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

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 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 April 29, 2022 was 78,805,547.

ALIGN TECHNOLOGY, INC.

TABLE OF CONTENTS

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

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

	Three Months Ended March 31, 2022	Three Months Ended March 31, 2021
Net revenues	$ 973,219	$ 894,771
Cost of net revenues	263,873	217,673
Gross profit	709,346	677,098
Operating expenses:		
Selling, general and administrative	439,457	397,115
Research and development	71,807	54,537
Total operating expenses	511,264	451,652
Income from operations	198,082	225,446
Interest income and other income (expense), net:		
Interest income	677	1,643
Other income (expense), net	(11,273)	34,532
Total interest income and other income (expense), net	(10,596)	36,175
Net income before provision for income taxes	187,486	261,621
Provision for income taxes	53,188	61,245
Net income	$ 134,298	$ 200,376
Net income per share:		
Basic	$ 1.71	$ 2.54
Diluted	$ 1.70	$ 2.51
Shares used in computing net income per share:		
Basic	78,742	79,000
Diluted	79,193	79,798

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

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

	Three Months Ended March 31,	
	2022	**2021**
Net income	$ 134,298	$ 200,376
Other comprehensive loss:		
Change in foreign currency translation adjustment, net of tax	(7,311)	(14,451)
Change in unrealized gains (losses) on investments, net of tax	(2,728)	(20)
Other comprehensive loss	(10,039)	(14,471)
Comprehensive income	$ 124,259	$ 185,905

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

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

	March 31, 2022	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 926,119	$ 1,099,370
Marketable securities, short-term	86,749	71,972
Accounts receivable, net of allowance for doubtful accounts of $9,764 and $9,245, respectively	950,892	897,198
Inventories	275,669	230,230
Prepaid expenses and other current assets	241,339	195,305
Total current assets	2,480,768	2,494,075
Marketable securities, long-term	107,695	125,320
Property, plant and equipment, net	1,140,922	1,081,926
Operating lease right-of-use assets, net	125,252	121,257
Goodwill	411,965	418,547
Intangible assets, net	103,499	109,709
Deferred tax assets	1,515,620	1,533,767
Other assets	57,693	57,509
Total assets	$ 5,943,414	$ 5,942,110
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 186,509	$ 163,886
Accrued liabilities	465,071	607,315
Deferred revenues	1,212,067	1,152,870
Total current liabilities	1,863,647	1,924,071
Income tax payable	123,476	118,072
Operating lease liabilities	104,983	102,656
Other long-term liabilities	184,456	174,597
Total liabilities	2,276,562	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; 78,805 and 78,710 issued and outstanding, respectively)	8	8
Additional paid-in capital	992,287	999,006
Accumulated other comprehensive income (loss), net	(5,713)	4,326
Retained earnings	2,680,270	2,619,374
Total stockholders' equity	3,666,852	3,622,714
Total liabilities and stockholders' equity	$ 5,943,414	$ 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 March 31, 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	—	—	—	—	134,298	134,298
Net change in unrealized gains (losses) from investments	—	—	—	(2,728)	—	(2,728)
Net change in foreign currency translation adjustment	—	—	—	(7,311)	—	(7,311)
Issuance of common stock relating to employee equity compensation plans	239	—	14,827	—	—	14,827
Tax withholdings related to net share settlements of equity awards	—	—	(51,533)	—	—	(51,533)
Common stock repurchased and retired	(144)	—	(1,634)	—	(73,402)	(75,036)
Stock-based compensation	—	—	31,621	—	—	31,621
Balance as of March 31, 2022	78,805	$ 8	$ 992,287	$ (5,713)	$ 2,680,270	$ 3,666,852

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

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

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

	Three Months Ended March 31, 2022	Three Months Ended March 31, 2021
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net income	$ 134,298	$ 200,376
Adjustments to reconcile net income to net cash provided by operating activities:		
Deferred taxes	17,464	28,979
Depreciation and amortization	29,626	25,635
Stock-based compensation	31,621	27,241
Non-cash operating lease cost	7,526	5,911
Arbitration award gain	—	(43,403)
Other non-cash operating activities	8,612	5,795
Changes in assets and liabilities:		
Accounts receivable	(55,543)	(67,423)
Inventories	(49,455)	(15,582)
Prepaid expenses and other assets	(48,665)	(34,858)
Accounts payable	7,025	(14,936)
Accrued and other long-term liabilities	(126,400)	(475)
Long-term income tax payable	5,405	3,920
Deferred revenues	68,984	106,007
Net cash provided by operating activities	30,498	227,187
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property, plant and equipment	(87,328)	(43,431)
Purchase of marketable securities	(15,041)	—
Proceeds from maturities of marketable securities	6,095	—
Proceeds from sales of marketable securities	8,528	—
Repayment on unsecured promissory note	—	4,594
Proceeds from arbitration award	—	43,403
Other investing activities	(2,452)	—
Net cash (used in) provided by investing activities	(90,198)	4,566
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock	14,827	13,133
Common stock repurchases	(75,036)	—
Payroll taxes paid upon the vesting of equity awards	(51,533)	(66,568)
Net cash used in financing activities	(111,742)	(53,435)
Effect of foreign exchange rate changes on cash, cash equivalents, and restricted cash	(1,826)	(7,487)
Net (decrease) increase in cash, cash equivalents, and restricted cash	(173,268)	170,831
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	$ 926,871	$ 1,132,305

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 months ended March 31, 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 and 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

As the pandemic continues and new variants of the virus emerge, we are seeing a resurgence of severe preventative measures to prevent its spread in China 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 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. Further, we could also be materially adversely affected by supply chain disruptions, including shortages and inflationary pressures, uncertain or reduced demand, labor shortages, delays in collection of outstanding receivables and the impact of any initiatives or programs that we may undertake to address financial and operational challenges faced by our customers.

The military conflict between Russia and Ukraine and its related impacts on the economy has caused significant worldwide challenges. While the situation is highly uncertain and evolving, its impact on the economy such as inflation, 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.

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 an 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 March 31, 2022 and December 31, 2021 (in thousands):

					Reported as:		
March 31, 2022	**Amortized Cost**	**Gross Unrealized Gains**	**Gross Unrealized Losses**	**Fair Value**	**Cash and Cash Equivalents**	**Marketable securities, short-term**	**Marketable securities, long-term**
Cash	$ 689,175	$ —	$ —	$ 689,175	$ 689,175	$ —	$ —
Money market funds	236,960	—	(16)	236,944	236,944	—	—
Corporate bonds	116,307	3	(2,389)	113,921	—	41,164	72,757
U.S. government treasury bonds	46,638	—	(511)	46,127	—	31,055	15,072
Asset-backed securities	27,453	—	(197)	27,256	—	10,984	16,272
Municipal bonds	6,049	—	(77)	5,972	—	3,546	2,426
U.S. government agency bonds	1,204	—	(36)	1,168	—	—	1,168
Total	$ 1,123,786	$ 3	$ (3,226)	$ 1,120,563	$ 926,119	$ 86,749	$ 107,695

					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 March 31, 2022 and December 31, 2021 (in thousands):

	March 31, 2022	**December 31, 2021**
Due in 1 year or less	$ 67,225	$ 59,737
Due in 1 year through 5 years	$ 127,219	139,113
Total	$ 194,444	$ 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 March 31, 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 March 31, 2022 and December 31, 2021 (in thousands):

Description	**Balance as of March 31, 2022**	**Level 1**	**Level 2**	**Level 3**
Cash equivalents:				
Money market funds	$ 236,944	$ 236,944	$ —	$ —
Short-term investments:				
U.S. government treasury bonds	31,055	31,055	—	—
Corporate bonds	41,164	—	41,164	—
Municipal bonds	3,546	—	3,546	—
Asset-backed securities	10,984	—	10,984	—
Long-term investments:				
U.S. government treasury bonds	15,072	15,072	—	—
Corporate bonds	72,757	—	72,757	—
Municipal bonds	2,426	—	2,426	—
U.S. government agency bonds	1,168	—	1,168	—
Asset-backed securities	16,272	—	16,272	—
Other assets:				
Investments in privately held companies	11,225	—	—	11,225
	$ 442,613	$ 283,071	$ 148,317	$ 11,225

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, the net losses we recognized during the three months ended March 31, 2022 were not material and we recognized net gains of $12.4 million during the three months ended March 31, 2021. The fair value of foreign exchange forward contracts outstanding was $8.4 million as of March 31, 2022 and was not material as of December 31, 2021.

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

	March 31, 2022	
	Local Currency Amount	Notional Contract Amount (USD)
Euro	€189,795	$ 210,031
Chinese Yuan	¥520,500	81,862
Polish Zloty	PLN324,500	77,086
Canadian Dollar	C$96,000	76,733
Brazilian Real	R$323,700	67,665
Japanese Yen	¥5,666,200	46,621
British Pound	£32,275	42,394
Russian Ruble	3,700,000	35,885
Swiss Franc	CHF17,270	18,692
Israeli Shekel	ILS54,210	17,085
Mexican Peso	M$281,560	14,127
Australian Dollar	A$5,000	3,748
		$ 691,929

	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):

	March 31, 2022	December 31, 2021
Raw materials	$ 133,808	$ 123,234
Work in process	79,495	51,706
Finished goods	62,366	55,290
Total inventories	$ 275,669	$ 230,230

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

	March 31, 2022	December 31, 2021
Value added tax receivables	$ 134,941	$ 93,610
Prepaid expenses	74,069	70,218
Other current assets	32,329	31,477
Total prepaid expenses and other current assets	$ 241,339	$ 195,305

Accrued liabilities consist of the following (in thousands):

	March 31, 2022	December 31, 2021
Accrued payroll and benefits	$ 156,272	$ 288,355
Accrued expenses	66,211	67,169
Accrued income taxes	45,646	33,838
Accrued sales and marketing expenses	41,221	41,387
Accrued professional fees	36,340	31,457
Accrued property, plant and equipment	25,296	46,561
Current operating lease liabilities	25,243	22,719
Other accrued liabilities	68,842	75,829
Total accrued liabilities	$ 465,071	$ 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):

	Three Months Ended March 31,	
	2022	2021
Balance at beginning of period	$ 16,169	$ 12,615
Charged to cost of net revenues	3,536	4,280
Actual warranty expenditures	(3,612)	(3,160)
Balance at end of period	$ 16,093	$ 13,735

Deferred revenues consist of the following (in thousands):

	March 31, 2022	December 31, 2021
Deferred revenues - current	$ 1,212,067	$ 1,152,870
Deferred revenues - long-term [1]	$ 146,998	$ 136,684

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

During the three months ended March 31, 2022 and 2021, we recognized $973.2 million and $894.8 million of net revenues, respectively, of which $184.9 million and $125.8 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 March 31, 2022 were $1,385.4 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 three months ended March 31, 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	(642)	(5,940)	(6,582)
Balance as of March 31, 2022	$ 111,566	$ 300,399	$ 411,965

Intangible Long-Lived Assets

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

	Weighted Average Amortization Period (in years)	Gross Carrying Amount as of March 31, 2022	Accumulated Amortization	Accumulated Impairment Loss	Net Carrying Value as of March 31, 2022
Existing technology	10	$ 104,531	$ (25,068)	$ (4,328)	$ 75,135
Customer relationships	11	55,000	(26,894)	(10,751)	17,355
Trademarks and tradenames	10	17,200	(5,006)	(4,179)	8,015
Patents	8	6,511	(4,693)	—	1,818
		$ 183,242	$ (61,661)	$ (19,258)	102,323
Foreign currency translation adjustments					1,176
Total intangible assets, net					$ 103,499

	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 March 31, 2022 is as follows (in thousands):

Fiscal Year Ending December 31,	Amortization
Remainder of 2022	$ 11,459
2023	14,997
2024	13,831
2025	13,455
2026	12,849
Thereafter	35,732
Total	$ 102,323

Amortization expense for the three months ended March 31, 2022 and 2021 was $4.3 million and $3.9 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 March 31, 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

2018 Securities Class Action Lawsuit

On November 5, 2018, a class action lawsuit against Align and three of our executive officers was filed in the U.S. District Court for the Northern District of California on behalf of a purported class of purchasers of our common stock. The complaint generally alleged claims under the federal securities laws and sought monetary damages in an unspecified amount and costs and expenses incurred in the litigation. On December 12, 2018, a similar lawsuit was filed in the same court on behalf of a purported class of purchasers of our common stock. On November 29, 2019, the lead plaintiff filed an amended consolidated complaint against Align and two of our executive officers alleging similar claims as the initial complaints on behalf of a purported class of purchasers of our common stock from May 23, 2018 and October 24, 2018. On September 9, 2020, Defendants’ motion to dismiss the amended consolidated complaint was granted in part and denied in part. On June 30, 2021, counsel for the parties signed a Stipulation and Agreement of Settlement to resolve all claims for $16 million. The settlement amount will be funded by insurance proceeds and consequently, we recorded a short term liability and a receivable for this amount in our consolidated financial statements. The Court granted final approval of the settlement on April 28, 2022 and dismissed the case with prejudice.

2019 Shareholder Derivative Lawsuit

In January 2019, three derivative lawsuits were filed in the U.S. District Court for the Northern District of California which were later consolidated, purportedly on behalf of Align, naming as defendants the then current members of our Board of Directors along with certain of our executive officers. The allegations in the complaints are similar to those asserted in the 2018 Securities Class Action Lawsuit, but the complaints assert various state law causes of action, including for breaches of fiduciary duty, insider trading, and unjust enrichment. The complaints seek unspecified monetary damages on behalf of Align, which is named solely as a nominal defendant against whom no recovery is sought, as well as disgorgement and the costs and expenses associated with the litigation, including attorneys' fees. The consolidated action was stayed until the final disposition of the 2018 Securities Class Action Lawsuit on 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 the final disposition of the 2018 Securities Class Action Lawsuit on 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 and the Panel took the matter under submission. 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.

3Shape Litigation

On February 7, 2022, Align and 3Shape, a Danish corporation, settled their outstanding patent infringement and antitrust litigation, which began in November 2017. The terms of the settlement are confidential, and the settlement has not had a material effect on Align's ongoing operations and financial results. The outstanding cases have all been dismissed with prejudice.

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 January 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. Align filed a motion to dismiss the third amended complaint, which the Court denied. Align has not yet responded to the third amended complaint. A jury trial is scheduled to begin in this matter on January 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.

As required by the Award, Align tendered its membership interests for a purchase price that SDC claimed to be Align's "capital account" balance. Align disputed that the SDC Entities properly determined the value of Align's "capital account" balance as of October 31, 2017. Consequently, on July 3, 2019, Align filed a confidential demand for arbitration challenging the propriety of the SDC Entities' determination. On March 12, 2021 the Arbitrator issued a final award in favor of Align and against SDC finding that the SDC entities owed Align an additional $43.4 million plus interest. SDC paid the amount due to Align on March 17, 2021.

On August 27, 2020, Align initiated a confidential arbitration proceeding against the SDC entities before the American Arbitration Association in San Jose, California. This arbitration relates to the Strategic Supply Agreement ("Supply Agreement") entered into between the parties in 2016. The complaint alleges that the SDC Entities breached the Supply Agreement's terms, causing damages to Align in an amount to be determined. On January 19, 2021, SDC filed a counterclaim alleging that Align breached the Supply Agreement. Align denies the SDC Entities' allegations in the counterclaim and will vigorously defend itself against them. This arbitration hearing is set for July 18-29, 2022.

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

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

Note 7. Commitments and Contingencies

Off-Balance Sheet Arrangements

As of March 31, 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 March 31, 2022, we did not have any material indemnification claims that were probable or reasonably possible.

Note 8. Stockholders' Equity

As of March 31, 2022, the 2005 Incentive Plan, as amended, has a total reserve of 27,783,379 shares of which 3,752,174 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 months ended March 31, 2022 and 2021 is as follows (in thousands):

	Three Months Ended March 31,	
	2022	2021
Cost of net revenues	$ 1,514	$ 1,306
Selling, general and administrative	24,725	21,844
Research and development	5,382	4,091
Total stock-based compensation	$ 31,621	$ 27,241

Restricted Stock Units ("RSUs")

The fair value of RSUs is based on our closing stock price on the date of grant. RSUs granted generally vest over a period of four years. A summary for the three months ended March 31, 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	217	499.14		
Vested and released	(176)	330.33		
Forfeited	(11)	423.61		
Unvested as of March 31, 2022	522	$ 435.22	1.8	$ 227,614

As of March 31, 2022, we expect to recognize $192.2 million of total unamortized compensation costs, net of estimated forfeitures, related to RSUs over a weighted average period of 2.8 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 of eligible to vest in the future is 250% of the MSUs initially granted.

The following table summarizes the MSU performance for the three months ended March 31, 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 March 31, 2022	144	$ 725.73	1.7	$ 62,814

[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 March 31, 2022, we expect to recognize $62.3 million of total unamortized compensation costs, net of estimated forfeitures, related to MSUs over a weighted average period of 1.7 years.

Employee Stock Purchase Plan

As of March 31, 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:

	Three Months Ended March 31,	
	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 March 31, 2022, we expect to recognize $20.0 million of total unamortized compensation costs related to future employee stock purchases over a weighted average period of 1.0 year.

Note 9. Common Stock Repurchase Program

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 March 31, 2022, we have $649.9 million available for repurchase under the May 2021 Repurchase Program.

During February 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.

Subsequent to the first quarter, on April 29, 2022, we entered into an ASR to repurchase $200.0 million of our common stock. We paid $200.0 million and received an initial delivery of approximately 0.6 million shares based on current market prices. The final number of shares to be repurchased will be based on our volume-weighted average stock price under the terms of the ASR, less an agreed upon discount.

Note 10. Accounting for Income Taxes

Our provision for income taxes was $53.2 million and $61.2 million for the three months ended March 31, 2022 and 2021, respectively representing effective tax rates of 28.4% and 23.4%, respectively. Our effective tax rate differs from the statutory federal income tax rate of 21% for both the three months ended March 31, 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 months ended March 31, 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 2016, 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 three months ended March 31, 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 $68.3 million and $63.3 million as of March 31, 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 March 31, 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 March 31,	
	2022	**2021**
Numerator:		
Net income	$ 134,298	$ 200,376
Denominator:		
Weighted average common shares outstanding, basic	78,742	79,000
Dilutive effect of potential common stock	451	798
Total shares, diluted	79,193	79,798
Net income per share, basic	$ 1.71	$ 2.54
Net income per share, diluted	$ 1.70	$ 2.51
Anti-dilutive potential common shares [1]	151	76

[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):

	Three Months Ended March 31,	
	2022	2021
Non-cash investing and financing activities:		
Acquisition of property, plant and equipment in accounts payable and accrued liabilities	$ 58,876	$ 45,354
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	$ 7,292	$ 6,923
Right-of-use assets obtained in exchange for lease obligations:		
Operating leases	$ 12,262	$ 7,369

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 March 31, 2022	Three Months Ended March 31, 2021
Net revenues		
Clear Aligner	$ 809,696	$ 753,269
Systems and Services	163,523	141,502
Total net revenues	$ 973,219	$ 894,771
Gross profit		
Clear Aligner	$ 605,696	$ 584,534
Systems and Services	103,650	92,564
Total gross profit	$ 709,346	$ 677,098
Income from operations		
Clear Aligner	$ 312,719	$ 327,465
Systems and Services	50,799	47,228
Unallocated corporate expenses	(165,436)	(149,247)
Total income from operations	$ 198,082	$ 225,446
Stock-based compensation		
Clear Aligner	$ 2,854	$ 2,294
Systems and Services	214	171
Unallocated corporate expenses	28,553	24,776
Total stock-based compensation	$ 31,621	$ 27,241
Depreciation and amortization		
Clear Aligner	$ 13,767	$ 11,120
Systems and Services	6,922	4,545
Unallocated corporate expenses	8,937	9,970
Total depreciation and amortization	$ 29,626	$ 25,635

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 March 31, 2022	Three Months Ended March 31, 2021
Total segment income from operations	$ 363,518	$ 374,693
Unallocated corporate expenses	(165,436)	(149,247)
Total income from operations	198,082	225,446
Interest income	677	1,643
Other income (expense), net	(11,273)	34,532
Net income before provision for income taxes	$ 187,486	$ 261,621

Geographical Information

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

	Three Months Ended March 31, 2022	Three Months Ended March 31, 2021
Net revenues [1]:		
U.S.	$ 420,920	$ 383,002
Switzerland	331,739	315,450
Other International	220,560	196,319
Total net revenues	$ 973,219	$ 894,771

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

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

	March 31, 2022	December 31, 2021
Long-lived assets [1]:		
Switzerland	$ 477,312	$ 444,205
U.S.	209,220	210,582
China	126,623	125,346
Other International	453,019	423,050
Total long-lived assets	$ 1,266,174	$ 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 expectations regarding the near and long-term implications of the COVID-19 pandemic on the global and regional economies, our beliefs and expectations regarding macroeconomic conditions, including inflation, customer and consumer sentiments, 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, 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, including sanctions and retaliatory sanctions related to the military conflict in Ukraine, 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 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:

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 the pandemic continues and new variants of the virus emerge, we are seeing a resurgence of measures 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. Vaccinations and pandemic containment measures are driving the pace of economic recovery unevenly in various regions. These preventative measures 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., and consequently, we expect to substantially reopen our offices in those countries in the second quarter of 2022 and are adopting a flexible hybrid schedule that will allow many of our employees the opportunity to collaborate and connect with others in the office three days per week while having the option to work remotely other days. We believe that this added flexibility will benefit employees and Align overall.

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

Macroeconomic Challenges and Military Conflict in Ukraine

Our revenues and costs are also susceptible to fluctuations in macroeconomic conditions, in line with changes in customer and consumer sentiment and demand, capital equipment seasonality, inflation and slowing economic growth and contractions, increasing prices for commodities and services and transportation costs, disruptions in the manufacturing, supply and distribution operations of us and our suppliers. These factors are further exacerbated by projections for slowing economic growth and contractions in the future. The nature and extent of the impact of these factors varies by region and remain uncertain and unpredictable.

The military conflict between Russia and Ukraine is increasing the unpredictability of the already uncertain macroeconomic conditions. We are deeply concerned about the devastating events unfolding in Ukraine and the significant humanitarian, economic and societal tragedy unfolding there. Our top priority is ensuring 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 employ a significant number of research and development personnel in Russia as well as sales and marketing 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. Our leadership continues to closely monitor the situation and evaluate ways in which we can support local leadership and 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 are creating significant global and regional economic challenges that bring significant uncertainty and unpredictability to our operations.

Moreover, many of our international operations are denominated in currencies other than the U.S. dollar and any weakening of the foreign currencies against the U.S. dollar could have a negative impact on our financial condition and results of operations. During the first quarter 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. While the weakening did not materially impact our financial results in the first quarter of 2022, we continue to monitor the situation for future risks.

Overall, we expect the ramifications from the impacts of COVID-19, unpredictable macroeconomic conditions, and the military conflict in Ukraine 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 efficiencies in our processes, and adjusting our business models to the changing circumstances. Specifically, we are managing cost impacts through pricing actions and implementing cost saving measures and averting supply chain shortages and delays 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 greater than historically required. We have also increased our cybersecurity measures to detect, protect and recover against potential incidents. We are actively monitoring the impact of COVID-19 cases and restrictions, macroeconomic challenges and the conflict in Ukraine and assessing various means to potentially mitigate material unfavorable impacts on our future results.

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 March 31, 2022, we achieved the following:

- Revenues of $973.2 million, an increase of 8.8% year-over-year;
- Clear Aligner revenues of $809.7 million, an increase of 7.5% year-over-year reflecting the expanding opportunity for Invisalign system treatment among adults globally, as well as the underlying orthodontic market as we continue to build awareness of the Invisalign brand and drive utilization among teens and younger patients through increased consumer marketing
    - Americas Clear Aligner revenues of $376.2 million, an increase of 5.2% year-over-year;
    - International Clear Aligner revenues of $371.1 million, an increase of 5.0% year-over-year;
    - Clear Aligner volume increase of 0.5% year-over-year and Clear Aligner volume increase for teenage patients of 6.0% year-over-year;
- Imaging Systems and CAD/CAM Services revenues of $163.5 million, an increase of 15.6% year-over-year primarily as a result of higher iTero service revenues mostly due to a larger scanner install base;
- Income from operations of $198.1 million and operating margin of 20.4%;
- Effective tax rate of 28.4%;
- Net income of $134.3 million with diluted net income per share of $1.70;
- Cash, cash equivalents and marketable securities of $1,120.6 million as of March 31, 2022;
- Operating cash flow of $30.5 million;
- Capital expenditures of $87.3 million, predominantly related to increases in our manufacturing capacity and facilities; and
- Number of employees was 23,625 as of March 31, 2022, an increase of 24.5% year-over-year.

Other Statistical Data and Trends

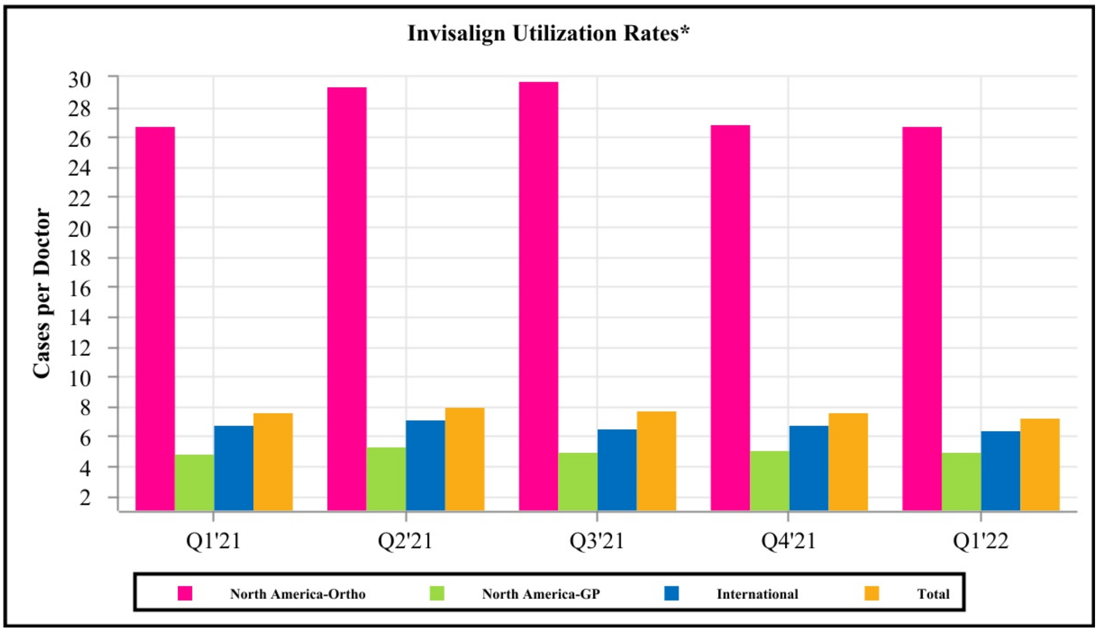
- As of March 31, 2022, approximately 12.8 million people worldwide have been treated with our Invisalign system, approximately 73,000 iTero scanners have been sold and approximately 49,000 exocad software licenses have been installed. Management measures these results by comparing to the millions of 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 first quarter of 2022, total Invisalign cases submitted with a digital scanner in the Americas increased to 90.6%, up from 85.5% in the first quarter of 2021 and international scans increased to 82.8%, up from 75.1% in the first quarter of 2021. For the first quarter of 2022, 97.1% of Invisalign cases submitted by North American orthodontists were submitted digitally.

- Total utilization rate in the first quarter of 2022 decreased to 7.3 cases per doctor compared to 7.6 cases per doctor in the first 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 remained consistent at 26.8 cases per doctor in both the first quarter of 2022 and 2021 and the utilization rate among our North American GP customers increased to 5.0 cases per doctor in the first quarter of 2022 compared to 4.8 cases per doctor in the first quarter of 2021.

    - *International:* International doctor utilization rate was 6.4 cases per doctor in the first quarter of 2022 compared to 6.8 cases per doctor in the first 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 months ended March 31, 2022 and 2021 are as follows (in millions):

	Three Months Ended March 31,			
Net Revenues	2022	2021	Change	
Clear Aligner net revenues:				
Americas	$ 376.2	$ 357.5	$ 18.8	5.2 %
International	371.1	353.3	17.8	5.0 %
Non-case	62.4	42.5	19.9	46.8 %
Total Clear Aligner net revenues	$ 809.7	$ 753.3	$ 56.4	7.5 %
Systems and Services net revenues	163.5	141.5	22.0	15.6 %
Total net revenues	$ 973.2	$ 894.8	$ 78.4	8.8 %

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 months ended March 31, 2022 and 2021 is as follows (in thousands):

	Three Months Ended March 31,			
	2022	2021	Change	
Total case volume	598.8	595.8	3.0	0.5 %

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

For the three months ended March 31, 2022, total net revenues increased by $78.4 million as compared to the same period in 2021, primarily due to an increase in Clear Aligner ASP, an increase in Clear Aligner non-case revenues, and increased service revenues.

Clear Aligner - Americas

For the three months ended March 31, 2022, Americas net revenues increased by $18.8 million as compared to the same period in 2021, primarily due to an increase in ASP which increased net revenues by $24.3 million. Higher ASP was mainly due to processing fees charged on most clear aligner orders and price increases in certain markets which increased revenues by $11.6 million and lower net deferrals which increased net revenues by $9.8 million. Higher ASP was partially offset by 1.5% decrease in case volume, which resulted in lower net revenues of $5.5 million.

Clear Aligner - International

For the three months ended March 31, 2022, International net revenues increased by $17.8 million as compared to the same period in 2021, primarily due to a 3.0% increase in case volume, which resulted in higher net revenues of $10.7 million. Higher ASP increased net revenues by $7.1 million largely due to lower net deferrals which increased net revenues by $20.6 million, and processing fees charged on most clear aligner orders which increased net revenues by $13.9 million. The increase in ASP were partially offset by unfavorable exchange rates which decreased net revenues by $22.9 million.

Clear Aligner - Non-Case

For the three months ended March 31, 2022, non-case net revenues increased by $19.9 million as compared to the same period 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 March 31, 2022, Systems and Services net revenues increased by $22.0 million as compared to the same period in 2021 primarily due to higher service revenues which increased $17.1 million mostly due to a larger install base. Net revenues also increased $4.9 million mainly due to a higher number of scanners sold.

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

	Three Months Ended March 31, 2022	Three Months Ended March 31, 2021	Change
Clear Aligner			
Cost of net revenues	$ 204.0	$ 168.7	$ 35.3
% of net segment revenues	*25.2 %*	*22.4 %*	
Gross profit	$ 605.7	$ 584.5	$ 21.2
Gross margin %	*74.8 %*	*77.6 %*	
Systems and Services			
Cost of net revenues	$ 59.9	$ 48.9	$ 10.9
% of net segment revenues	*36.6 %*	*34.6 %*	
Gross profit	$ 103.7	$ 92.6	$ 11.1
Gross margin %	*63.4 %*	*65.4 %*	
Total cost of net revenues	$ 263.9	$ 217.7	$ 46.2
% of net revenues	*27.1 %*	*24.3 %*	
Gross profit	$ 709.3	$ 677.1	$ 32.2
Gross margin %	*72.9 %*	*75.7 %*	

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 months ended March 31, 2022, our gross margin percentage decreased as compared to the same period in 2021, primarily due to a higher mix of additional aligners, higher freight costs and manufacturing spend. These factors were offset in part by higher ASP.

Systems and Services

For the three months ended March 31, 2022, our gross margin percentage decreased as compared to the same period in 2021, primarily due to manufacturing inefficiencies driven by lower production volumes which was offset in part by higher service revenues and ASP.

Selling, general and administrative (in millions):

	Three Months Ended March 31, 2022	Three Months Ended March 31, 2021	Change
Selling, general and administrative	$ 439.5	$ 397.1	$ 42.3
% of net revenues	*45.2 %*	*44.4 %*	

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 March 31, 2022, selling, general and administrative expense increased compared to the same period in 2021, primarily due to higher compensation related costs of $18.4 million from higher salaries and fringe benefits due to increased headcount as we continue to invest in sales and marketing to penetrate into new markets. Additionally, we also incurred higher advertising and marketing costs of $27.8 million during the three months ended March 31, 2022.

Research and development (in millions):

	Three Months Ended March 31,		
	2022	2021	Change
Research and development	$ 71.8	$ 54.5	$ 17.3
% of net revenues	*7.4 %*	*6.1 %*	

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 months ended March 31, 2022, research and development expense increased compared to the same period 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 March 31,		
	2022	2021	Change
Clear Aligner			
Income from operations	$ 312.7	$ 327.5	$ (14.7)
Operating margin %	*38.6 %*	*43.5 %*	
Systems and Services			
Income from operations	$ 50.8	$ 47.2	$ 3.6
Operating margin %	*31.1 %*	*33.4 %*	
Total income from operations [1]	$ 198.1	$ 225.4	$ (27.4)
Operating margin %	*20.4 %*	*25.2 %*	

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 March 31, 2022, our operating margin percentage decreased compared to the same period in 2021, primarily due to lower gross margins in addition to higher operating expenses as a percentage of revenues.

Systems and Services

For the three months ended March 31, 2022, our operating margin percentage decreased compared to the same period in 2021, primarily due to lower gross margins.

Interest income (in millions):

	Three Months Ended March 31,		
	2022	2021	Change
Interest income	$ 0.7	$ 1.6	$ (1.0)
% of net revenues	*0.1 %*	*0.2 %*	

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

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

For the three months ended March 31, 2022, interest income decreased compared to the same period in 2021 mainly due to interest earned from the SDC arbitration award in the first quarter of 2021.

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

	Three Months Ended March 31,		
	2022	2021	Change
Other income (expense), net	$ (11.3)	$ 34.5	$ (45.8)
% of net revenues	*(1.2)%*	*3.9 %*	

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

Other income (expense), net, generally includes foreign exchange gains and losses, gains and losses on foreign currency forward contracts, interest expense, gains and losses on equity investments and other miscellaneous charges.

For the three months ended March 31, 2022, other income (expense), net decreased compared to the same period in 2021 primarily due to a $43.4 million gain related to the SDC arbitration award recognized in the first quarter of 2021.

Provision for income taxes (in millions):

	Three Months Ended March 31,		
	2022	2021	Change
Provision for income taxes	$ 53.2	$ 61.2	$ (8.1)
Effective tax rates	*28.4 %*	*23.4 %*	

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 months ended March 31, 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 months ended March 31, 2022.

The increase in our effective tax rate for the three months ended March 31, 2022 compared to the same period 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 March 31, 2022 and December 31, 2021, we had the following cash and cash equivalents and short-term and long term marketable securities (in thousands):

	March 31, 2022	December 31, 2021
Cash and cash equivalents	$ 926,119	$ 1,099,370
Marketable securities, short-term	86,749	71,972
Marketable securities, long-term	107,695	125,320
Total	$ 1,120,563	$ 1,296,662

As of March 31, 2022 and December 31, 2021, approximately $667.6 million and $713.8 million of cash, cash equivalents and marketable securities were held by our foreign subsidiaries, respectively. Our intent is to permanently reinvest our earnings from our international operations going forward, and our current plans do not require us to repatriate them to fund our U.S. operations as we generate sufficient domestic operating cash flow and have access to external funding under our $300.0 million revolving line of credit. We believe that our current cash balances and the borrowing capacity under our credit facility, if necessary, will be sufficient to fund our business for at least the next 12 months.

The geopolitical situation between Russia and Ukraine and the imposition of sanctions against Russian banks or international bank messaging systems could impact our ability to access our cash in Russia but would not materially impact our liquidity position. As of March 31, 2022, cash and cash equivalents domiciled in Russia represent approximately 5.0% of our total cash, cash equivalents and marketable securities which is required to fund their working capital.

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 is expected to begin serving doctors in 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 March 31, 2022, we have $649.9 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. Subsequent to the first quarter, on April 29, 2022, we entered into an accelerated stock repurchase agreement to repurchase $200.0 million under the program.

- There have been no material changes to the purchase commitments for goods and services and future operating lease payments during the period 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 three months ended March 31, 2022 and 2021 (in thousands):

	Three Months Ended March 31,	
	2022	**2021**
Net cash flow provided by (used in):		
Operating activities	$ 30,498	$ 227,187
Investing activities	(90,198)	4,566
Financing activities	(111,742)	(53,435)
Effect of exchange rate changes on cash, cash equivalents, and restricted cash	(1,826)	(7,487)
Net (decrease) increase in cash, cash equivalents, and restricted cash	$ (173,268)	$ 170,831

Operating Activities

For the three months ended March 31, 2022, cash flows from operations of $30.5 million resulted primarily from our net income of approximately $134.3 million, as well as the following:

Significant adjustments to net income

- Stock-based compensation of $31.6 million related to equity awards granted to employees and directors;
- Depreciation and amortization of $29.6 million related to our investments in property, plant and equipment and intangible assets; and
- Changes in deferred taxes of $17.5 million primarily related to amortization and adjustments to our deferred tax assets of our Swiss entity.

Significant changes in working capital

- Decrease of $126.4 million in accrued and other long-term liabilities primarily due to payments of our 2021 corporate bonus in addition to the timing of payment of other activities;
- Increase of $69.0 million in deferred revenues primarily related to increased sales volume in both our Clear Aligner and Systems and Services segments and timing of revenue recognition;
- Increase of $55.5 million in accounts receivable which is primarily a result of increased sales;
- Increase of $49.5 million in inventories to support our demand, including safety stock, due to shipping delays during the COVID-19 pandemic as well as long lead times with our suppliers; and
- Increase of $48.7 million in prepaid expenses and other assets due to the timing of payment and activities.

Investing Activities

Net cash used in investing activities was $90.2 million for the three months ended March 31, 2022, which primarily consisted of purchases of property and plant and equipment of $87.3 million.

Financing Activities

Net cash used in financing activities was $111.7 million for the three months ended March 31, 2022, which consisted of our open market common stock repurchases of $75.0 million and payroll taxes paid for equity awards through share withholdings of $51.5 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 and 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 the COVID-19 pandemic and the military conflict between Russia and Ukraine. Further discussion of the impact on our business due to the COVID-19 pandemic and the military conflict between Russia and Ukraine 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 March 31, 2022, we had approximately $194.4 million invested in available-for-sale marketable securities. An immediate 10% change in interest rates would not have a material adverse impact on our future operating results and cash flows.

We do not enter into investments for trading or speculative purposes and have not used any derivative financial instruments to manage our interest rate risk exposure. Based on interest bearing liabilities we have as of March 31, 2022, we are not subject to risks from immediate interest rate increases.

Currency Rate Risk

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

We primarily enter into foreign currency forward contracts to minimize the short-term impact of foreign currency exchange rate fluctuations on cash and certain trade and intercompany receivables and payables. These forward contracts are not designated as hedging instruments and do not subject us to material balance sheet risk due to fluctuations in foreign currency exchange rates. The gains and losses on these forward contracts are intended to offset the gains and losses in the underlying foreign currency denominated monetary assets and liabilities being economically hedged. These instruments are marked to market through earnings every period and generally are one month in original maturity. 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., the European Union and the United Kingdom 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 March 31, 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

While inflation may impact our costs and revenues, we believe the effects of inflation, if any, on our results of operations and financial condition have not been significant. Nonetheless, 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 March 31, 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 March 31, 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

- 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.
- Demand for our products may not increase as rapidly as we anticipate or may decrease due to a variety of factors, including changing consumer demand, inflation, weakness in general economic conditions, recessions and resistance to non-traditional treatment methods.
- 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.
- If we fail to sustain or increase revenue growth while controlling expenses, our profitability may decline.
- Our operating results have and will continue to fluctuate in the future, which makes predicting the timing and amount of our revenues, costs and expenditures difficult.
- 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 stock price.
- 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 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 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.
- Compliance with current or future environmental, social, and governance ("ESG") laws may materially increase our costs, expose us to potential liability and otherwise materially impact our business.

General Risk Factors

- 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.
- Business disruptions could seriously harm our financial condition.
- Changes in, or interpretations of, accounting rules and regulations, could result in unfavorable accounting charges.
- We are required to annually assess our internal control over financial reporting and any adverse results from such assessment may result in a loss of investor confidence in our financial reports and have an adverse effect on our stock price.
- We are exposed to fluctuations in currency exchange rates and inflation, each of which could negatively affect our financial condition and results of operations.
- 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.
- Increased scrutiny of our ESG policies and practices have and will likely continue to result in additional costs and risks, and may adversely impact our reputation, employee retention, and willingness of customers and suppliers to do business with us.

Risks Relating to our Business Operations and Strategy

Our results of operations have been materially adversely affected by global and regional efforts to mitigate the spread of COVID-19 and we expect this will continue in as yet unknown ways and to varying degrees 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 the pandemic, 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, many continue to operate at less than pre-pandemic capacities. In addition, new variants of the virus have caused unpredictable fluctuations in the number of patients seeking dental treatment and doctors providing services and treatments. For instance, we believe recent outbreaks of the Omicron variant in the U.S., Europe and other regions in the fourth quarter of 2021 contributed to depressed demand for our products in that quarter and outbreaks in China in the first quarter of 2022 caused widespread population lockdowns that broadly impacted economic activities there. 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 have 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, in 2020 we implemented measures aimed at limiting its spread for the health and safety of our employees, customers, patients and the communities in which we live and work as well as in accordance with orders and decrees of governmental agencies. These measures included diagnostic screenings at our facilities, increased social distancing mandates, closures of physical offices, manufacturing and treatment planning facilities, including our U.S. corporate headquarters and regional facilities worldwide, implementing remote working where feasible, 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. Furthermore, if employees perceive the protocols and requirements we implement to create a safe and effective work environment to be inadequate, overly burdensome or no longer necessary, or alternatively, if we require employees to return to the office when they prefer the safety or convenience of working from home, employees may choose to leave, 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 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 by competitors such as price reductions, aggressive product promotions, changes in or the launch or termination of products or product lines, and mergers, consolidations and liquidations;
- the confidence of our customers and patients that our products and solutions are sanitary and safe to use;
- data privacy and cybersecurity risks from new or expanded use of remote working and/or teledentistry by our suppliers, customers, and us, including new or expanded use of online service platforms, products and solutions such as video conferencing applications, doctor, consumer and patient apps, inadequately secured computing networks,

servers, software or software applications, overheard telephone conversations, viewable computer screens, stolen passwords or access information, increased phishing and other cyber threats;
- the impact of remote working arrangements on our financial reporting systems and internal control over financial reporting, including our ability to ensure information required to be disclosed is timely and accurately recorded, processed, summarized, reported, and communicated to management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow for timely decisions regarding required disclosure; and
- diversion of management'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 in the U.S., United Kingdom, and 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. 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, making many of the risks listed in this Quarterly Report on Form 10-Q more likely to occur and more harmful 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.

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, should hostilities spread to other countries such as Poland, where we are building our new aligner fabrication facility scheduled to begin in the second quarter this year, completion could be delayed or production impaired, once it is operational.

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 and business outlook.

Demand for our products may not increase as rapidly as we anticipate or may decrease due to a variety of factors, including changing consumer demand, inflation, weakness in general economic conditions, recessions and resistance to non-traditional treatment methods.

Consumer spending habits are affected by, among other things, pandemics, inflation, weakness in general economic conditions, recessions, wars and military actions, levels of employment, salaries and wage rates, debt obligations, discretionary income, 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. In addition, 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.

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 scanners have become 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 expected;
- the growth of CAD/CAM solutions does not produce the results expected; 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 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 any of the foregoing were to occur, our net revenues, gross profit, gross margin and net income may decline.

Competition in the markets for our products is increasing and we expect aggressive competition from existing competitors, other companies that may introduce new technologies 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 as new offerings become available 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 in the clear aligner market 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. 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 many 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 manufacturing facility in Poland currently under construction. Also, we maintain significant regional sales and marketing operations in Switzerland, Singapore and China along with research and development operations globally, including in the U.S., Russia, Israel and Germany. Our reliance on international operations exposes us to risks and uncertainties that may affect our business or results of operations, including:

- difficulties managing international operations, including any travel restrictions on us or our customers;
- fluctuations in currency exchange rates;
- import and export risks, including shipping delays, 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 local 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 tax consequences.

The potential impacts of the United Kingdom's ("UK") withdrawal from the EU are still unfolding and have impacted varying parts of its economy at different times since the withdrawal. As the UK negotiates new trade deals and implements new laws and regulations following its withdrawal, the UK's actions could, among other potential outcomes, adversely affect the tax, tax treaty, currency, operational, legal and regulatory regimes to which our businesses are subject, including those involving data privacy and the regulation of medical devices. The withdrawal could also, among other potential outcomes, disrupt the free and timely movement of goods, services, people, data and information and significantly disrupt trade. Further, uncertainty around these and related issues could lead to adverse effects on the economies and political stability of the UK, EU and the other economies in which we operate.

Should any of these factors, either individually or in combination, occur they could materially impact our international operations and adversely affect our business as a whole.

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, bring to market, market, and 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.

Moreover, we have a complex, global intraoral scanner install base of older and newer models. These models are continually updated to add, expand or improve on existing or new features with our software releases or hardware improvements, updates from third party software or 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 third party software or any changes to the foregoing will not be incompatible with, or have a negative impact on the functionality of our intraoral scanners. As a result, there have been and may be widespread failures of our intraoral scanners or we may experience epidemic failures of our 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 our 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.

In addition, as part of our effort to accommodate our customers' needs and demands, we periodically introduce new business and sales initiatives, 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.

As we continue to grow, we are subject to growth related risks, including risks related to excess or constrained capacity and operational inefficiencies at our manufacturing and treat facilities.

We are subject to growth related risks, including excess or constrained capacity and pressure on our internal systems, personnel and suppliers. In order to manage current operations and future growth effectively, we must continue implementing and improving our operational, financial and management information systems, hire, train, motivate, manage and retain employees, and ensure our suppliers remain diverse and capable of meeting growing demand for the systems, raw materials, parts and components essential to the manufacture and delivery of our products. We may be unable to manage such growth effectively while balancing near-term efforts to meet existing demand, including adding personnel, creating scalable, secure and robust systems and operations, and automating processes needed for long term efficiencies. Any such failure could have a material adverse impact on our business, operations and prospects.

We continue to establish treatment planning and manufacturing facilities closer to our international customers in order to provide 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 is required to temporarily or permanently, partially or fully shut down, or demand for our products outpaces our ability to hire qualified personnel and effectively implement systems and infrastructure, we may be unable to fulfill orders timely, or at all, which may negatively impact our financial results, reputation and overall business.

In addition, because adapting production capacity and related cost structures to changing market conditions takes time, our facilities' capacity may at times exceed or fall short of our production requirements. For instance, as a result of the COVID-19 pandemic, sales in the final weeks of the first quarter of 2020 declined substantially and operations at our manufacturing facilities declined shortly thereafter. 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 variants such as Delta and Omicron, 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. Additionally, if we are required to implement new or modify existing health and safety protocols to safeguard our employees, customers or their patients, productivity could decline. Production of our clear aligners and intraoral scanners are also limited by capacity constraints due to a variety of factors, including labor shortages, shipping delays, our dependency on third-party vendors for key materials, parts, components and equipment, and limited production yields. Any or all of these problems could result in the loss of customers, provide an opportunity for competing products to gain market acceptance and otherwise harm our business and financial results 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.

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 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 install 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. 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.

If we fail to sustain or increase revenue growth while controlling expenses, our profitability may decline.

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

Our operating results have and will continue to fluctuate in the future, which makes predicting the timing and amount of our revenues, costs and expenditures difficult.

Our quarterly and annual operating results have and will continue to fluctuate for a variety of reasons, including as a result of changing doctor and consumer product demand. Some of the factors that have historically and in the future could cause our operating results to fluctuate include:

- limited visibility into, and difficulty predicting from quarter to quarter, the types of procedures and level of activities in our customers' practices;
- fluctuations in the number of patients seeking treatment and the number of doctors providing services and treatment as a result of the pandemic and new variants in the virus;
- changes in demand based on geographies, channels, or product mix;
- the level of confidence of doctors in our products and changes in the rates at which they recommend or utilize our products for their patients;
- weakness in consumer spending and confidence, inflation, a slowdown or recession in domestic or international economies;
- higher manufacturing, delivery and inventory costs;
- unanticipated delays and disruptions in the manufacturing process caused by insufficient capacity or availability of raw materials, parts or components, shortages or turnover in the labor force or the introduction of new production processes, power outages or insufficient power, natural or other disasters, pandemics or general economic conditions impacting the solvency of vendors in our supply chain;
- competition in general and competitive developments in our target markets;
- new programs or business models, new product or services introductions or changes or modifications to existing products and services offerings, including any impacts related to the timing of orders, product mix or market cannibalization;
- changes in relationships with DSOs and distributors, including the timing of orders;
- changes in the timing of revenue recognition and changes in our average selling prices, including as a result of the timing of receipt of product orders and shipments, product and services mix, geographic mix, product and services deferrals, the introduction of new products and software releases, product pricing, bundling and promotions, 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;
- the creditworthiness, liquidity and solvency of our customers and their ability to timely make payments when due;
- fluctuations in currency exchange rates against the U.S. dollar;
- our inability to scale, suspend or reduce production and treatment operations based on variations in product demand;
- seasonal fluctuations, including those related to patient demographics such as the seasonality of teen treatments in the U.S., China and Europe as well as the number of doctors in their offices and their availability to take appointments;
- 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;
- timing and fluctuation of spending around marketing and brand awareness campaigns and industry trade shows;
- our reliance on our contract manufacturers for the production of sub-assemblies for our intraoral scanners;
- increased advertising or marketing efforts or aggressive price competition from competitors;
- changes to our effective tax rate;
- major changes in available technology or the preferences of customers may cause our current product offerings to become less competitive or obsolete;

- unanticipated delays or disruptions in our receipt of patient records made through intraoral scanners for any reason;
- disruptions to our business due to political, economic or other social instability or any governmental regulatory or similar actions, including the impact of epidemics and pandemics such as COVID-19, any of which results in changes in consumer spending habits, limiting or restricting patient visits to orthodontists or general practitioners, as well as any impact on workforce absenteeism;
- inaccurate forecasting of net revenues, production and other operating costs;
- investments in research and development to develop new products and enhancements; and
- material impairments of goodwill and long-lived assets.

To respond to these and other factors, we may make business decisions that adversely affect our operating results such as modifications to our pricing policy and payment terms, promotions, development efforts, product releases, business structure or operations. Most of our expenses, such as employee compensation and lease obligations, are relatively fixed in the short term. Moreover, our expense levels are based, in part, on our expectations for future revenues. As a result, if our net revenues for a particular period fall below expectations, we may be unable to timely or effectively reduce spending to offset any shortfall in net revenues. Due to these and other factors, we do not believe that quarter-to-quarter comparisons of our operating results are meaningful.

A disruption in the operations of a primary freight carrier, higher shipping costs or shipping delays could 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 causing our net revenues and gross margin to decline, possibly materially. 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. 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 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 an 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 stock price.

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, these agreements may not provide meaningful protection against the unauthorized use or disclosure of our trade secrets or other confidential information, and adequate remedies may not exist 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 adversely affect our results of operations and stock price.

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

As a supplier of medical devices and solutions, we and many of our 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 marketing and advertising of our products.

The healthcare market itself is 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. Our critical vendors and service providers are similarly subject to various regulations. Our failure or the failure of our suppliers, customers, advertisers and influencers to strictly adhere to clearances or approvals in the labeling, marketing and sales of our products and services could subject us to claims or litigation, including actions alleging false or misleading advertising, unfair or anti-competitive business practices or other violations of laws or regulations, which may result in costly investigations, fines, penalties, as well as material judgments, settlements or decrees. There can be no assurance that we will adequately address the business risks associated with the implementation and compliance with such laws or that we will be able to take advantage of any resulting business opportunities.

Furthermore, in general before we can sell a new medical device or market a new use of or claim for an existing product, we must obtain clearance or approval 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 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 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.

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.

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 or retain personnel, or if our growth harms our corporate culture, it may be more difficult to grow effectively and pursue our strategic priorities.”*

If we are unable to expand our workforce, including key sales and other skilled personnel, retain key personnel or quickly replace personnel with individuals of equivalent technical expertise and qualifications, our net revenues and our ability to maintain market share could be materially harmed.

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

Compliance with current or future environmental, social, and governance (“ESG”) laws may materially increase our costs, expose us to potential liability and otherwise materially impact our business.

Our operations are subject to a variety of existing local, regional and global 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.

General Risk Factors

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.

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.

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

- difficulties maintaining our corporate culture, disruption of morale or decreased loyalty;
- negative impacts to collaboration, performance and productivity;
- increased employee stress, fatigue or “burn out” by employees unable to disengage their work life from the home life;
- increased operational, governance, compliance, and tax risks;
- increased attrition or limits to our ability to attract employees who prefer 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.

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, 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 Mexico and China. 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 can have a significant effect on our reported results and may even retroactively affect previously reported transactions.

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

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

We are exposed to fluctuations in currency exchange rates and inflation, each of which could negatively affect our financial condition and results of operations.

Although the U.S. dollar is our reporting currency, a growing portion of our net revenues and net income are generated in foreign currencies. Net revenues and net income generated by subsidiaries operating outside of the U.S. are translated into U.S. dollars using constantly, often substantially, fluctuating exchange rates. As a result, negative movements in exchange rates against the U.S. dollar have and may increasingly adversely affect our net revenues and net income in our consolidated financial statements. We enter into currency forward contract transactions in an effort to cover some of our exposure to currency fluctuations, but there is no assurance these transactions will fully or effectively hedge our exposure to currency fluctuations, and, under certain circumstances, these transactions could have an adverse effect on our financial condition.

Our customers and consumers are experiencing rising inflation which decreases customer and consumer buying power and demand for our products. We also experienced rising inflationary pressures in 2021 and those pressures are increasing in 2022. In addition to reducing customer and consumer demand, cost inflation, including increases in ocean container rates, raw material prices, labor rates, and domestic transportation costs threaten to impact our profitability and our ability to recover these cost increases through price increases may continue to lag, resulting in downward pressure on our gross margin and operating margin. Any attempts to offset cost increases with price increases may result in greater reductions in sales, increase customer dissatisfaction or otherwise harm our reputation.

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. We continue to monitor this matter and evaluate the related risks and potential impact of LIBOR’s expiration. 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 which could be material and could have an 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 of more acquisitions could lead to negative ratings by analysts or investors, give rise to objections by one or more stockholders or result in stockholder activism, any of which could harm our stock price. Acquisitions can also lead to large non-cash charges that can have an adverse effect on our results of operations as a result of write-offs for items such as future impairments of intangible assets and goodwill or the recording of stock-based compensation.

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

The market price of our common stock is subject to 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;
- 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 economic and industry factors unrelated to our actual performance and future changes in monetary policies, austerity, and other market factors may seriously harm the market price of our common stock, regardless of our operating performance. Historically, 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.

Increased scrutiny of our ESG policies and practices have and will likely continue to result in additional costs and risks, and may adversely impact our reputation, employee retention, and willingness of customers and suppliers to do business with us.

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

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

Unregistered Sales of Equity Securities

None.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

The following table summarizes the stock repurchase activity for the three months ended March 31, 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]
January 1, 2022 through January 31, 2022	—	$ —	—	$ 724,962,500
February 1, 2022 through February 28, 2022	143,581	$ 522.61	143,581	$ 649,926,094
March 1, 2022 through March 31, 2022	—	$ —	—	$ 649,926,094
Total	143,581		143,581	

[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. Subsequent to the first quarter, on April 29, 2022, we entered into an ASR to repurchase $200.0 million of our common stock. We paid $200.0 million and received an initial delivery of approximately 0.6 million shares based on current market prices. The final number of shares to be repurchased will be based on our volume-weighted average stock price under the terms of the ASR, less an agreed upon discount. 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
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.

May 5, 2022	By: /s/ JOSEPH M. HOGAN **Joseph M. Hogan** **President and Chief Executive Officer**
May 5, 2022	By: /s/ JOHN F. MORICI **John F. Morici** **Chief Financial Officer and Executive Vice President, Global Finance**

Exhibit 31.1

CERTIFICATION

I, Joseph M. Hogan, certify that:

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

Date: May 5, 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: May 5, 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 March 31, 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: May 5, 2022

In connection with the Quarterly Report of Align Technology, Inc. (the "Company") on Form 10-Q for the period ending March 31, 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: May 5, 2022