 2022, we expect our investments in capital expenditures to exceed $300.0 million. Capital expenditures primarily relate to building construction and improvements as well as additional manufacturing capacity to support our international expansion. This includes our investment in an aligner fabrication facility in Wroclaw, Poland which began serving doctors during the second quarter of 2022 as a part of our strategy to bring operational facilities closer to customers. As we continue growing, we intend to expand our investments in research and development, manufacturing, treatment planning, sales and marketing operations to meet actual and anticipated local and regional demands.

- As of June 30, 2022, we have $449.9 million available for repurchase under the stock repurchase program authorized by our Board of Directors in May 2021. Refer to *Note 9 "Common Stock Repurchase Program" of the Notes to Condensed Consolidated Financial Statements* for details on our stock repurchase programs.

- There have been no material changes to our purchase commitments for goods and services and future operating lease payments during the periods covered by this 10-Q outside the normal course of business compared to the disclosures in Part II, Item 7 of our Annual Report on Form 10-K for the year ended December 31, 2021.

Sources and Uses of Cash

The following table summarizes our condensed consolidated cash flows for the six months ended June 30, 2022 and 2021 (in thousands):

	Six Months Ended June 30,	
	2022	**2021**
Net cash flow provided by (used in):		
Operating activities	$ 157,543	$ 544,691
Investing activities	(72,078)	(123,920)
Financing activities	(312,396)	(291,756)
Effect of exchange rate changes on cash, cash equivalents, and restricted cash	4,978	(3,511)
Net (decrease) increase in cash, cash equivalents, and restricted cash	$ (221,953)	$ 125,504

Operating Activities

For the six months ended June 30, 2022, cash flows from operations of $157.5 million resulted primarily from our net income of approximately $247.1 million, as well as the following:

Significant adjustments to net income

- Stock-based compensation of $65.8 million related to equity awards granted to employees and directors;
- Depreciation and amortization of $59.9 million related to our investments in property, plant and equipment and intangible assets;
- Non-cash operating lease costs of $15.1 million; and
- Changes in deferred taxes of $14.7 million primarily related to amortization and adjustments to our deferred tax assets of our Swiss entity.

Significant changes in working capital

- Decrease of $212.9 million in accrued and other long-term liabilities primarily due to payment of our 2021 corporate bonus and the timing of payment of other activities;
- Increase of $136.0 million in deferred revenues due to the deferral of revenue on shipments over the period as well as timing of revenue recognition;
- Increase of $91.1 million in inventories primarily due to lower shipment volumes over the period in addition to higher safety stock requirements to secure materials with long lead times to support our demand; and
- Increase of $53.5 million in accounts receivable primarily related to timing of shipments and collections.

Investing Activities

Net cash used in investing activities was $72.1 million for the six months ended June 30, 2022 which primarily consisted of purchases of property, plant and equipment of $163.3 million and purchases of marketable securities of $20.5 million. These outflows were partially offset by sales and maturities of our marketable securities of $113.9 million.

Financing Activities

Net cash used in financing activities was $312.4 million for the six months ended June 30, 2022 which consisted of common stock repurchases of $275.0 million and payroll taxes paid for equity awards through share withholdings of $52.2 million which were partially offset by $14.8 million of proceeds from the issuance of common stock under our employee stock purchase plan.

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 acquired intangible assets, income taxes, legal proceedings and litigations. We use authoritative pronouncements, historical experience and other assumptions as the basis for making the estimates. Actual results could differ from those estimates.

Revenue Recognition

Our revenues are derived primarily from the sale of aligners, scanners, and services from our Clear Aligner and Systems and Services segments. We enter into sales contracts that may consist of multiple distinct performance obligations where certain performance obligations of the sales contract are not delivered in one reporting period. We measure and allocate revenues according to ASC 606-10, *“Revenues from Contracts with Customers.”*

Determining the standalone selling price (“SSP”) in order to allocate consideration from the contract to the individual performance obligations is the result of various factors, such as changing trends and market conditions, historical prices, costs, and gross margins. While changes in the allocation of the SSP between performance obligations will not affect the amount of total revenues recognized for a particular contract, any material changes could impact the timing of revenue recognition, which would have a material effect on our financial position and result of operations. This is because the contract consideration is allocated to each performance obligation, delivered or undelivered, at the inception of the contract based on the SSP of each distinct performance obligation.

We allocate revenues for each clear aligner treatment plan based on each unit’s SSP. Management considers a variety of factors such as same or similar product historical sales, costs, and gross margin, which may vary over time depending upon the unique facts and circumstances related to each performance obligation in making these estimates. In addition to historical data, we take into consideration changing trends and market conditions. For treatment plans with multiple future performance obligations, we also consider usage rates, which is the number of times a customer is expected to order more aligners after the initial shipment. Our process for estimating usage rates requires significant judgment and evaluation of inputs, including historical usage data by region, country and channel.

We estimate the SSP of each element in a scanner system and services sale taking into consideration same or similar product historical prices as well as our discounting strategies.

Recent Accounting Pronouncements

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

In the normal course of business, we are exposed to interest rate, foreign currency exchange and inflation risks that could impact our financial position and results of operations. In addition, we are subject to the broad market risk that is created by the global market disruptions and uncertainties resulting from macroeconomic challenges, the military conflict between Russia and Ukraine and the COVID-19 pandemic. Further discussion on these risks may be found in *Item 1A* of this is Quarterly Report on Form 10-Q under the heading *"Risk Factors."*

Interest Rate Risk

Changes in interest rates could impact our anticipated interest income on our cash equivalents and investments in marketable securities. Our investments are fixed-rate short-term and long-term securities. Fixed-rate securities may have their fair market value adversely impacted due to a rise in interest rates, and, as a result, our future investment income may fall short of expectations due to changes in interest rates or we may suffer losses in principal if forced to sell securities which have declined in market value due to changes in interest rates. As of June 30, 2022, we had approximately $99.7 million invested in available-for-sale marketable securities. An immediate 10% change in interest rates would not have a material adverse impact on our future operating results and cash flows.

We do not enter into investments for trading or speculative purposes and have not used any derivative financial instruments to manage our interest rate risk exposure. As of June 30, 2022, we are not subject to risks from immediate interest rate increases on our unsecured revolving line of credit facility.

Currency Rate Risk

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

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

Although we will continue to monitor our exposure to currency fluctuations, and, where appropriate, may use forward contracts to minimize the effect of these fluctuations, the impact of an aggregate change of 10% in foreign currency exchange rates relative to the U.S. dollar on our results of operations and financial position could be material.

Military Conflict in Ukraine

The U.S. and other nations have imposed sanctions on various sectors of the Russian economy and on transactions with certain Russian nationals and entities. Russia has also announced economic sanctions against the U.S. and other nations that include a ban on imports of certain products. As of June 30, 2022, we do not expect these events to have any material impact on our operations. Our Russia net revenues as a percentage of our consolidated net revenues and our assets domiciled in Russia, including cash and cash equivalents, as a percentage of our total assets are immaterial.

Inflation Risk

The economy has been impacted by certain macroeconomic challenges which have contributed to a rising inflationary trend that have impacted both our revenues and costs globally, and which we expect will continue into the foreseeable future. If our costs become subject to significant inflationary pressures, we may not be able to fully offset such higher costs through price increases. There can be no assurance that our results of operations and financial condition will not be materially impacted by inflation in the future.

Item 4. Controls and Procedures.

Evaluation of disclosure controls and procedures.

Under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, we have evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of the end of the period covered by this Quarterly Report on Form 10-Q. Based upon that evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that our disclosure controls and procedures are effective as of June 30, 2022, 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 June 30, 2022 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

- Inflation, fluctuations in currency exchange rates, consumer confidence and demand, weakness in general economic conditions and recessions could negatively affect our financial condition and results of operations.
- 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 as the virus evolves and circumstances dictate.

- The outbreak of military conflict between Russia and Ukraine has created a humanitarian crisis, materially impacted economic activities and may in the future materially impact our global and regional operations.
- 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 orthodontic appliances and solutions 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, military and other risks that may harm our business.
- Our success depends on our ability to develop, successfully introduce, achieve market acceptance of, and manage new products and services.
- 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 or fail 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.
- Demand for our products may not increase as rapidly as we anticipate or may decrease due to resistance to non-traditional treatment methods, which could have a material adverse impact on our business and operating results.
- 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.
- A disruption in the operations of a primary freight carrier, higher shipping costs or shipping delays could disrupt our supply chain and cause a decline in our net revenues or a reduction in our earnings.
- If we fail to accurately predict our volume growth, hire too many or too few technicians, or manufacture too many or too few products, the delivery time for 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 ("IP") 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 adversely impact 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.
- Obtaining approvals and complying with governmental regulations, particularly those related to personal healthcare information, financial information, quality systems, competition, anti-trust, data governance 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.
- 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 rely on highly skilled personnel and, if we fail to attract, motivate, train or retain highly skilled personnel, it may be more difficult to grow effectively and pursue our strategic priorities.
- 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, including the risk that these distributors do not comply with applicable laws or our internal procedures.
- 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.
- Increased focus on compliance with current or future ESG laws and increased scrutiny of our ESG policies and practices may materially increase our costs, expose us to potential liability, may adversely impact our reputation, employee retention, willingness of customers and suppliers to do business with us and willingness of investors to invest in us, and otherwise materially impact our business.

General Risk Factors

- We rely on our personnel and, if we fail to attract, motivate, train 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.
- If we fail to manage our exposure to global financial and securities market risks 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.
- New tax laws and practice, changes to existing tax laws and practice, or disputes regarding the positions we take regarding tax laws, could negatively affect our provision for income taxes as well as our ongoing operations.
- We have in the past and may again in the future invest in or acquire other businesses, products or technologies which may 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.

Risks Relating to our Business Operations and Strategy

Inflation, fluctuations in currency exchange rates, consumer confidence and demand, weakness in general economic conditions and recessions could negatively affect our financial condition and results of operations.

Our operations and financial performance are affected by general macroeconomic conditions, consumer confidence and discretionary spending. Consumer spending habits are affected by, among other things, inflation, weakness in general economic conditions, recessions, pandemics, wars and military actions, levels of employment, salaries and wage rates, debt obligations, discretionary income, interest rates, volatility in capital markets, 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 revenues and operating results. Conversely, to the extent social distancing, travel, work and other restrictions have limited options for consumer spending, demand for our products may decline once any or all of these restrictions ease. Inflation, weakness in the global or regional economies and recessions can decrease demand for dental technologies, causing dentists to postpone investments in capital equipment, such as intraoral scanners and CAD/CAM software. We observed increased inflation in 2021 that has continued in 2022 and we are unable to predict the impacts of higher inflation on global and regional economies. Higher inflation may also increase domestic and international shipping costs, raw material prices, and labor rates. Our ability to recover these cost increases through price increases may continue to lag, resulting in downward pressure on our operating results. Any attempts to offset cost increases with price increases may result in greater reductions in sales, increase customer dissatisfaction or otherwise harm our reputation. The continued increase in fuel prices could also have an effect on consumer spending and on our costs of producing, procuring and shipping our products. We are also unable to predict the impact of efforts by central banks to combat elevated levels of inflation. Increases in lending rates may reduce economic activity. If downward pressures continue due to these economic factors, this may lead to a recession. If a recession occurs, economies weaken, fuel prices continue to increase or inflationary trends continue, our business and operating results could be materially adversely affected.

Although the U.S. dollar is our reporting currency, a growing portion of our net revenues and net income are generated in foreign currencies. In our foreign subsidiaries where the local currency is the functional currency, our net revenues and net income are translated into U.S. dollars using the average period exchange rate which may fluctuate significantly. 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. For example, the recent substantial decline in the value of the Euro compared to the U.S. dollar has adversely impacted our operating results in Europe. 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 a material adverse effect on our financial condition.

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 as the virus evolves and circumstances dictate.

The broad and extensive impact of the COVID-19 pandemic on virtually all aspects of our business and society has exacerbated many 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 described in this risk factor in addition to, and not in lieu of, the risks described elsewhere throughout these risk factors.

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 mutated variants and outbreaks globally or regionally continue to harm recovering consumer confidence and have led to renewed implementation of harsh preventative measures by local and regional governments and businesses. Therefore, comparing our financial results for the reporting periods of 2022 to the same reporting periods of 2021 or earlier may not be a useful means by which to evaluate the health of our business and our results of operations.

As a result of outbreaks of COVID-19 and new variants of the virus such as Delta and Omicron, customer demand and doctor availability has been inconsistent and difficult to predict. Although the practices of the doctors, dental service organizations and labs that are our principal customers have largely reopened following the initial outbreak of COVID-19 in 2020, many continue to operate at less than pre-pandemic capacities. For example, in China the impact of widespread population lockdowns under the country’s zero tolerance policies has been more pronounced in the first half of 2022 than in prior periods, leading to the complete closure of dental offices in major metropolitan and other areas for extended periods of time. While the pandemic increased demand for digital solutions such as the products and solutions we offer for the dental field, it is unclear if this will continue. For instance, if the use of video conferencing declines when employees return to office environments or travel, dining, entertainment and other consumer spending categories rebound, demand or growth rates for our products may decline. These fluctuations are currently and have previously adversely impacted our results of operations from time to time and are expected to continue to impact our results, particularly in the near term.

In response to the pandemic, 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, and prohibiting non-essential travel. Many of these actions remain in effect to varying degrees and we may implement new or revise existing measures as circumstances require. The actions and reactions to voluntary and involuntary protective measures have been highly disruptive to our business and may continue to be disruptive.

The rules and regulations for reopening and operating our offices will likely increase in complexity, making compliance more difficult. Beginning and continuing in 2022, we are gradually reopening many of our offices. Where our offices have reopened, we have adopted a flexible hybrid schedule that will allow many of our employees the opportunity to collaborate and connect with others in our offices three days per week while having the option to work remotely other days. If employees perceive our approach to reopening our offices to be inadequate, overly burdensome, or prefer the safety or convenience of working from home, employees may choose to terminate their employment with us, productivity may decline or we may experience employee unrest, slowdowns, stoppages or other demands. Additionally, 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. For further discussion or the risks related to our hybrid schedule approach to reopening our offices, employee satisfaction, retention and engagement see the risk factor “*We rely on our 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.*”

As the economic and societal impact of the pandemic continues, we are continually evaluating macroeconomic as well as industry-specific factors, including the extent our business and financial results and the business and financial results of our customers’ and suppliers’ have been and in the future may be impacted. 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 as well as actions taken by central banks and governments, including in response to the growing impact of inflation, or the occurrence of regional or global recessions as a result of fiscal tightening or other factors;
- customer and consumer purchasing behavior changes as pandemic-related restrictions are curtailed, lifted or reinstated, and travel and discretionary spending patterns shift;
- the response of employees, customers and suppliers to the reimplementation or 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 of funds 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 capacity limits on the number of patients doctors can see in their offices;
- actions taken by competitors as a result of consumer demand or consumer spending pressures related to COVID-19, such as price reductions, aggressive product promotions, changes in or the launch or termination of products or product lines, and mergers, consolidations and liquidations;
- 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; and
- diversion of management's attention 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 future direct and ancillary impacts 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.

The outbreak of military conflict between Russia and Ukraine has created a humanitarian crisis, materially impacted economic activities, and may in the future materially impact our global and regional operations.

The global economy has been negatively impacted by the military conflict between Russia and Ukraine. Governments including the U.S., United Kingdom, and those of the European Union have imposed export controls on certain products and financial and economic sanctions on certain industry sectors and parties in Russia which has triggered retaliatory sanctions by the Russian government and its allies that have materially impacted business inside Russia. Although immaterial to our consolidated financial statements, our commercial business operations in Russia have been materially impacted by the conflict. Additionally, if due to the conflict, we are unable to retain key skilled personnel workforce located in Russia, particularly research and development personnel, or quickly replace such personnel with individuals of equivalent technical expertise and qualifications, our business and financial condition could be materially adversely effected. The outcome and future impacts of the conflict remain highly uncertain, continue to evolve and are likely to grow more severe the longer the military action and sanctions remain in effect. Moreover, this conflict and existing and future sanctions may have broad and pervasive impacts to the global economy and our operations, heightening and affecting many of the other risks listed in this Quarterly Report on Form 10-Q, any of which could materially and adversely affect our business and results of operations. Such risks include, but are not limited to, adverse effects on general economic and political conditions, including inflation, supply chain disruptions and consumer spending; disruptions to our information systems, including through network failures, malicious or disruptive software, or cyberattacks; trade disruptions; rising fuel and/or rising costs of producing, procuring and shipping our products; our exposure to foreign currency exchange rate fluctuations; and constraints, volatility or disruption in the financial markets. We may not be successful in our efforts to mitigate all or any of the negative impacts of the conflict, particularly the longer sanctions and retaliatory sanctions remain in effect. How we respond to these impacts will also subject us to risk. The suspension or resumption of our commercial operations in Russia or our decision to continue supporting our personnel in Russia may result in reputational harm or boycotts of our products that could impact our sales and operations inside and outside of Russia or subject us to litigation for which we may be found liable in courts or other tribunals in Russia or elsewhere. Moreover, production could be impaired should hostilities spread to other countries such as Poland, where we have built our new aligner fabrication facility.

We have no way to predict the progress or outcome of the situation in Ukraine, as the conflict and governmental reactions are rapidly developing and beyond our control. A prolonged conflict, intensified military activities or more extensive sanctions impacting the region and the resulting economic impact could have a material adverse effect on our operations, results of operations, financial condition, liquidity, growth prospects and business outlook.

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. Our iTero business contributes a material percentage of our overall revenues. Although exocad and its CAD/CAM software solutions are important to the continuing evolution of the Align Digital Platform, the contributions to our total net revenues from the exocad solutions remain immaterial. Our operating results could be harmed if:

- orthodontists and GPs experience a reduction in consumer demand for orthodontic services;
- consumers prove unwilling to adopt Invisalign system treatment as rapidly or in the volumes we anticipate and at the prices offered;
- 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;
- sales of our iTero scanners decline or fail to grow sufficiently or as anticipated;
- the growth of CAD/CAM solutions does not produce the results anticipated; or
- if the average selling price of our products declines.

The average selling prices of our products, particularly our Invisalign system, are influenced by numerous factors, including the type and timing of products sold (particularly the timing of orders for additional clear aligners for certain Invisalign products) and foreign exchange rates. In addition, we sell a number of products at different list prices which may differ based on country. Our average selling prices for our Invisalign system and iTero scanners have been impacted in the past and may be adversely affected again in the future if:

- we introduce new or change existing promotions, general or volume-based discount programs, product or services bundles, or consumer rebate programs;
- participation in any promotions or programs unexpectedly increases or decreases or drives demand in unexpected and material ways;
- our geographic, channel, or product mix shifts to lower priced products or to products that have a higher percentage of deferred revenue;
- we decrease prices on one or more products or services in response to increasing competitive pricing pressures;
- 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; or
- our critical accounting estimates materially differ from actual behavior or results.

If our average selling prices decline, our net revenues, gross profit, gross margin and net income may be adversely affected.

Competition in the markets for our products is increasing and we expect aggressive competition from existing competitors, other companies that may introduce new technologies or products in the future and customers who alone or with others create orthodontic appliances and solutions 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 Invisalign system, iTero scanners and CAD/CAM software facilitate this transition, whether our technologies will achieve market acceptance and, if adopted, whether and when they may become obsolete remains unclear.

Currently, the Invisalign system competes directly against traditional metal wires and brackets and increasingly against clear aligners manufactured and distributed by new market entrants and manufacturers of traditional wires and brackets, both within and outside the U.S., and from traditional medical device companies, laboratories, startups and, in some cases, doctors and DSOs themselves. Due in part to market opportunities and the expiration of certain of our key patents beginning in 2017, competition from providers of clear aligners is increasing. The number and types of competitors are diverse and growing rapidly. They vary by segment, geography, and size, and include new and well-established regional competitors, as well as larger companies or divisions of larger companies with substantial sales, marketing, research financial capabilities, and existing dental market channels. Our competitors also include direct-to-consumer ("DTC") companies that provide clear aligners using a remote business 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 3D printing technology. Large consumer product companies may also start supplying orthodontic products.

The manipulation and movement of teeth and bone is a complex and 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. The Invisalign system 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 dental practices that may impact our primary selling channels. Doctors and DSOs are sampling alternative products and taking advantage of competitive promotions and sale opportunities. In addition, we 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 have had and may in the future have unexpected and unintended consequences, including reduced gross margins, profitability and average selling prices, net revenues, volume growth, and net income.

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, military 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, we perform most of our key production steps in locations outside of the U.S. For instance, 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 constructed manufacturing facility in Poland. Also, we maintain significant global 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 contractors, consultants or customers;
- fluctuations in currency exchange rates;
- import and export risks, including shipping delays, cost increases, penalties, controls, license requirements and restrictions;
- controlling production volume and quality of the manufacturing process;
- the engagement in activities by our employees, contractors, partners and agents prohibited by our policies and procedures as well as international and local trade, labor and other laws such as those prohibiting bribery and corrupt payments to government officials, including the U.S. Foreign Corrupt Practices Act, the U.K. Bribery Act of 2010 and export control laws;
- 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;
- increased expense of developing, testing, manufacturing and marketing localized versions of our products;
- threats, tensions, actions and responses to any social, economic, business, geopolitical, military, terrorism, or acts of war, including the possibility, threat of, imposition of, or changes in sanctions, trade restrictions and tariffs, as well as retaliatory military actions, sanctions, trade restrictions and tariffs particularly involving key customers, development or manufacturing markets such as China, Mexico, Russia, the Middle East, Eastern Europe or other countries;
- 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 critical to our iTero operations. If any of these events or conditions 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 disrupts our product development, data or information exchange, payroll or banking operations, product or materials shipping by us or our suppliers and other unanticipated business disruptions, interruptions and limitations in telecommunication services or critical systems or applications reliant on a stable and uninterrupted communications infrastructure;
- burdens of complying with a wide variety of regional and foreign laws, including anti-trust, fair competition and environmental laws;
- the impact of nationalism or initiatives to encourage the purchase or support of domestic vendors, which can influence customers to purchase products from, or collaborate to promote interoperability of products with, companies whose headquarters or primary operations are not domestic;
- reduced IP rights protections as compared to the protections afforded under the laws of the U.S.;
- longer customer payment cycles and greater difficulty in accounts receivable collection; and
- potential adverse direct and indirect tax consequences.

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.

Our success depends on our ability to develop, successfully introduce, achieve market acceptance of, and manage 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 new products and services. The extent of, and rate at which, new products or offerings may achieve market acceptance and penetration is a function of many variables, including our ability to:

- successfully predict and timely innovate and develop new technologies and applications with the features and functionality customers desire or expect;
- successfully and timely obtain approval or clearance of new products or services from government agencies such as the FDA and analogous agencies in other countries;
- cost effectively and efficiently manufacture, quality test, dispose of, bring to market, market, and/or sell new products and services offerings;
- properly forecast the amount and timing of new product demand;
- 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 innovate in response to new competitive products, product offerings and technologies;
- differentiate our products and product offerings from our competitors as well as other products in our own portfolio and successfully articulate the benefits to our customers;
- qualify for third-party reimbursement for procedures involving our products; 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. Even if we successfully innovate and develop new products and product enhancements, we may incur substantial costs doing so and our profitability may suffer. It may be difficult to gain market share and acceptance for new or enhanced products. Introduction and acceptance of new products may take significant time and effort if the products or services require doctor education and training to understand the benefits of the new products or they measure the success of a product only after using it 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 products until they successfully complete one or more cases or until more historical clinical results are available.

In addition, as part of our effort to accommodate our customers’ needs and demands, we periodically introduce new business and sales initiatives to meet these needs and demands, such as our commercial teeth whitening products announced in 2021. In general, our internal resources support these new businesses or sales initiatives, and we frequently provide such support without clear indications it will prove successful or be without short-term execution challenges. Should these new business or sale initiatives be unsuccessful, our business, results of operations and financial condition could be materially impacted.

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 continually implement and improve 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 to provide them with better experiences, improve their confidence using the Invisalign system and iTero intraoral scanners to treat 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 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 all or partially out of our control and can negatively impact our gross margin. In addition, operating facilities located in higher cost regions compared to Mexico, China and Costa Rica negatively impact our gross margin. If the construction or transition into additional facilities is significantly delayed, if a facility temporarily or permanently, partially or fully shuts 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. Then, as dental practices reopened we experienced a rapid increase in demand. These fluctuations in demand and sales have recurred several times since the first quarter of 2020 corresponding with increases in the number of people infected with COVID-19 and its variants, and may continue to arise in the future. 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. Production of our Invisalign clear aligners and iTero 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 and those of our business partners.

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 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. We have a complex, global iTero intraoral scanner installed base of older and newer models. These models are continually updated to add, expand or improve on existing or new features with hardware improvements, improvements to third party components, or part repair or replacement. We have experienced hardware issues in the past and may in the future, including issues relating to manufacturing, design, quality, or safety, of which we become aware only after products or changes have been introduced into the market. We also have not been and may not be able to ensure that third party components or any changes to the foregoing will not be incompatible with, or have a negative impact on the functionality of our iTero intraoral scanners. As a result, there have been and may be widespread failures of our iTero intraoral scanners or we may experience epidemic failures of our iTero intraoral scanner to perform as anticipated. Previously, we have not been and in the future may not be prepared for, or have the infrastructure to, timely and adequately remediate or implement corrective measures for such failures, including due to our dependency on third party providers or suppliers. As a consequence, remediation has been and may be in the future time-consuming and difficult to achieve, which may significantly impact our customers and our business partners, damage our reputation and result in lost business and revenue opportunities, and prove costly, possibly materially.

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. Additionally, the third-party software integrated into or interoperable with our products and services will routinely reach end of life, and as a consequence, certain models of our iTero intraoral scanners may be exposed to additional vulnerabilities, including increased security risks, errors and malfunctions that may be irreparable or difficult to repair. 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, significant remediation costs, 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 our operations and the operations of our customers or our business partners.

A significant portion of our clear aligner production is dependent on digital scans from our globally dispersed and decentralized installed base of 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, interference or disruptions for us, our customers, labs or other business partners in the use of our products or the transmission or processing of data needed for the use or ordering of our products, 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 restorative procedures or treatments and services or otherwise service our customers which may, amongst other things, harm our sales, damage our reputation, adversely impact our strategic partners or result in litigation.

Additionally, our globally-dispersed installed base of iTero intraoral scanners at customer, strategic business partner or other locations may be independently or collectively the target of a cybersecurity incident or attack or subject to the intrusion of a virus, bug, or other similar negative intruder. Due to the large and growing number of these decentralized locations, we may not be able to, or not have the capacity, knowledge, or infrastructure to, respond to or remedy a cybersecurity issue in a timely manner or sufficiently, either of which may cause loss or damage to us or our customers or strategic business partners or may cause further malfunctions in, or damage to, our servers, databases, systems or products and services, loss or damage of our data, interruption or temporary cessation of our operations, or an overall negative impact to our business or reputation.

If the information we rely on to run our businesses is inaccurate or unreliable, if the data governance controls in place fail or change, if compliance with such controls fails, 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 or strategic business partners, experience difficulties attracting new customers or implementing our growth strategies, or suffer other adverse consequences. In addition, experienced computer programmers and hackers, some of whom may be employed by state actors, organized groups, or be part of loosely aligned associations, 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 loss that may have a material adverse impact on our operations, net revenues and operating results.

There can be no assurance that our process of improving existing or developing new 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 or fail 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, malware and ransomware, employee error or malfeasance or similar disruptive problems by third parties, including organized groups or state actors. 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 and more recently the military conflict in Ukraine. The military conflict in Ukraine may cause nation-state actors to carry out cyber attacks to achieve their goals, which may include espionage, information operations, monetary gain, ransomware, disruption, and destruction. In response to potential increases in cyber attacks anticipated in response to the military conflict in Ukraine, we increased efforts to identify and respond to any attacks, including placing our cybersecurity operations team on high alert. Significant service disruptions, breaches in our infrastructure and IT systems or other cybersecurity incidents could expose us to litigation or regulatory investigations, impair our reputation and competitive position, be distracting to our management, and require significant time and resources to address. Affected parties or regulatory agencies could initiate legal or regulatory action against us, which could prevent us from resolving the issues quickly or in unanticipated ways, 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 oversight, investigations and disclosure obligations as well as 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 and do not cover the time and effort we incur investigating and responding to any incidents, which may be significant.

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 such laws, any of which could be costly. 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 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 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, many of whom are comprised of individual or small operations with limited IT experience and inadequate or untested security protocols, in managing data privacy and data security requirements.

Demand for our products may not increase as rapidly as we anticipate or may decrease due to resistance to non-traditional treatment methods, which could have a material adverse impact on our business and operating results.

Invisalign treatment represents a significant change from traditional metal wires and brackets 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 efficacy, safety, ease of use, reliability, aesthetics, and price compared to competing products and treatment methods. If demand for our products remains flat or decreases due to resistance to nontraditional treatment methods, this could materially adversely affect our business and operating results.

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. In addition to the factors otherwise described herein, some of the other factors that have historically and in the future could cause our operating results to fluctuate include:

- higher manufacturing, delivery and inventory costs;
- the creditworthiness, liquidity and solvency of our customers and their ability to timely make payments when due;
- 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, pricing for fees or expenses, 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;
- 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;
- costs and expenditures in connection with such things as the establishment of new treatment planning and fabrication facilities, the hiring and deployment of personnel, and litigation, and the success of or changes to our marketing programs from quarter to quarter; and
- timing and fluctuation of spending around marketing and brand awareness campaigns and industry trade shows.

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 timely or effectively reduce spending to offset any shortfall in net revenues.

A disruption in the operations of a primary freight carrier, higher shipping costs or shipping delays could disrupt our supply chain and 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 who may choose alternative products which could cause our net revenues and gross margin to materially decline. For example, after Russia's military attacks began in Ukraine, UPS ceased shipments to Russia and we suspended our commercial operations there as well. Moreover, when fuel costs increase, our freight costs generally do so as well. Due to the recent increase in fuel costs, we have experienced a material increase in 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 successfully pass all or significant portions of the increase along to our customers, or we cannot otherwise offset such increases in our cost of net revenues, our gross margin and financial results could be materially adversely affected.

If we fail to accurately predict our volume growth, hire too many or too few technicians, or manufacture too many or too few products, the delivery time for our products could be delayed or our costs may exceed our revenues, each of which could adversely affect our results of operations.

If we fail to accurately predict our volume growth, we may inaccurately estimate the staffing, materials or storage required to manufacture our products.

If we underestimate volume growth, our growth may exceed our manufacturing capacity of one or more of our suppliers or manufacturing facilities, we may be understaffed and we may not have sufficient materials. Specifically, our manufacturing process relies on sophisticated computer software and 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. Without sufficient capacity, trained personnel or materials, we may be unable to provide our products to customers in a timely manner, which could damage our relationships with our existing customers or harm our ability to attract new customers. Specifically, production levels for our intraoral scanner are generally forecasted based on forecasts and historic product demand and we often place orders with suppliers for materials, components and sub-assemblies (“materials and components”) as well as finished products weeks or more in advance of projected customer orders. Actual customer demand depends on many factors and may vary significantly from forecasts. We will lose opportunities to increase revenues and profits and may incur increased costs if we underestimate customer demand. The effects of underestimating our demand could cause a decline in our net revenues and net income and could adversely affect our results of operations.

Conversely, if we over estimate our growth, we may have excess expenses caused by excess staffing, materials, components and finished products, and capacity. 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 revenues or revenue growth, harming our gross margin and financial results. Additionally, 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.

Improvements to or changes in our products may affect the demand and make demand less predictable. We routinely review inventory for usage potential, including fulfillment of customer warranty obligations and spare part requirements, and we write down to the lower of cost or net realized value the excess and obsolete inventory, which may materially adversely affect our results of operations. For instance, periodically we announce new products, capabilities, or technologies that replace or shorten the life cycles of legacy products or cause customers to defer or stop purchasing legacy products until new products become available. These risks increase the difficulty of accurately forecasting demand for discontinued and new products as well as the likelihood of inventory obsolescence, loss of revenue and associated gross profit.

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 in multiple countries 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, increase brand or product awareness sufficiently to sustain or increase our growth goals or generate goodwill and positive reputational goals. Moreover, should any entity or individual endorsing us or our products take actions, 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 a material adverse effect on our gross margin and business overall.

In addition, various countries prohibit certain types of marketing activities. For example, some countries restrict direct to consumer advertising of medical devices. We could run afoul of restrictions and be ordered to stop certain marketing activities. Moreover, competitors do not always follow these restrictions, creating an unfair advantage and making it more difficult and costly for us to compete.

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 ("IP") 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 adversely impact our reputation.

Our success depends in part on our ability to maintain existing 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 other countries to protect a large part of our IP and our competitive position; however, these patents may be insufficient to protect our IP rights because our patents 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 and foreign patents protections may be more limited than those provided under U.S. patents and IP laws.

We may not be afforded the protection of a patent if our currently pending or future patent filings do not result in the issuance of patents or we fail to apply for patent protection. We may fail to apply for a patent if our personnel fail to disclose or recognize new patentable ideas or innovations. Remote working can decrease the opportunities for our personnel to collaborate, thereby reducing the opportunities for effective invention disclosures and patent application filings. We may choose not to file a foreign patent application if the limited protections provided by a foreign patent do not outweigh the costs to obtain it. 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 collaborative partners upon commencement of a relationship with us. However, despite the existence of these agreements, we have experienced incidents in which our proprietary information has been misappropriated in the past and believe that it could be misappropriated again in the future. If these agreements do not provide meaningful protection against the unauthorized use or disclosure of our trade secrets or other confidential information, adequate remedies may not exist when unauthorized uses or disclosures 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 IP rights might allow competitors to copy our technology or create counterfeit or pirated versions of our products, which could adversely affect our reputation, pricing and market share.

Litigation, interferences, oppositions, re-exams, *inter partes* reviews, post grant reviews or other proceedings have been necessary and will likely 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 and the products of competitors. Asserting or defending these types of proceedings can be unpredictable, protracted, time consuming, expensive and distracting to management and technical personnel. The outcome of such proceedings could adversely affect the validity and scope of our patent or other IP rights, hinder our ability to manufacture and market our products, require us to seek a license for infringing products or technologies 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 IP 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. 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 could materially adversely affect our results of operations and 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.

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 parties' patents in the past and we are currently defending patent infringement lawsuits 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 lawsuits, 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.

Obtaining approvals and complying with governmental regulations, particularly those related to personal healthcare information, financial information, quality systems, competition, anti-trust, data governance 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 technology company and supplier of medical devices and solutions, we and many of our healthcare provider customers, suppliers and distributors are subject to extensive and frequently changing regulations under numerous federal, state, local and foreign laws, including those regulating:

- 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 design, marketing and advertising of our products.

The healthcare and technology markets are also 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. Additionally, we are expanding our product portfolio into the areas of software as a medical device and the use of artificial intelligence. Global regulators are rapidly expanding and changing the regulations and guidance regarding the market access pathways for these innovative products, which could result in market withdrawal of existing products or protracted review timelines for new product introductions. 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.

We are and may be in the future subject to antitrust or competition related investigations, enforcement actions, and settlements, by governmental agencies, competitors, consumers, customers, and others which could cause us to incur substantial costs or require us to change our business practices in a manner materially adverse to our business. Governments, enforcement authorities and other legislative bodies are actively developing new competition laws and regulations aimed at the technology sector, artificial intelligence and digital platforms, coordinating globally, and enforcing competition laws and regulations, and this includes scrutiny in potentially large markets such as the EU, U.S., and China. Government regulatory actions and court decisions may result in fines or hinder our ability to provide certain benefits to our consumers, reducing the attractiveness of our products and the revenue that comes from them.

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 to gain market access 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 and there is no guarantee we will successfully or timely obtain or maintain approvals in all or any of the countries in which we do business now or in the future. In other countries, the requirements to obtain and maintain similar approvals may differ materially from those of the FDA and may require additional time and expense. Moreover, these laws may change resulting in additional time and expense or loss of approvals. Additionally, the impact of the COVID-19 pandemic 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 offer them in markets we deem important to our business. Failure or delays to obtain or maintain regulatory approvals may materially harm our domestic or international operations, and our business as a whole adversely impacted.

Any 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, while we provide significant training to our personnel, they may not properly adhere to our policies or applicable laws or regulations. If our employees fail to comply with any or all laws or regulations or our policies or procedures, it could result in violations of laws or regulations and subject us to harm to our reputation, loss of customers, loss or revenues, or regulatory investigations and actions.

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.

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 rely on a single third-party manufacturer to supply key sub-assemblies for our iTero Element scanner. 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. By using single suppliers for materials and manufacturing in a limited number of locations, we risk multiple supply chain vulnerabilities. For example, damage or destruction of a facility can materially disrupt our ability to timely deliver key components and materials or products or a supplier could encounter financial, operating or other difficulties, be unable to hire or maintain personnel, fail to timely obtain supplies, fail to maintain manufacturing standards or controls, or fail to timely deliver materials, parts or components. To the extent any of our suppliers or others' suppliers in our supply chain are dependent on raw materials, components or other parts from Russia or Ukraine, the foregoing risks may be more likely to occur as a result of the military conflict in Ukraine. Any one of these occurrences would impact our supply chain.

Restrictions in response to the COVID-19 pandemic and other macroeconomic factors have affected and are expected to continue to affect our supply chain. The manufacture of product components, the final assembly of our products and other critical operations are concentrated in certain geographic locations, including China. A significant portion of our finished goods product distribution occurs through China and EMEA. Each of these areas has been affected by the COVID-19 pandemic and has implemented measures to try to contain its spread, including restrictions on manufacturing facilities, commerce, travel, our support operations and workforce, and our customers, strategic partners, vendors and suppliers. There is considerable uncertainty regarding the current and future impact of such measures, including reduced availability or increased cost of air transport, port closures and increased border controls and closures. Any or all restrictions can limit our manufacturers' capacity to produce our parts or products and have a material adverse effect on our supply chain.

Due to the military conflict between Russia and Ukraine, some countries have placed export controls on certain products and financial and economic sanctions on various industry sectors and parties in Russia. The outcome and future impacts of the conflict remain highly uncertain and are continuing to evolve but they have impacted and could materially affect our supply chain in the future.

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 and our suppliers rely.

Because of our dependence on our suppliers, changes in one or more of our relationships with them or changes in their circumstances can result in disruptions to the supply chain, which can materially impact our business. For instance, we may be unable to quickly establish or qualify replacement suppliers creating 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 causing us to lose revenues and suffer damage to our customer relationships. 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. In the event of technology changes, delivery delays, labor stoppages or shortages, or shortages of, or increases in price for these items, sales may decrease and our business and growth prospects may be harmed.

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

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 on our clinical engineering, technology development and sales teams. To be successful, we must effectively manage our growth through our ability to identify, hire, develop, motivate, train and retain these skilled employees as well as personnel throughout our organization.

We provide significant training to our personnel and our business will be impacted if our training fails to properly prepare our personnel to perform the work required, we are unable to successfully instill technical expertise in new and existing personnel or if our techniques prove unsuccessful or not cost-effective.

Moreover, for certain roles, this training and experience can make key personnel, such as our sales personnel, highly desirable by competitors and lead to increased attrition. The loss of the services and knowledge from our highly skilled employees may significantly delay or prevent the achievement of our development and business objectives and could harm our business. For example, 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 retain our workforce, including key sales and other skilled personnel, or quickly replace personnel with individuals of equivalent technical expertise and qualifications, our results of operations and our ability to maintain market share could be materially adversely effected.

For more discussion related to our personnel and corporate culture see the risk factor, "*We rely on our personnel and, if we fail to attract, motivate, train or retain personnel, or if our growth harms our corporate culture, it may be more difficult to grow effectively and pursue our strategic priorities.*"

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, including the risk that these distributors do not comply with applicable laws or our internal procedures.

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 if alternative distributors must be 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 fair competition, bribery and corruption, trade compliance, and 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 or prevents us from taking control of any such authorization. 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. If our products are safe but 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 approvals rescinded or we may be required to defend ourselves in litigation. Although we 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 be insufficient for actual 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 divert management’s attention.

Increased focus on compliance with current or future ESG laws and increased scrutiny of our ESG policies and practices may materially increase our costs, expose us to potential liability, may adversely impact our reputation, employee retention, willingness of customers and suppliers to do business with us and willingness of investors to invest in us, and otherwise materially impact our business.

Our operations are subject to a variety of existing local, regional and global ESG laws and regulations, and we will likely be required to comply with new, broader, more complex and costly laws and regulations that focus on ESG 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, disposal activities and workers’ rights.

The environmental regulations related to greenhouse gases may have an impact on our or our suppliers’ energy sources. Many U.S. and foreign regulators have enacted or are considering enacting new or additional disclosure requirements or 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, levels of emissions reductions and the scope and types of emissions regulated. 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. Moreover, alternative energy sources that supply the power to meet our current and future demands as well as those of 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 we, our suppliers and other businesses need for operations.

Regulations related to sourcing of certain metals may have an impact on our business. 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.

Meeting our obligations under existing laws, rules, or regulations is already costly to us and our suppliers, 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 efforts or operations will be compliant. If we fail to comply with any requirements, 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. Further these laws are subject to unpredictable changes. Even if we successfully comply with these laws and regulations, our suppliers may fail to comply. We may also suffer financial and reputational harm if customers require, and we are unable to deliver, certification that our products are conflict free. In all of these situations, customers may stop purchasing products from us, and may take legal action against us, which could harm our reputation, revenues and results of operations.

Investor advocacy groups, institutional investors, investment funds, proxy advisory services, stockholders, and customers are also increasingly focused on 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 investor or other industry stakeholders' evolving expectations and standards for ESG 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, customers and suppliers may be unwilling to do business with us and investors may be unwilling to invest in 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 disclosure and other expectations of stakeholders, our reputation, business, financial performance, growth, and stock price may be adversely impacted.

General Risk Factors

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

We 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. 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. 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.

Beginning and continuing in 2022, we are gradually reopening many of our offices that have been substantially closed to employees during the COVID-19 pandemic. Where our offices have reopened, we have adopted a flexible hybrid schedule that will allow many of our employees the opportunity to collaborate and connect with others in our offices three days per week while having the option to work remotely other days. This hybrid approach that we have adopted may materially increase our costs or create unforeseen challenges or complications, including:

- difficulties maintaining our corporate culture, disruption of morale or decreased loyalty;
- difficulties with 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;
- 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 for convenience or for safety reasons to continue working remotely full time, or in offices or geographies different from where they were hired to work or are expected to work;
- problems managing office space requirements;
- 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.

Furthermore, our compensation and benefit arrangements, such as our equity award programs, may not always be successful in attracting new employees and retaining and motivating existing employees. In addition, 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, an increase in employees choosing to retire or quit with no immediate intentions to continue working and significantly higher demand for technical and digital talent.

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. This could have a material adverse effect on our results of operations and our ability to maintain market share.

Business disruptions could seriously harm our financial condition.

Our global operations have been disrupted in the past and will likely be disrupted and harmed again in the future. The occurrence of any material or prolonged business disruptions could harm our growth and expansion, result in significant losses, seriously harm our revenues, 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.

Human error can have a significant effect on our business. While we train our employees and perform our due diligence when contracting with third parties, mistakes and accidents still occur. For instance, in March 2021, a container ship carrying some of our products was stuck in the Suez Canal for six days. Although this did not have a material adverse effect on our business, there is no assurance that such incidents may not impact us in a material way in the future.

Natural disasters can impact our business and third-party vendors that may be critical to our business, including as a result of earthquakes, tsunamis, floods, droughts, hurricanes, wildfires, extreme weather conditions, power outages, restrictions and shortages, telecommunications failures, materials scarcity and price volatility, and medical epidemics or health pandemics. Climate change is likely to increase both the frequency and severity of natural disasters and, consequently, risks to our operations and growth. Our digital dental modeling and certain of our customer facing operations are primarily processed in our facilities located in Costa Rica. Our aligner molds and finished aligners are fabricated in China, Mexico and Poland. Our locations in Costa Rica and Mexico as well as others are in earthquake zones and may be subject to other natural disasters. Moreover, a significant portion of our research and development activities are located in California, which suffers from earthquakes, periodic droughts, power shortages and wildfires. If there is a major earthquake or any other natural disaster in a region where one of these facilities is located, our employees could be impacted, our research could be lost, and 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.

When human induced or natural disasters 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, any of which 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 could have a significant effect on our reported results and may even retroactively affect previously reported financial statements.

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 required to furnish in our Form 10-K a report by our management regarding the effectiveness of our internal control over financial reporting that 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 our internal control over financial reporting is effective. Our internal controls may become inadequate because of changes in personnel, updates and upgrades to existing software, changes in accounting standards or interpretations of existing standards, and, as a result, the degree of compliance of our internal control over financial reporting with the existing policies or procedures may become ineffective. Establishing, testing and maintaining an effective system of internal control over financial reporting requires significant resources and time commitments on the part of our management and our finance staff, may require additional staffing and infrastructure investments and increases our costs of doing business. If we are unable to assert that our internal control over financial reporting is effective in any future period (or if our auditors are unable to express an opinion on the effectiveness of our internal controls or conclude that our internal controls are ineffective), the timely filing of our financial reports could be delayed or we could be required to restate past reports, and cause us to lose investor confidence in the accuracy and completeness of our financial reports in the future, which could have an adverse effect on our stock price.

If we fail to manage our exposure to global financial and securities market risks 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 would 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 on an approved replacement benchmark. We also have other contracts indexed to LIBOR. 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 the 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 and practice, changes to existing tax laws and practice, or disputes regarding the positions we take regarding tax laws, could negatively affect our provision for income taxes as well as our ongoing operations.

As a U.S. multinational corporation, we are subject to tax laws both within and outside of the U.S. and significant judgment is required in determining our worldwide provision for income taxes. Changes in tax laws or changes to how those laws are applied to our business in practice, could affect the amount of tax to which we are subject and the manner in which we operate. Additionally, the Organization for Economic Cooperation and Development's ("OECD") Base Erosion and Profit Shifting ("BEPS") project has resulted in considerable new reporting obligations worldwide as OECD member countries have implemented its guidance. The OECD continues to publish guidance pursuant to the BEPS and other projects which, if adopted by member countries, may affect our tax positions 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 and exemptions 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. 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.

We are routinely subject to audits regarding our tax reporting and remissions by local and national governments. We may also be subject to audits in U.S. states, local and foreign jurisdictions for which we have not accrued tax liabilities. The positions we take and assumptions we make 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. If we dispute rulings or positions taken by tax authorities, we may incur expenses and expend significant time and effort to defend our positions, which may be costly.

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 and defending our positions in the numerous markets in which we conduct or will conduct business.

We have in the past and may again in the future invest in or acquire other businesses, products or technologies which may 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 investment or acquisition targets in the future, and we may not be able to complete investments or 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. As such we are subject to multiple vulnerabilities and risks when making a strategic investment or acquisition, including we may:

- fail to perform proper due diligence and inherit or fail to uncover material issues of the acquired company or assets, including IP or other litigation or ongoing investigations, accounting irregularities or improprieties, bribery, corruption or other compliance liabilities;
- fail to comply with regulations, governmental orders or decrees;
- create IT security and privacy compliance issues;
- invest in companies that generate net losses and the market for their products, services or technologies may be slow to develop;
- not realize a positive return on investment or determine that our investments have declined in value, such that we may be required to record impairments such as future impairments of intangible assets and goodwill or the recording of stock-based compensation, which could have a material adverse impact on our financial results;
- have to pay cash, incur debt or issue equity securities to pay for an acquisition, adversely affecting 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;
- find it difficult to implement and harmonize company-wide financial reporting, forecasting and budgeting, accounting, billing, information technology and other systems due to inconsistencies in standards, internal controls, procedures and policies;

- require significant time and resources to effectuate the transition;
- fail to retain key personnel;
- inaccurately forecast the financial impact of an acquired business;
- not realize any or all or material portions of the expected synergies and benefits of the acquisition; or
- unsuccessfully evaluate or utilize the acquired technology or acquired company’s know-how or fail to successfully integrate any acquisitions or the technologies acquired.

Moreover, opposition to one or 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.

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

The market price of our common stock is subject to rapid and 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;
- our ability in the future to sustain or regain our historical growth rates;
- 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, new litigation, settlements, judgments or decrees;
- sales of stock by us, our officers or directors; and
- general economic market conditions, including rising interest rates, inflationary pressures, recessions, and global political conflict.

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 general economic market 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 actual operating performance. Historically, securities litigation, including securities class action lawsuits and securities derivative lawsuits, 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. Future stock repurchase programs are 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.

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 June 30, 2022:

Period	Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Programs	Approximate Dollar Value of Shares that May Yet Be Repurchased Under the Programs[1]
April 1, 2022 through April 30, 2022	—	$ —	—	$ 649,926,094
May 1, 2022 through May 31, 2022	551,895	$ 289.91	551,895	$ 449,926,094
June 1, 2022 through June 30, 2022	204,607	$ 195.50	204,607	$ 449,926,094
Total	756,502		756,502	

[1] *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. See *Note 9 "Common Stock Repurchase Programs" of the Notes to Condensed Consolidated Financial Statements* for details on the May 2021 Repurchase Program.

Item 3. Defaults Upon Senior Securities.

Not applicable.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None

Item 6. Exhibits.

(a) Exhibits:

Exhibit Number	Description	Filing	Date	Exhibit Number	Filed herewith
10.1	Fixed Dollar Accelerated Share Repurchase Transaction between Citibank, N.A. and Align Technology, Inc. dated April 29, 2022				*
31.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				*
31.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				*
32.1†	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				*
101.INS	Inline XBRL Instance Document (the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document).				*
101.SCH	Inline XBRL Taxonomy Extension Schema Document				*
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document				*
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document				*
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document				*
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document				*
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101)				*

† 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.

SIGNATURES

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

ALIGN TECHNOLOGY, INC.

August 4, 2022	By: /s/ JOSEPH M. HOGAN **Joseph M. Hogan** **President and Chief Executive Officer**
August 4, 2022	By: /s/ JOHN F. MORICI **John F. Morici** **Chief Financial Officer and Executive Vice President, Global Finance**

Citibank, N.A.
390 Greenwich Street, 4th Floor
New York, NY 10013 Attention: Equity Derivatives

Opening Transaction

To:	Align Technology, Inc. 410 N. Scottsdale Road, Suite 1300 Tempe, Arizona 85281
A/C:	________________
From:	Citibank, N.A.
Re:	Fixed Dollar Accelerated Share Repurchase Transaction
Date:	April 29, 2022

Dear Sir/Madam:

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

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

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

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

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

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

GENERAL TERMS:

Trade Date:	As specified in Schedule I
Buyer:	Issuer
Seller:	Dealer
Shares:	Common Stock, par value USD 0.0001 per share, of Issuer (Ticker: ALGN)
Forward Price:	A price per Share (as determined by the Calculation Agent) equal to the greater of (A) (i) the arithmetic mean (not a weighted average, 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 Exchange Act of 1934, as amended (the “**Exchange Act**”) on such Trading Day) or, if the price displayed on such screen is clearly erroneous, as determined by the Calculation Agent in good faith and in a commercially reasonable manner.
Observation Dates:	As specified in Schedule I
Calculation Period:	The period from, and including, the first Observation Date that is a Trading Day that occurs on or after the Prepayment Date to, but excluding, the relevant Valuation Date; provided, however, that if the Valuation Date is the Scheduled Valuation Date, then the Valuation Date shall be included in the Calculation Period; provided further that in no event shall any Scheduled Valuation Date be postponed to a date later than the Final Termination Date.
Final Termination Date:	As specified in Schedule I; provided that if a Market Disruption Event has occurred pursuant to Section 7 of this Confirmation, such Final Termination Date shall be postponed by one Trading Day for every Trading Day that is a Disrupted Day as a result of such Merger Transaction during the Calculation Period
Trading Day:	Any Exchange Business Day that is not a Disrupted Day in whole

Initial Shares:	As specified in Schedule I; provided that if Dealer is unable to borrow or otherwise acquire a number of Shares equal to the Initial Shares for delivery to Issuer on the Initial Share Delivery Date, the Initial Shares delivered on the Initial Share Delivery Date shall be reduced to such number of Shares that Dealer is able to so borrow or otherwise acquire, and thereafter Dealer shall continue to use commercially reasonable efforts to borrow or otherwise acquire a number of Shares, at a stock borrow cost no greater than the Initial Stock Loan Rate, equal to the shortfall in the Initial Shares and to deliver such additional Shares as soon as reasonably practicable. For the avoidance of doubt, the aggregate of all shares delivered to Dealer in respect of the Transaction pursuant to this paragraph shall be the "Initial Shares" for purposes of determining the "Settlement Amount" below.
Initial Share Delivery Date:	One Exchange Business Day following the Trade Date. On the Initial Share Delivery Date, Seller shall deliver to Buyer a number of Shares equal to the Initial Shares in accordance with Section 9.4 of the Equity Definitions, with the Initial Share Delivery Date being deemed to be a "Settlement Date" for purposes of such Section 9.4.
Prepayment:	Applicable
Prepayment Amount:	As specified in Schedule I
Prepayment Date:	One Exchange Business Day following the Trade Date. On the Prepayment Date, Buyer shall pay to Seller the Prepayment Amount.
Exchange:	The Nasdaq Global Select Market
Related Exchange:	All Exchanges; provided that Section 1.26 of the Equity Definitions shall be amended to add the words "United States" before the word "exchange" in the tenth line of such Section.

Market Disruption Event:

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

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

Notwithstanding anything to the contrary in the Equity Definitions, if any Exchange Business Day in the Calculation Period 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:	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; <u>provided</u> that if at any time after the Lock-Out Date Dealer expects the Settlement Amount to be a negative number, then Dealer shall provide Issuer notice of any such expectation. Dealer shall specify in each Acceleration Notice the portion of the Prepayment Amount that is subject to acceleration (which may be less than the full Prepayment Amount, but only so long as such portion is not less than USD 25,000,000). If the portion of the Prepayment Amount that is subject to acceleration is less than the full Prepayment Amount, then the Calculation Agent shall adjust the terms of the Transaction as appropriate in order to take into account the occurrence of such accelerated Valuation Date (including cumulative adjustments to take into account all prior accelerated Valuation Dates). On each Valuation Date, the Calculation Agent shall calculate the Settlement Amount.
Scheduled Valuation Date:	As specified in Schedule I, subject to postponement in accordance with "Market Disruption Event" above
Lock-Out Date:	As specified in Schedule I
SETTLEMENT TERMS:	
Physical Settlement:	Applicable. On the Settlement Date, Seller shall deliver to Buyer a number of Shares equal to (a) (i) the Prepayment Amount <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.
Settlement Currency:	USD
Settlement Date:	The date that falls one Settlement Cycle after the relevant Valuation Date.
Other Applicable Provisions:	The last sentence of Section 9.2, Sections 9.8, 9.9, 9.10 and 9.11 (except that the Representation and Agreement contained in Section 9.11 of the Equity Definitions shall be modified by excluding any representations therein relating to restrictions, obligations, limitations or requirements under applicable securities laws arising as a result of the fact that Buyer is the issuer of the Shares) and Section 9.12 of the Equity Definitions will be applicable to the Transaction.
SHARE ADJUSTMENTS:	

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

EXTRAORDINARY EVENTS:

Consequences of Merger Events:	
Share-for-Share:	Modified Calculation Agent Adjustment
Share-for-Other:	Cancellation and Payment on that portion of the Other Consideration that consists of cash; Modified Calculation Agent Adjustment on the remainder of the Other Consideration
Share-for-Combined:	Component Adjustment
Tender Offer:	Applicable; provided that the definition of “Tender Offer” in Section 12.1 of the Equity Definitions will be amended by replacing the phrase “greater than 10% and less than 100% of the outstanding voting shares of the Issuer” in the third and fourth line thereof with “(a) greater than 15% and less than 100% of the outstanding Shares of the Issuer in the event that such Tender Offer is being made by any entity or person other than the Issuer or any subsidiary thereof or (b) greater than 20% and less than 100% of the outstanding Shares of the Issuer in the event that such Tender Offer is being made by the Issuer or any subsidiary thereof”.
Consequences of Tender Offers:	
Share-for-Share:	Modified Calculation Agent Adjustment
Share-for-Other:	Modified Calculation Agent Adjustment
Share-for-Combined:	Modified Calculation Agent Adjustment
New Shares:	In the definition of New Shares in Section 12.1(i) of the Equity Definitions, the text in clause (i) thereof shall be deleted in its entirety 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; provided that in addition to the provisions of Section 12.6(a)(iii) of the Equity Definitions, it shall constitute a Delisting if the Exchange is located in the United States and the Shares are not immediately re-listed, re- traded or re-quoted on any of the New York Stock Exchange, The NASDAQ Global Market or The NASDAQ Global Select Market (or their respective successors); if the Shares are immediately re-listed, re-traded or re-quoted on any such exchange or quotation system, such exchange or quotation system shall thereafter be deemed to be the Exchange.
Additional Disruption Events:	
Change in Law:	Applicable; provided that (i) any determination as to whether (A) the adoption of or any change in any applicable law or regulation (including, for the avoidance of doubt and without limitation, (x) any tax law or (y) adoption or promulgation of new regulations authorized or mandated by existing statute) or (B) the promulgation of or any change in the interpretation by any court, tribunal or regulatory authority with competent jurisdiction of any applicable law or regulation (including any action taken by a taxing authority), in each case, constitutes a "Change in Law" shall be made without regard to Section 739 of the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 or any similar legal certainty provision in any legislation enacted, or rule or regulation promulgated, on or after the Trade Date, (ii) Section 12.9(a)(ii) of the Equity Definitions is hereby amended by replacing the parenthetical beginning after the word "regulation" in the second line thereof the words "(including, for the avoidance of doubt and without limitation, (x) any tax law or (y) adoption or promulgation of new regulations authorized or mandated by existing statute)" and (iii) by, immediately following the word "Transaction" in clause (x) thereof, adding the phrase "in the manner contemplated by the Hedging Party on the Trade Date".
Failure to Deliver:	Applicable
Insolvency Filing:	Applicable

Hedging Disruption:	Applicable
Increased Cost of Hedging:	Not Applicable
Loss of Stock Borrow:	Applicable
Maximum Stock Loan Rate:	200 bps
Increased Cost of Stock Borrow:	Applicable
Initial Stock Loan Rate:	25 bps
Determining Party:	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.
Hedging Party:	For all applicable events, Dealer
Non-Reliance:	Applicable
Agreements and Acknowledgements Regarding Hedging Activities:	Applicable

Additional Acknowledgments:	Applicable
3. Calculation Agent:	Dealer; provided that following the occurrence of an Event of Default of the type described in Section 5(a)(vii) of the Agreement with respect to which Dealer is the sole Defaulting Party, if the Calculation Agent fails to timely make any calculation, adjustment or determination required to be made by the Calculation Agent hereunder or to perform any obligation of the Calculation Agent hereunder and such failure continues for five (5) Exchange Business Days following notice to the Calculation Agent by Issuer of such failure the Issuer shall have the right to designate a nationally recognized third-party dealer in over-the-counter corporate equity derivatives to act, during the period commencing on the date such Event of Default occurred and ending on the Early Termination Date with respect to such Event of Default, as the Calculation Agent. All calculations and determinations by the Calculation Agent shall be made in good faith and in a commercially reasonable manner. Following any calculation made by the Calculation Agent hereunder, upon a prior written request by the Issuer, the Calculation Agent will provide to the Issuer by email to the email address provided by the Issuer in such prior written request a report (in a commonly used file format for the storage and manipulation of financial data) displaying in reasonable detail the basis for such calculation and specifying the particular section of the Confirmation pursuant to which such calculation or determination is being made (and in the event that more than one section of the Confirmation would permit the Calculation Agent to make an adjustment upon the occurrence of a specific event, then the Calculation Agent shall specify the particular section number pursuant to which the Calculation Agent is making the adjustment hereunder); provided, however, that in no event will the Calculation Agent be obligated to share with the Issuer any proprietary or confidential data or information or any proprietary models used by it.

4. Account Details and Notices:

(a) Account for delivery of Shares to Issuer:

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

(b) Account for payments to Issuer:

Bank of America Acct: provided
ABA: provided

(c) Account for payments to Dealer:

Bank: Citibank NA New York
BIC: provided
F/O: Citibank New York
A/C: provided
Ref: NY Swap Operations

Financial Institution’s delivery instructions:

Citigroup Global Markets Inc
DTC 0505
Name: Citibank NA
A/C: 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:

Citibank, N.A.
390 Greenwich Street, 4th Floor
New York, NY 10013
Attention: Equity Derivatives
Telephone No.: provided
Email: provided

5. Amendments to the Equity Definitions and Agreement.

(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. Alternative Termination Settlement.

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 any purchases on May 4, 2022 by affiliated purchasers (as defined in Rule 10b-18) of the Issuer. "**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) Issuer 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 Issuer 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 Issuer, and that Issuer 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 Issuer to fail to satisfy any condition for application for or receipt or retention of the Financial Assistance (collectively "**Restricted Financial Assistance**"); provided, that Issuer or any of its subsidiaries may apply for Restricted Financial Assistance if Issuer either (a) determines based on the advice of outside counsel of national standing that the terms of the Transaction would not cause Issuer 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 authority with jurisdiction for such program or facility that the Transaction is permitted under such program or facility (either by 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 (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. <u>Delivery of Cash</u>.

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. <u>Other Provisions</u>.

(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.

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. US Resolution Stay.

(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) Issuer 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 Issuer being the beneficiary of such Affiliate Credit Enhancement in violation of any law applicable to the Issuer.

(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 Issuer 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, Issuer 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 Issuer 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 Issuer 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.

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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

CITIBANK, N.A.

By: /s/ Eric Natelson

Name: Eric Natelson

Title: Authorized Signatory

ANNEX A

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, plus USD 0.05 (in each case, plus 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.

Exhibit 31.1

CERTIFICATION

I, Joseph M. Hogan, certify that:

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

Date: August 4, 2022

/s/ JOSEPH M. HOGAN

Joseph M. Hogan
President and Chief Executive Officer

Exhibit 31.2

CERTIFICATION

I, John F. Morici, certify that:

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

Date: August 4, 2022

/s/ JOHN F. MORICI

John F. Morici
Chief Financial Officer and Executive Vice President, Global Finance

Exhibit 32.1

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

In connection with the Quarterly Report of Align Technology, Inc. (the "Company") on Form 10-Q for the period ending June 30, 2022 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: August 4, 2022

In connection with the Quarterly Report of Align Technology, Inc. (the "Company") on Form 10-Q for the period ending June 30, 2022 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 Executive Vice President, Global Finance**

Date: August 4, 2022