

**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 September 30, 2024
or
 TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission File Number: 000-32259

ALIGN TECHNOLOGY, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

94-3267295
(I.R.S. Employer
Identification No.)

410 North Scottsdale Road, Suite 1300
Tempe, Arizona 85288
(Address of principal executive offices, including zip code)
(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 the 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	<input checked="" type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input type="checkbox"/>
Emerging growth company	<input type="checkbox"/>		

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

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

As of November 1, 2024, the number of shares outstanding of the registrant's Common Stock, \$0.0001 par value, was 74,653,060.

ALIGN TECHNOLOGY, INC.

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PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Net revenues	\$ 977,872	\$ 960,214	\$ 3,003,793	\$ 2,905,534
Cost of net revenues	296,098	297,138	901,575	868,195
Gross profit	681,774	663,076	2,102,218	2,037,339
Operating expenses:				
Selling, general and administrative	434,138	407,992	1,338,222	1,300,876
Research and development	85,272	88,738	269,324	264,670
Legal settlement loss	66	—	31,193	—
Total operating expenses	519,476	496,730	1,638,739	1,565,546
Income from operations	162,298	166,346	463,479	471,793
Interest income and other income (expense), net:				
Interest income	4,003	5,522	11,696	12,280
Other income (expense), net	(371)	(9,757)	(6,993)	(15,749)
Total interest income and other income (expense), net	3,632	(4,235)	4,703	(3,469)
Net income before provision for income taxes	165,930	162,111	468,182	468,324
Provision for income taxes	49,967	40,684	150,627	147,285
Net income	\$ 115,963	\$ 121,427	\$ 317,555	\$ 321,039
Net income per share:				
Basic	\$ 1.55	\$ 1.59	\$ 4.23	\$ 4.19
Diluted	\$ 1.55	\$ 1.58	\$ 4.23	\$ 4.18
Shares used in computing net income per share:				
Basic	74,736	76,569	75,031	76,670
Diluted	74,757	76,826	75,149	76,849

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 September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Net income	\$ 115,963	\$ 121,427	\$ 317,555	\$ 321,039
Other comprehensive income (loss):				
Change in foreign currency translation adjustment, net of tax	10,713	(9,822)	14,140	9,810
Change in unrealized gains (losses) on investments, net of tax	159	526	605	2,521
Other comprehensive income (loss)	10,872	(9,296)	14,745	12,331
Comprehensive income	<u>\$ 126,835</u>	<u>\$ 112,131</u>	<u>\$ 332,300</u>	<u>\$ 333,370</u>

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)

	September 30, 2024	December 31, 2023
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 1,041,935	\$ 937,438
Marketable securities, short-term	—	35,304
Accounts receivable, net of allowance for doubtful accounts of \$19,141 and \$14,893, respectively	1,010,601	903,424
Inventories	254,119	296,902
Prepaid expenses and other current assets	290,732	273,550
Total current assets	2,597,387	2,446,618
Marketable securities, long-term	—	8,022
Property, plant and equipment, net	1,290,427	1,290,863
Operating lease right-of-use assets, net	121,079	117,999
Goodwill	471,512	419,530
Intangible assets, net	115,905	82,118
Deferred tax assets	1,569,950	1,590,045
Other assets	199,714	128,682
Total assets	\$ 6,365,974	\$ 6,083,877
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 109,035	\$ 113,125
Accrued liabilities	574,556	525,780
Deferred revenues	1,380,022	1,427,706
Total current liabilities	2,063,613	2,066,611
Income tax payable	111,558	116,744
Operating lease liabilities	96,435	96,968
Other long-term liabilities	150,014	173,065
Total liabilities	2,421,620	2,453,388
Commitments and contingencies (Note 7 and Note 8)		
Stockholders' equity:		
Preferred stock, \$0.0001 par value (5,000 shares authorized; none issued)	—	—
Common stock, \$0.0001 par value (200,000 shares authorized; 74,757 and 75,075 issued and outstanding, respectively)	7	7
Additional paid-in capital	1,335,909	1,162,140
Accumulated other comprehensive income (loss), net	35,913	21,168
Retained earnings	2,572,525	2,447,174
Total stockholders' equity	3,944,354	3,630,489
Total liabilities and stockholders' equity	\$ 6,365,974	\$ 6,083,877

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 September 30, 2024	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss), Net	Retained Earnings	Total
	Shares	Amount				
Balance as of June 30, 2024	74,696	\$ 7	\$ 1,276,298	\$ 25,041	\$ 2,456,562	\$ 3,757,908
Net income	—	—	—	—	115,963	115,963
Net change in unrealized gains (losses) from investments	—	—	—	159	—	159
Net change in foreign currency translation adjustment	—	—	—	10,713	—	10,713
Issuance of common stock relating to employee equity compensation plans	63	—	10,942	—	—	10,942
Tax withholdings related to net share settlements of equity awards	(2)	—	(370)	—	—	(370)
Common stock repurchased and retired	—	—	—	—	—	—
Equity forward contract related to accelerated stock repurchase	—	—	—	—	—	—
Stock-based compensation	—	—	49,039	—	—	49,039
Balance as of September 30, 2024	<u>74,757</u>	<u>\$ 7</u>	<u>\$ 1,335,909</u>	<u>\$ 35,913</u>	<u>\$ 2,572,525</u>	<u>\$ 3,944,354</u>

Nine Months Ended September 30, 2024	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss), Net	Retained Earnings	Total
	Shares	Amount				
Balance as of December 31, 2023	75,075	\$ 7	\$ 1,162,140	\$ 21,168	\$ 2,447,174	\$ 3,630,489
Net income	—	—	—	—	317,555	317,555
Net change in unrealized gains (losses) from investments	—	—	—	605	—	605
Net change in foreign currency translation adjustment	—	—	—	14,140	—	14,140
Issuance of common stock relating to employee equity compensation plans	408	—	25,281	—	—	25,281
Tax withholdings related to net share settlements of equity awards	(92)	—	(27,972)	—	—	(27,972)
Common stock repurchased and retired	(634)	—	(7,922)	—	(142,677)	(150,599)
Equity forward contract related to accelerated stock repurchase	—	—	49,527	—	(49,527)	—
Stock-based compensation	—	—	134,855	—	—	134,855
Balance as of September 30, 2024	<u>74,757</u>	<u>\$ 7</u>	<u>\$ 1,335,909</u>	<u>\$ 35,913</u>	<u>\$ 2,572,525</u>	<u>\$ 3,944,354</u>

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

Three Months Ended September 30, 2023	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss), Net	Retained Earnings	Total
	Shares	Amount				
Balance as of June 30, 2023	76,532	\$ 8	\$ 1,141,623	\$ 11,343	\$ 2,485,327	\$ 3,638,301
Net income	—	—	—	—	121,427	121,427
Net change in unrealized gains (losses) from investments	—	—	—	526	—	526
Net change in foreign currency translation adjustment	—	—	—	(9,822)	—	(9,822)
Issuance of common stock relating to employee equity compensation plans ¹	56	—	12,339	—	—	12,339
Tax withholdings related to net share settlements of equity awards	—	—	(507)	—	—	(507)
Stock-based compensation	—	—	39,602	—	—	39,602
Balance as of September 30, 2023	76,588	\$ 8	\$ 1,193,057	\$ 2,047	\$ 2,606,754	\$ 3,801,866

¹ Includes tax withholding shares related to net share settlements of equity awards.

Nine Months Ended September 30, 2023	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss), Net	Retained Earnings	Total
	Shares	Amount				
Balance as of December 31, 2022	77,267	\$ 8	\$ 1,044,946	\$ (10,284)	\$ 2,566,688	\$ 3,601,358
Net income	—	—	—	—	321,039	321,039
Net change in unrealized gains (losses) from investments	—	—	—	2,521	—	2,521
Net change in foreign currency translation adjustment	—	—	—	9,810	—	9,810
Issuance of common stock relating to employee equity compensation plans ¹	263	—	26,595	—	—	26,595
Tax withholdings related to net share settlements of equity awards	—	—	(22,294)	—	—	(22,294)
Common stock repurchased and retired	(942)	—	(11,387)	—	(280,973)	(292,360)
Equity forward contract related to accelerated stock repurchase	—	—	40,000	—	—	40,000
Stock-based compensation	—	—	115,197	—	—	115,197
Balance as of September 30, 2023	76,588	\$ 8	\$ 1,193,057	\$ 2,047	\$ 2,606,754	\$ 3,801,866

¹ Includes tax withholding shares related to net share settlements of equity awards.

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)

	Nine Months Ended September 30,	
	2024	2023
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net income	\$ 317,555	\$ 321,039
Adjustments to reconcile net income to net cash provided by operating activities:		
Deferred taxes	17,465	(22,749)
Depreciation and amortization	106,905	108,669
Stock-based compensation	134,855	115,197
Non-cash operating lease cost	28,603	24,034
Impairment of equity investment	115	3,329
Other non-cash operating activities	6,931	28,435
Changes in assets and liabilities, net of effects of acquisitions:		
Accounts receivable	(135,239)	(80,297)
Inventories	32,304	31,639
Prepaid expenses and other assets	(26,283)	1,773
Accounts payable	(13,283)	(23,130)
Accrued and other long-term liabilities	47,618	156,024
Long-term income tax payable	(5,186)	(7,979)
Deferred revenues	(60,207)	82,894
Net cash provided by operating activities	<u>452,153</u>	<u>738,878</u>
CASH FLOWS FROM INVESTING ACTIVITIES:		
Acquisitions, net of cash acquired	(77,075)	—
Purchase of property, plant and equipment	(92,619)	(144,302)
Purchase of marketable securities	—	(2,373)
Proceeds from maturities of marketable securities	25,660	35,754
Proceeds from sales of marketable securities	18,193	5,173
Purchase of equity investments	(75,390)	(76,999)
Other investing activities	235	128
Net cash used in investing activities	<u>(200,996)</u>	<u>(182,619)</u>
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock	25,281	26,595
Common stock repurchases	(150,012)	(292,360)
Activity for equity forward contracts related to accelerated stock repurchase agreements, net	—	40,000
Payroll taxes paid upon the vesting of equity awards	(27,972)	(22,294)
Net cash used in financing activities	<u>(152,703)</u>	<u>(248,059)</u>
Effect of foreign exchange rate changes on cash, cash equivalents, and restricted cash	6,008	(11,205)
Net increase in cash, cash equivalents, and restricted cash	104,462	296,995
Cash, cash equivalents, and restricted cash at beginning of the period	938,519	942,355
Cash, cash equivalents, and restricted cash at end of the period	<u>\$ 1,042,981</u>	<u>\$ 1,239,350</u>

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 and Preparation

The accompanying unaudited Condensed Consolidated Financial Statements have been prepared by Align Technology, Inc. (“we”, “our”, the “Company”, or “Align”) on a consistent basis with the audited Consolidated Financial Statements for the year ended December 31, 2023, and contain all adjustments, including normal recurring adjustments, necessary to fairly state the information set forth herein. These 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. GAAP”).

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, 2023 as filed with the SEC. The results of operations for the three and nine months ended September 30, 2024 are not necessarily indicative of the results that may be expected for the year ending December 31, 2024 or any other future period, and we make no representations related thereto.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires 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 and assumptions, including those that impact revenue recognition, long-lived and intangible assets, goodwill, income taxes, contingent liabilities, the fair values of financial instruments, stock-based compensation and the valuation of investments in privately held companies, among others. We base our estimates on historical experience and on various other assumptions that are believed to be reasonable, the results of which form the basis for making judgments about the carrying values of assets and liabilities, as well as the reported amounts of revenues and expenses.

Certain Risks and Uncertainties

We are subject to risks including, but not limited to, global and regional economic market conditions, inflation, fluctuations in foreign currency exchange rates, changes in consumer confidence and demand, increased competition, dependence on key personnel, protection and litigation of proprietary technology, shifts in taxable income between tax jurisdictions and compliance with regulations of the U.S. Food and Drug Administration (“FDA”) and similar international agencies.

Our cash and investments are held primarily by five financial institutions. Financial instruments which potentially expose us to concentrations of credit risk consist primarily of cash equivalents and marketable securities. Historically, we have invested excess cash primarily in money market funds, corporate bonds, asset-backed securities, municipal and U.S. government agency bonds and treasury bonds. We periodically evaluate our investments for credit losses. Such credit losses have not been material to our financial statements.

We purchase certain inventory from sole suppliers. Additionally, we rely on a limited number of hardware manufacturers. The inability of any supplier or manufacturer to fulfill our supply requirements could materially and adversely impact our future operating results.

Recent Accounting Pronouncements

Recent Accounting Pronouncements Not Yet Effective

On November 27, 2023, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) 2023-07, “Improvements to Reportable Segment Disclosures.” The amendments in this update improve reportable segment disclosure requirements, primarily through enhanced disclosures about significant segment expenses. For public business entities, the provisions of ASU 2023-07 are effective for fiscal years beginning after December 15, 2023 and interim periods within fiscal years beginning after December 15, 2024. Early adoption is permitted. Companies must apply the

guidance retrospectively to all prior periods presented in the financial statements. The Company expects this pronouncement may result in changes to the nature of our reportable segment disclosures.

On December 14, 2023, the FASB issued ASU 2023-09, "Improvements to Income Tax Disclosures." The amendments in this ASU require a public entity to disclose in tabular format, using both percentages and reporting currency amounts, specific categories in the rate reconciliation and to provide additional information for reconciling items that meet a quantitative threshold. The amendments in this ASU also require taxes paid (net of refunds received) to be disaggregated by federal, state, and foreign taxes and further disaggregated for specific jurisdictions to the extent the related amounts exceed a quantitative threshold. For public business entities, the provisions of ASU 2023-09 are effective for fiscal years beginning after December 15, 2024. Early adoption is permitted. The Company is evaluating the effect of this pronouncement on its annual consolidated financial statements.

Note 2. Financial Instruments

Cash, Cash Equivalents and Marketable Securities

The following tables summarize our cash and cash equivalents, and marketable securities on our Condensed Consolidated Balance Sheets as of September 30, 2024 and December 31, 2023 (in thousands):

September 30, 2024	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value	Reported as:		
					Cash and Cash Equivalents	Marketable securities, short-term	Marketable securities, long-term
Cash	\$ 860,461	\$ —	\$ —	\$ 860,461	\$ 860,461	\$ —	\$ —
Money market funds	181,474	—	—	181,474	181,474	—	—
Total	\$ 1,041,935	\$ —	\$ —	\$ 1,041,935	\$ 1,041,935	\$ —	\$ —

We have no short-term or long-term marketable securities as of September 30, 2024.

December 31, 2023	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value	Reported as:		
					Cash and Cash Equivalents	Marketable securities, short-term	Marketable securities, long-term
Cash	\$ 887,682	\$ —	\$ —	\$ 887,682	\$ 887,682	\$ —	\$ —
Money market funds	49,756	—	—	49,756	49,756	—	—
Corporate bonds	31,943	5	(676)	31,272	—	28,704	2,568
U.S. government treasury bonds	4,855	—	(99)	4,756	—	—	4,756
Asset-backed securities	1,416	2	(1)	1,417	—	719	698
Municipal bonds	702	—	(2)	700	—	700	—
U.S. government agency bonds	5,215	—	(34)	5,181	—	5,181	—
Total	\$ 981,569	\$ 7	\$ (812)	\$ 980,764	\$ 937,438	\$ 35,304	\$ 8,022

The following table summarizes the fair value of our available-for-sale marketable securities classified by contractual maturity as of December 31, 2023 (in thousands):

	December 31, 2023
Due in 1 year or less	\$ 34,617
Due in 1 year through 5 years	8,709
Total	\$ 43,326

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 December 31, 2023 are primarily due to changes in interest rates and credit spreads.

The following table summarizes the fair value and gross unrealized losses as of December 31, 2023, aggregated by investment category and length of time that individual securities have been in a continuous unrealized loss position (in thousands):

December 31, 2023	As of December 31, 2023					
	Less than 12 months		12 Months of Greater		Total	
	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss
Corporate bonds	\$ —	\$ —	\$ 27,939	\$ (676)	\$ 27,939	\$ (676)
U.S. government treasury bonds	2,044	(11)	2,712	(88)	4,756	(99)
Asset-backed securities	1,018	(1)	83	—	1,101	(1)
Municipal bonds	—	—	700	(2)	700	(2)
U.S. government agency bonds	4,003	(11)	1,178	(23)	5,181	(34)
Total	\$ 7,065	\$ (23)	\$ 32,612	\$ (789)	\$ 39,677	\$ (812)

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 U.S. 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 — Inputs to the valuation techniques that are quoted prices in active markets for identical assets or liabilities.

Level 2 — Inputs to the valuation techniques that are other than quoted prices but are observable for the assets or liabilities, either directly or indirectly.

Level 3 — Inputs to the valuation techniques that are unobservable for the assets or liabilities.

The following tables summarize our financial assets measured at fair value as of September 30, 2024 and December 31, 2023 (in thousands):

Description	Balance as of September 30, 2024	Level 1	Level 2
Cash equivalents:			
Money market funds	\$ 181,474	\$ 181,474	\$ —
	\$ 181,474	\$ 181,474	\$ —

Description	Balance as of December 31, 2023	Level 1	Level 2
Cash equivalents:			
Money market funds	\$ 49,756	\$ 49,756	\$ —
Short-term investments:			
Corporate bonds	28,704	—	28,704
Municipal bonds	700	—	700
U.S. government agency bonds	5,181	—	5,181
Asset-backed securities	719	—	719
Long-term investments:			
U.S. government treasury bonds	4,756	—	4,756
Corporate bonds	2,568	—	2,568
Asset-backed securities	698	—	698
	\$ 93,082	\$ 49,756	\$ 43,326

Accounts Receivable Factoring

We enter into factoring transactions on a non-recourse basis with financial institutions to sell certain of our non-U.S. accounts receivable. We account for these transactions as sales of financial assets and include the cash proceeds as a part of our cash flows from operations in the Condensed Consolidated Statements of Cash Flows. Total accounts receivable sold under factoring arrangements was \$8.2 million and \$24.2 million during the three months ended September 30, 2024 and 2023, respectively, and \$34.2 million and \$40.4 million during the nine months ended September 30, 2024 and 2023, respectively. Factoring fees on the sales of receivables were recorded in Other income (expense), net in our Condensed Consolidated Statement of Operations and were not material.

Investments in Privately Held Companies

Our investments in privately held companies in which we cannot exercise significant influence and do not own a majority equity interest or otherwise control are accounted for as investments in equity securities. We have elected to account for all investments in equity securities in accordance with the measurement alternative. Under the measurement alternative, we record the value of our investments in equity securities at cost, minus impairment, if any. Additionally, we adjust the carrying value of our investments in equity securities to fair value for observable transactions for identical or similar investments of the same issuer.

On April 24, 2023 and April 22, 2024, we entered into Subscription Agreements (the “Subscription Agreements”) with Heartland Dental Holding Corporation (“Heartland”). Pursuant to the Subscription Agreements we acquired less than a 5% equity interest through the purchase of Class A Common Stock for \$150 million in total. We are accounting for our investment in Heartland as an investment in equity securities. Based on a review of the relevant facts and circumstances, primarily observable transactions for Heartland’s Class A Common Stock, we determined that no adjustment to the carrying value of our investment was necessary for the three or nine months ended September 30, 2024.

Our investments in privately held companies in which we can exercise significant influence are accounted for as equity method investments. We have elected to account for our equity method investments under the fair value option.

The carrying value of our investments in equity securities and equity method investments are reported on our Condensed Consolidated Balance Sheets as Other assets and any fair value adjustments or impairment, if any, are recorded in Other income (expense), net on our Condensed Consolidated Statement of Operations.

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 assets and liabilities. These forward contracts are classified within Level 2 of the fair value hierarchy. As a result of the settlement of foreign currency forward contracts, we recognized a net loss of \$24.5 million and a net gain of \$19.8 million, respectively, during the three months ended September 30, 2024 and 2023, and a net gain of \$2.7 million and \$14.4 million, respectively, during the nine months ended September 30, 2024 and 2023. Recognized gains and losses from the settlement of foreign currency forward contracts are recorded to Other income (expense), net in our Condensed Consolidated Statements of Operations. As of September 30, 2024 and December 31, 2023, the fair value of foreign exchange forward contracts outstanding were not material.

The following tables present the gross notional value of all our foreign exchange forward contracts outstanding as of September 30, 2024 and December 31, 2023 (in thousands):

	September 30, 2024	
	Local Currency Amount	Notional Contract Amount (USD)
Euro	€176,900	\$ 197,946
British Pound	£105,720	141,511
Canadian Dollar	\$96,300	71,439
Polish Zloty	PLN272,000	71,001
Chinese Yuan	¥473,500	67,816
Japanese Yen	¥5,000,000	35,176
Israeli Shekel	ILS79,600	21,458
Brazilian Real	R\$109,800	20,044
Swiss Franc	CHF5,700	6,783
New Zealand Dollar	NZ\$7,700	4,898
Australian Dollar	A\$4,800	3,330
New Taiwan Dollar	NT\$98,000	3,110
Czech Koruna	Kč64,400	2,860
Korean Won	₩2,500,000	1,914
		<u>\$ 649,286</u>

	December 31, 2023	
	Local Currency Amount	Notional Contract Amount (USD)
Euro	€337,780	\$ 373,705
Canadian Dollar	\$108,900	82,166
Polish Zloty	PLN276,900	70,393
British Pound	£45,590	58,005
Chinese Yuan	¥244,500	34,361
Swiss Franc	CHF28,600	34,132
Japanese Yen	¥3,577,000	25,347
Israeli Shekel	ILS78,700	21,800
Brazilian Real	R\$80,500	16,563
Mexican Peso	M\$230,000	13,593
New Zealand Dollar	NZ\$6,600	4,161
Australian Dollar	A\$4,300	2,921
New Taiwan Dollar	NT\$89,000	2,919
Czech Koruna	Kč60,200	2,687
Korean Won	₩2,200,000	1,709
		<u>\$ 744,462</u>

Note 3. Balance Sheet Components

Inventories consist of the following (in thousands):

	September 30, 2024	December 31, 2023
Raw materials	\$ 126,959	\$ 145,492
Work in process	77,174	91,259
Finished goods	49,986	60,151
Total inventories	<u>\$ 254,119</u>	<u>\$ 296,902</u>

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

	September 30, 2024	December 31, 2023
Value added tax receivables	\$ 148,903	\$ 143,728
Prepaid expenses	72,985	52,487
Other current assets	68,844	77,335
Total prepaid expenses and other current assets	<u>\$ 290,732</u>	<u>\$ 273,550</u>

Accrued liabilities consist of the following (in thousands):

	September 30, 2024	December 31, 2023
Accrued payroll and benefits	\$ 241,638	\$ 220,862
Accrued expenses	74,158	71,109
Accrued sales and marketing expenses	38,152	34,035
Accrued income taxes	36,860	38,103
Current operating lease liabilities	31,168	29,651
Accrued property, plant and equipment	11,132	23,618
Other accrued liabilities	141,448	108,402
Total accrued liabilities	<u>\$ 574,556</u>	<u>\$ 525,780</u>

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

	Nine Months Ended September 30,	
	2024	2023
Balance at beginning of period	\$ 22,426	\$ 17,873
Charged to cost of net revenues	14,658	14,329
Actual warranty expenditures	(9,889)	(10,327)
Balance at end of period	<u>\$ 27,195</u>	<u>\$ 21,875</u>

Deferred revenues consist of the following (in thousands):

	September 30, 2024	December 31, 2023
Deferred revenues - current	\$ 1,380,022	\$ 1,427,706
Deferred revenues - long-term ¹	\$ 108,676	\$ 138,000

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

During the three months ended September 30, 2024 and 2023, we recognized \$977.9 million and \$960.2 million of net revenues, respectively, of which \$199.0 million and \$178.8 million was included in the deferred revenues balance at December 31, 2023 and 2022, respectively.

During the nine months ended September 30, 2024 and 2023, we recognized \$3,003.8 million and \$2,905.5 million of net revenues, respectively, of which \$658.2 million and \$583.5 million was included in the deferred revenues balance at December 31, 2023 and 2022, respectively.

Our unfulfilled performance obligations, including deferred revenues and backlog, as of September 30, 2024 were \$1,495.6 million. These performance obligations are expected to be fulfilled over the next six months to five years.

Note 4. Business Combination

On January 2, 2024 (the “Cubicure Acquisition Date”), we completed the acquisition of privately-held Cubicure GmbH (“Cubicure”) (the “Cubicure Acquisition”). Cubicure is an Austrian company and specializes in direct 3D printing solutions for polymer additive manufacturing that develops, produces, and distributes innovative materials, equipment, and processes for 3D printing solutions. The Cubicure Acquisition is intended to support and scale our strategic innovation roadmap and strengthen the Align Digital Platform. In fiscal year 2021, we acquired a 9.04% equity interest in Cubicure. Subsequently, on the Cubicure Acquisition Date, we acquired the remaining equity of Cubicure. Prior to the acquisition, we also had technology license and joint development agreements with Cubicure.

The fair value of consideration transferred in the acquisition is shown in the table below (in thousands):

Cash paid to Cubicure stockholders	\$	80,142
Fair value of pre-existing equity interest ownership		7,968
Settlement of pre-existing relationship - accounts payable		(2,316)
Total purchase consideration paid	\$	<u>85,794</u>

The Cubicure Acquisition was accounted for as a business combination under ASC Topic 805, Business Combinations (“ASC 805”) that was achieved in stages. As a result of the Cubicure Acquisition, we remeasured our pre-existing equity interest in Cubicure at fair value prior to the Cubicure Acquisition. Based on the fair value of this equity interest, derived from the purchase price, we estimated the fair value of our 9.04% pre-existing investment in Cubicure to be approximately \$8.0 million. The remeasurement resulted in the recognition of a pre-tax gain of \$4.1 million, which was reflected as a component of Other income (expense), net within our Condensed Consolidated Statement of Operations.

In 2021, we initiated Joint development (“JDA”) and Technology license agreements (“TLA”) to provide us with access to Cubicure's technology. The settlement of the JDA and TLA were concluded to be at market terms on the Cubicure Acquisition Date; therefore, no gain or loss was recorded related to the settlement of these contracts. We also had accounts payable from the pre-existing arrangements with Cubicure of \$2.3 million, which were effectively settled and reduced from the purchase consideration of the Cubicure Acquisition.

The allocation of the purchase price to the assets acquired and liabilities assumed is as follows (in thousands):

Working capital	\$	1,039
Property & equipment		975
Developed technology		47,000
Other non-current asset		1,483
Other liabilities		(12,279)
Goodwill		47,576
Total	\$	<u>85,794</u>

Goodwill represents the excess of the purchase price over the fair value of the underlying net tangible and identifiable intangible assets, and represents the value associated with future technology, future customer relationships, and the knowledge and experience of the workforce in place. None of this goodwill is deductible for tax purposes. We allocated all goodwill to our Clear Aligner reporting unit.

As part of the Cubicure Acquisition we acquired a developed technology intangible asset. The acquired developed technology had an estimated fair value of \$47.0 million as of the Cubicure Acquisition Date and will be amortized over a useful life of thirteen years.

The fair value of developed technology was estimated under the Multi-Period Excess Earnings Method and the fair value estimates for developed technology include significant assumptions in the prospective financial information which include, but are not limited to, projected future cash flows associated with the technology, the asset's life cycle and the present value factor.

Acquisition related costs are recognized separately from the business combination and are expensed as incurred. Acquisition related costs were not material.

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

Note 5. Goodwill and Intangible Assets

Goodwill

The change in the carrying value of goodwill for the nine months ended September 30, 2024, categorized by reportable segment, is as follows (in thousands):

	Clear Aligner	Systems and Services	Total
Balance as of December 31, 2023	\$ 111,086	\$ 308,444	\$ 419,530
Additions from acquisition	47,576	—	47,576
Foreign currency translation adjustments	963	3,443	4,406
Balance as of September 30, 2024	<u>\$ 159,625</u>	<u>\$ 311,887</u>	<u>\$ 471,512</u>

Finite-Lived Intangible Assets

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

	Weighted Average Amortization Period (in years)	Gross Carrying Amount as of September 30, 2024	Accumulated Amortization	Accumulated Impairment Loss	Net Carrying Value as of September 30, 2024
Existing technology	11	\$ 146,651	\$ (48,581)	\$ —	\$ 98,070
Customer relationships	10	21,500	(9,675)	—	11,825
Trademarks and tradenames	10	16,600	(8,759)	(4,122)	3,719
Patents	12	480	(270)	—	210
		<u>\$ 185,231</u>	<u>\$ (67,285)</u>	<u>\$ (4,122)</u>	<u>113,824</u>
Foreign currency translation adjustments					2,081
Total intangible assets, net					<u>\$ 115,905</u>

	Weighted Average Amortization Period (in years)	Gross Carrying Amount as of December 31, 2023	Accumulated Amortization	Accumulated Impairment Loss	Net Carrying Value as of December 31, 2023
Existing technology	10	\$ 112,051	\$ (45,331)	\$ (4,328)	\$ 62,392
Customer relationships	10	21,500	(8,063)	—	13,437
Trademarks and tradenames	10	16,600	(7,605)	(4,122)	4,873
Patents	8	6,511	(6,082)	—	429
		<u>\$ 156,662</u>	<u>\$ (67,081)</u>	<u>\$ (8,450)</u>	<u>81,131</u>
Foreign currency translation adjustments					987
Total intangible assets, net					<u>\$ 82,118</u>

Of the \$146.7 million recorded as Existing technology intangible assets as of September 30, 2024, \$47.0 million was acquired during the first quarter of 2024 as part of the Cubicure Acquisition. The existing technology acquired in the Cubicure Acquisition had an estimated useful life of 13 years, which had the effect of increasing the weighted average amortization period from approximately 10 years as of December 31, 2023 to approximately 11 years as of September 30, 2024. Refer to *Note 4. "Business Combination"*.

The total estimated annual future amortization expense for these acquired intangible assets as of September 30, 2024, is as follows (in thousands):

Fiscal Year Ending December 31,	Amortization
Remainder of 2024	\$ 4,643
2025	18,574
2026	17,969
2027	15,607
2028	14,505
2029	14,505
Thereafter	28,021
Total	<u>\$ 113,824</u>

Amortization expense for the three months ended September 30, 2024 and 2023 was \$4.6 million and \$4.2 million, respectively, and amortization expense for the nine months ended September 30, 2024 and 2023 was \$14.2 million and \$12.4 million, respectively.

Note 6. Credit Facility

We have a credit facility that provides for a \$300.0 million unsecured revolving line of credit, along with a \$50.0 million letter of credit. On December 23, 2022, we amended certain provisions in our credit facility which included extending the maturity date on the facility to December 23, 2027 and replacing the interest rate from the existing LIBOR with SOFR ("2022 Credit Facility"). The 2022 Credit Facility requires us to comply with specific financial conditions and performance requirements. Loans under the 2022 Credit Facility bear interest, at our option, at either a rate based on the SOFR for the applicable interest period or a base rate, in each case plus a margin. As of September 30, 2024, we had no outstanding borrowings under the 2022 Credit Facility and were in compliance with the conditions and performance requirements in all material respects.

Note 7. Legal Proceedings

2019 Shareholder Derivative Lawsuit

In January 2019, three derivative lawsuits were filed in the U.S. District Court for the Northern District of California which were later consolidated, purportedly on our behalf, naming as defendants the then current members of our Board of

Directors along with certain of our executive officers. The complaints assert various state law causes of action, including for breaches of fiduciary duty, insider trading, and unjust enrichment. The complaints seek unspecified monetary damages on our behalf, 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 is currently stayed. 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 our behalf, 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 is currently stayed. Defendants have not yet responded to the complaint.

In the first quarter of 2024, the parties to these actions entered into a settlement agreement whereby, subject to court approval, plaintiffs will dismiss the lawsuits and release their claims. In the settlement agreement, Align and the defendants deny any wrongdoing and are not making any monetary payments, other than a potential award of \$575,000 in attorney's fees to plaintiffs' counsel, covered by insurance. On August 2, 2024, the U.S. District Court for the Northern District of California granted preliminary approval of the settlement.

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 treble monetary damages, interest, costs, attorneys' fees, and injunctive relief relating to our alleged market activities in alleged clear aligner and intraoral scanner markets. Plaintiff filed an amended complaint and added VIP Dental Spas as a plaintiff on August 14, 2020. On December 18, 2023, the court certified a class of persons or entities that purchased Invisalign directly from Align between January 1, 2019 and March 31, 2022. The court denied Plaintiffs' motion to certify a class of purchasers of scanners. On February 21, 2024, the court granted Align's motion for summary judgment on all claims brought by the plaintiffs. The court entered judgment on March 22, 2024. Plaintiffs have appealed the district court's summary judgment ruling to the United States Court of Appeals for the Ninth Circuit. Plaintiff-Appellants' opening brief was filed July 15, 2024. Align's response brief was submitted October 21, 2024 and Plaintiff-Appellants' reply brief is due January 6, 2025.

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 treble monetary damages, interest, costs, attorneys' fees, and injunctive relief relating to our alleged market activities in alleged clear aligner and intraoral scanner markets based on Section 2 of the Sherman Act. Plaintiffs have filed several amended complaints adding new plaintiffs, various state law claims, and allegations based on Section 1 of the Sherman Act. On November 29, 2023, the court certified a class of indirect purchasers of Invisalign between July 1, 2018 and December 31, 2023 and a class of indirect purchasers of Invisalign seeking injunctive relief. On February 21, 2024, the court granted Align's motion for summary judgment on the claims related to Section 2 allegations. The court entered judgment for the Section 2 and related state law claims on March 22, 2024. Plaintiffs have appealed the district court's summary judgment ruling to the United States Court of Appeals for the Ninth Circuit. Plaintiff-Appellants' opening brief was filed July 15, 2024. Align's response brief was submitted October 21, 2024 and Plaintiff-Appellants' reply brief is due January 6, 2025.

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

In June 2024, Align and the Section 1 plaintiffs reached a settlement in principle that would resolve all remaining claims in the Section 1 lawsuit. The settlement terms included a \$27.5 million cash payment and an offer of a \$300 coupon for class members who elected to purchase Invisalign treatment. We agreed to settle the lawsuit to avoid the distraction and uncertainty of litigation. On September 18, 2024, the U.S. District Court for the Northern District of California denied plaintiffs' motion for preliminary approval of the settlement without prejudice, allowing plaintiffs to file a renewed motion within 35 days. Plaintiffs and Align filed a renewed motion for preliminary approval of the settlement on October 28, 2024. We are unable to predict the timeline or outcome of the motion to approve the settlement. We continue to believe that plaintiffs' Section 1 claims are without merit and remain ready to vigorously defend ourselves against those claims.

During the nine months ended September 30, 2024 we accrued a loss of \$31.1 million for legal settlements for multiple legal matters, but primarily related to the settlement of the Section 1 claims described above.

Straumann Litigation

On April 11, 2024, we filed a lawsuit in the U.S. District Court for the Western District of Texas against ClearCorrect Operating, LLC, ClearCorrect Holdings, Inc., and Institut Straumann AG. The complaint asserts claims of false advertising, unfair competition, civil conspiracy, and infringement of Align patents related to aligner material, treatment planning, and intraoral scanner technologies. Among other things, the complaint seeks relief enjoining the defendants' infringement of multiple Align multilayer material patents through defendants' manufacture, sale and offer for sale of aligners made with Zendura FLX/ClearQuartz materials. On June 20, 2024, Defendants filed motions to dismiss the Complaint, which are pending. On July 9, 2024, ClearCorrect Operating, LLC, ClearCorrect Holdings, Inc. and Straumann USA LLC filed counterclaims against Align for alleged antitrust violations, false advertising, unfair competition, and breach of contract. Among other things, the counterclaims seek relief enjoining Align's accused business practices, invalidating Align's asserted patents, and money damages. On September 13, 2024, we filed a motion to dismiss defendants' counterclaims. 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 cannot determine the likelihood of loss nor estimate a range of possible loss.

In addition to the above, in the ordinary course of our operations, we are 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 our view of these matters may change in the future as litigation and events related thereto unfold; we currently do not believe that these matters, individually or in the aggregate, will materially affect our financial position, results of operations or cash flows.

Note 8. Commitments and Contingencies

Tax Matter

Beginning in the third quarter of 2023 and continuing through the first quarter of 2024, the Company has received cumulative assessments of approximately \$100 million from His Majesty's Revenue and Customs ("HMRC") for unpaid value added tax ("VAT") related to certain clear aligner sales made during the period of October 2019 through May 2023. We are required to pay these assessments prior to contesting or litigating in statutory appeal. The Company has historically asserted and continues to assert that doctor prescribed clear aligners sold by dentists for the orthodontic treatment of patient malocclusions are exempt from VAT, that the Company has reasonably relied upon statements and guidance by HMRC and that the Company's interpretation of United Kingdom legislation is appropriate.

In October 2024, the Company and HMRC reached a settlement agreement regarding the unpaid VAT related to certain aligner sales made during the period of October 2019 through mid-October 2023. As part of the settlement, HMRC agreed to vacate the judicial review (before the Administrative Court) originally scheduled for October 9th and October 10th, 2024, refund to the Company all assessments paid, approximately \$100 million, for the period of October 2019 through May 2023 and withdraw any potential assessments for the period from June 2023 through mid-October 2023. Between October 21, 2024 and October 29, 2024, HMRC refunded to the Company all assessed amounts in full, approximately \$100 million.

The Company has remaining exposure in the amount of approximately \$7.5 million for periods up to December 2023. A statutory appeal (before the First-tier Tribunal - "Tax Tribunal") is listed for January 27th through January 30th, 2025, at which time we anticipate the Tax Tribunal will determine whether clear aligners are exempt from VAT as a matter of law and whether the Company has any liability as a matter of principle. It is not possible at this stage to accurately evaluate the likelihood of an unfavorable outcome from the Tax Tribunal statutory appeal. Accordingly, the Company has determined that a potential loss related to VAT accounted for in the periods up to December 2023 is not probable.

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 of future payments, if any, under these indemnification agreements due to the unique facts and circumstances involved in each particular agreement. Additionally, we have a limited history of prior indemnification claims and the payments we have made under such agreements have not had a material adverse effect on our results of operations, cash flows or financial position. However, to the extent that valid indemnification claims arise in the future, future payments by us could be significant and could have a material adverse effect on our results of operations or cash flows in a particular period. As of September 30, 2024, we did not have any material indemnification claims that were probable or reasonably possible.

Note 9. Stockholders' Equity

As of September 30, 2024, the Align Technology, Inc. 2005 Incentive Plan, as amended, has a total reserve of 32,168,895 shares, of which 3,398,202 shares are available for issuance.

Summary of Stock-Based Compensation Expense

The stock-based compensation related to our stock-based awards and employee stock purchase plan for the three and nine months ended September 30, 2024 and 2023 is as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Cost of net revenues	\$ 3,070	\$ 1,974	\$ 7,716	\$ 5,682
Selling, general and administrative	34,937	29,739	97,705	87,432
Research and development	11,032	7,889	29,434	22,083
Total stock-based compensation	<u>\$ 49,039</u>	<u>\$ 39,602</u>	<u>\$ 134,855</u>	<u>\$ 115,197</u>

Restricted Stock Units ("RSUs")

The fair value of RSUs is based on our closing stock price on the date of grant. RSUs granted generally vest over a period of four years. A summary for the nine months ended September 30, 2024 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, 2023	736	\$ 367.63		
Granted	638	309.22		
Vested and released	(254)	370.69		
Forfeited	(56)	345.74		
Unvested as of September 30, 2024	<u>1,064</u>	<u>\$ 333.03</u>	1.6	<u>\$ 270,565</u>

As of September 30, 2024, we expect to recognize \$254.4 million of total unamortized compensation costs, net of estimated forfeitures, related to RSUs over a weighted average period of 2.7 years.

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

We grant MSUs to members of senior management. Each MSU represents the right to one share of our 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 shares eligible to vest in the future is 250% of the MSUs initially granted.

The following table summarizes the MSU performance activity for the nine months ended September 30, 2024:

	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, 2023	158	\$ 811.06		
Granted	83	617.79		
Vested and released ¹	(32)	1,102.09		
Forfeited	(5)	1,102.09		
Unvested as of September 30, 2024	204	\$ 679.52	1.6	\$ 51,876

¹ Includes MSUs vested during the period below 100% of the original grant as actual shares released is based on Align's stock performance relative to a market index over the vesting period.

As of September 30, 2024, we expect to recognize \$67.2 million of total unamortized compensation costs, net of estimated forfeitures, related to MSUs over a weighted average period of 1.6 years.

Restricted Stock Units with Performance Conditions ("PSUs")

Our PSUs typically include a service and performance condition. We recognize share-based compensation expense for PSUs if it is probable that the performance condition will be achieved.

The following table summarizes the PSU performance activity for the nine months ended September 30, 2024:

	Number of Shares Underlying PSUs (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, 2023	\$ 5	\$ 201.63		
Granted	6	206.36		
Vested and released	—	—		
Forfeited	—	—		
Unvested as of September 30, 2024	\$ 11	\$ 204.33	1.4	\$ 2,805

As of September 30, 2024, we expect to recognize \$1.2 million of total unamortized compensation costs, net of estimated forfeitures, related to PSUs over a weighted average period of 1.4 years.

Employee Stock Purchase Plan

As of September 30, 2024, we have 1,875,920 shares available for future issuance under the Align Technology, Inc. 2010 Employee Stock Purchase Plan (as amended and restated, 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:

	Nine Months Ended September 30,	
	2024	2023
Expected term (in years)	1.3	1.2
Expected volatility	49.2 %	56.2 %
Risk-free interest rate	4.6 %	4.9 %
Expected dividends	—	—
Weighted average fair value at grant date	\$ 94.70	\$ 133.53

As of September 30, 2024, we expect to recognize \$17.1 million of total unamortized compensation costs related to future employee stock purchases over a weighted average period of 0.9 years.

Note 10. Common Stock Repurchase Programs

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”), which was completed in March 2023. In January 2023, our Board of Directors authorized a new plan to repurchase up to \$1.0 billion of our common stock (“January 2023 Repurchase Program”). The January 2023 Repurchase Program does not have an expiration date.

Accelerated Share Repurchase Agreements (“ASRs”)

The following table summarizes the total repurchases of our common stock pursuant to an ASR entered into or completed during the three and nine months ended September 30, 2024 and 2023:

Agreement Date	Repurchase Program	Amount Paid (in millions)	Completion Date	Total Shares Received	Average Price per Share
Q4 2022	May 2021	\$ 200.0	Q1 2023	984,714	\$ 203.10
Q1 2023	May 2021	\$ 250.0	Q1 2023	805,908	\$ 310.21
Q4 2023	January 2023	\$ 250.0	Q1 2024	1,086,334	\$ 230.13

Open Market Common Stock Repurchases

On June 3, 2024, we initiated a plan to repurchase \$150.0 million of our common stock through open market repurchases under the January 2023 Repurchase Program. This plan was completed on June 26, 2024. In total, we repurchased approximately 0.6 million shares of our common stock at an average price of \$250.73 per share, including commissions and fees.

During the twelve months ended December 31, 2023, we repurchased \$100.0 million of our common stock through open market repurchases under the January 2023 Repurchase Program, none of which occurred during the nine months ended September 30, 2023.

As of September 30, 2024, \$500.0 million remains available for repurchases under the January 2023 Repurchase Program.

Note 11. Accounting for Income Taxes

Our provision for income taxes was \$50.0 million and \$40.7 million for the three months ended September 30, 2024 and 2023, respectively, representing effective tax rates of 30.1% and 25.1%, respectively. Our provision for incomes taxes was \$150.6 million and \$147.3 million for the nine months ended September 30, 2024 and 2023, respectively, representing effective tax rates of 32.2% and 31.4%. Our effective tax rate differs from the statutory federal income tax rate of 21% for the three and nine months ended September 30, 2024 and 2023 primarily due to the recognition of additional tax expense resulting from U.S. taxes on foreign earnings, foreign income taxed at different rates, state income taxes, and non-deductible expenses in the U.S.

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 may be required to adjust the valuation allowance for deferred tax assets if we determine, based on available evidence at the time of the determination, that it is more likely than not that some portion or all of the deferred tax assets will not be realized. Changes to the valuation allowance could have a material adverse effect on our results of operations.

Our total gross unrecognized tax benefits, excluding interest and penalties, were \$156.2 million and \$149.2 million as of September 30, 2024 and December 31, 2023, respectively, a material amount of which would impact our effective tax rate if recognized. The increase in our unrecognized tax benefits relates primarily to positions taken on income tax return calculations finalized during the three and nine months ended September 30, 2024.

Note 12. 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 September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Numerator:				
Net income	\$ 115,963	\$ 121,427	\$ 317,555	\$ 321,039
Denominator:				
Weighted average common shares outstanding, basic	74,736	76,569	75,031	76,670
Dilutive effect of potential common stock	21	257	118	179
Total shares, diluted	74,757	76,826	75,149	76,849
Net income per share, basic	\$ 1.55	\$ 1.59	\$ 4.23	\$ 4.19
Net income per share, diluted	\$ 1.55	\$ 1.58	\$ 4.23	\$ 4.18
Anti-dilutive potential common shares ¹	1,173	245	689	263

¹ Represents approximately 1,169.7 thousand RSU and 3.1 thousand ESPP weighted-average outstanding common stock equivalent shares for the three months ended September 30, 2024 and approximately 687.7 thousand RSU and 0.8 thousand ESPP weighted-average outstanding common stock equivalent shares for the nine months ended September 30, 2024 that are excluded from the calculation of diluted net income per share as the effect would have been anti-dilutive. For the three and nine months ended September 30, 2023 all anti-dilutive shares were RSUs.

Note 13. Supplemental Cash Flow Information

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

	Nine Months Ended September 30,	
	2024	2023
Non-cash investing and financing activities:		
Acquisition of property, plant and equipment in accounts payable and accrued liabilities	\$ 17,631	\$ 25,979
Final settlement of prior year stock repurchase forward contract	50,000	—
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	\$ 29,854	\$ 25,559
Right-of-use assets obtained in exchange for lease obligations:		
Operating leases	\$ 25,422	\$ 25,048

Note 14. 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 ("CODM"), our Chief Executive Officer, 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 reportable segment. Certain operating expenses are not directly attributable to a reportable segment and must be allocated. Each allocation is measured differently based on the nature of the cost being allocated. Certain other operating expense are not specifically allocated to segment income from operations and generally include various corporate expenses such as stock-based compensation and costs related to IT, facilities, human resources, accounting and finance, legal and regulatory, other separately managed general and administrative costs outside the reportable segments and restructuring costs. 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 September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Net revenues				
Clear Aligner	\$ 786,844	\$ 794,939	\$ 2,435,833	\$ 2,417,417
Systems and Services	191,028	165,275	567,960	488,117
Total net revenues	\$ 977,872	\$ 960,214	\$ 3,003,793	\$ 2,905,534
Gross profit				
Clear Aligner	\$ 552,841	\$ 562,331	\$ 1,720,524	\$ 1,731,721
Systems and Services	128,933	100,745	381,694	305,618
Total gross profit	\$ 681,774	\$ 663,076	\$ 2,102,218	\$ 2,037,339
Income from operations				
Clear Aligner	\$ 276,319	\$ 296,319	\$ 862,183	\$ 879,933
Systems and Services	68,744	44,975	189,227	132,600
Unallocated corporate expenses	(182,765)	(174,948)	(587,931)	(540,740)
Total income from operations	\$ 162,298	\$ 166,346	\$ 463,479	\$ 471,793
Stock-based compensation				
Clear Aligner	\$ 7,648	\$ 5,772	\$ 20,031	\$ 14,917
Systems and Services	427	366	1,207	950
Unallocated corporate expenses	40,964	33,464	113,617	99,330
Total stock-based compensation	\$ 49,039	\$ 39,602	\$ 134,855	\$ 115,197
Depreciation and amortization				
Clear Aligner	\$ 17,971	\$ 17,737	\$ 49,027	\$ 50,725
Systems and Services	8,099	7,827	23,007	23,716
Unallocated corporate expenses	11,723	11,466	34,871	34,228
Total depreciation and amortization	\$ 37,793	\$ 37,030	\$ 106,905	\$ 108,669

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 September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Total segment income from operations	\$ 345,063	\$ 341,294	\$ 1,051,410	\$ 1,012,533
Unallocated corporate expenses	(182,765)	(174,948)	(587,931)	(540,740)
Total income from operations	162,298	166,346	463,479	471,793
Interest income	4,003	5,522	11,696	12,280
Other income (expense), net	(371)	(9,757)	(6,993)	(15,749)
Net income before provision for income taxes	\$ 165,930	\$ 162,111	\$ 468,182	\$ 468,324

Our CODM does not regularly review total assets at the reportable segment level; however, we have provided geographical information related to our long-lived assets below.

Geographical Information

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Net revenues ¹ :				
U.S.	\$ 421,204	\$ 421,272	\$ 1,291,838	\$ 1,262,008
Switzerland	216,638	259,587	739,342	913,724
Other International	340,030	279,355	972,613	729,802
Total net revenues	\$ 977,872	\$ 960,214	\$ 3,003,793	\$ 2,905,534

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):

	September 30, 2024	December 31, 2023
Long-lived assets ¹ :		
Switzerland	\$ 580,428	\$ 575,432
U.S.	203,772	210,275
Other International	627,306	623,155
Total long-lived assets	\$ 1,411,506	\$ 1,408,862

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

Note 15. Restructuring and Other Charges

During the fourth quarter of 2023, we initiated a restructuring plan to increase efficiencies across the organization and incurred approximately \$14.0 million in restructuring expenses, of which \$5.3 million remained unpaid and were included in Accrued liabilities as of December 31, 2023. As of September 30, 2024, substantially all restructuring activities initiated in the fourth quarter of 2023 were complete.

Note 16. Subsequent Event

Subsequent to our quarter end, on October 23, 2024, we announced a restructuring plan to reduce costs by adjusting headcount for the existing business environment. The plan includes a reduction of our total headcount by approximately 700 employees. The costs associated with this action primarily include severance and other one-time post-employment benefits and are currently estimated to be between approximately \$25.0 million and \$30.0 million. We expect these activities to be substantially completed by the end of fiscal year 2024.

Additionally, on October 25, 2024, we announced a plan to repurchase \$275.0 million of our common stock through open market repurchases beginning in the fourth quarter of 2024 and continuing through the first quarter of 2025. The number of shares to be repurchased and the average price per share are not determinable as of the filing of this Quarterly Report on Form 10-Q. Upon completion of these open market repurchases the Company will have \$225.0 million remaining available for repurchases under the January 2023 Repurchase Program.

Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations.

Forward-Looking Statements

In addition to historical information, this Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the “Securities Act”), and Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”). These statements include, among other things, our expectations and intentions regarding our strategic objectives and the means to achieve them, our beliefs and expectations regarding macroeconomic conditions, including inflation, fluctuations in currency exchange rates, higher interest rates, market volatility, weakness in general economic conditions and recessions and the impact of efforts by central banks and federal, state and local governments to combat inflation and recession, our expectations and beliefs regarding customer and consumer purchasing behavior and changes in consumer spending habits, our expectations regarding product mix and product adoption, our expectations regarding competition and our ability to compete in our target markets, our expectations regarding the sales growth of our intraoral scanners, clear aligners and other products, our expectations regarding the impact of the military conflicts in the Middle East and Ukraine and our operations and assets in Israel and Russia, our marketing and efforts to build our brand awareness, our estimates regarding the size and opportunities of the markets we are targeting along with our expectations for growth in those markets, our beliefs regarding the impact of technological innovation in general, and in our solutions and products in particular; on target markets and patient care, our beliefs regarding digital dentistry and its potential to impact our business, our intentions regarding expanding our business, including its impact on our operational flexibility and responsiveness to customer demand, our expectations regarding our tax positions and the judgements we make related to our tax obligations, our beliefs regarding the importance of our manufacturing operations on our success, our beliefs regarding the need for and benefits of our technological development on Invisalign treatment, the areas of development in which we focus our efforts, and the advantages of our intellectual property portfolio, our beliefs regarding our business strategy and growth drivers, our expectations regarding the utilization rates for our products, including the impact of marketing on those rates and causes for periodic fluctuations of the rates, our expectations regarding the existence and impact of seasonality, our expectations regarding the productivity impact sales representatives will have on our sales and the impact of specialization of those representatives in sales channels, our expectations regarding the continued expansion of our international markets and their growth, 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, our beliefs regarding our culture and commitment and its impact on our financial and operational performance and its importance to our future success, 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, 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 and investment balances and borrowing capacity, our judgments regarding the estimates used in our revenue recognition and assessment of goodwill and intangible assets, our predicted level of operating expenses and gross margins and other factors beyond our control, as well as other statements regarding our future operations, financial condition and prospects and business strategies. These statements may contain words such as “expects,” “anticipates,” “intends,” “plans,” “believes,” “estimates,” or other words indicating future results. These forward-looking statements are subject to certain risks and uncertainties that could cause actual results to differ materially from those reflected in the forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in 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, 2023 as filed with the Securities and Exchange Commission (the “SEC”).

Executive Overview of Results

Trends and Uncertainties

Our business strategic priorities focus on four principal pillars for growth: (i) international expansion; (ii) general dental practitioners (“GP”) treatment; (iii) patient demand; and (iv) orthodontic utilization. Our growth strategy depends on our ability to facilitate the digital transformation of dentistry happening around the world, our continuous focus on innovation, and expansion to meet and exceed evolving customer expectations as the array of products and services available to them increases. Below is a discussion of the significant trends and uncertainties that could impact our operations:

Macroeconomic Challenges and Military Conflicts in Ukraine and the Middle East

Our revenues are susceptible to fluctuations caused by macroeconomic conditions, inflation, changes to currency exchange rates, higher interest rates, actual and threatened wars and military actions, threats of or actual recessions, supply chain challenges, market volatility, and other factors, each of which impacts customer confidence, consumer sentiment and demand. Many of these same factors also impact our costs and those of our suppliers through higher raw material prices, transportation costs, labor costs, supply and distribution operations. During 2024, we believe sales of our products have been impacted by macroeconomic conditions that adversely impacted disposable income and consumer demand and we believe this trend will continue for the remainder of 2024. We also expect the military conflict between Russia and Ukraine to continue to create market uncertainties and dampen consumer sentiment and demand, particularly in Europe. The impact of declining demand may vary by time and region, making operational results uncertain and difficult to predict.

Additionally, many of our international operations are denominated in currencies other than the U.S. dollar. In the third quarter of 2024, on a sequential basis, there was no significant impact from foreign exchange on our financial condition. However, the U.S. dollar remained strong against major currencies on a year-over-year basis, which negatively impacted our financial condition and results of operations for the quarter. Foreign exchange volatility and the subsequent strengthening or weakening of the U.S dollar against other currencies remains uncertain and unpredictable.

The ongoing conflict in the Middle East may further exacerbate general and regional macroeconomic instability, particularly if fighting continues to spread to other locations, create shipping and logistical challenges or cost increases, lead to sanctions or boycotts, or otherwise may materially impact our operations. For instance, our iTero business is headquartered in Israel. To date in 2024, the timing and cost of shipping our products has not been materially impacted and we have put measures in place to help reduce the risk of experiencing significant delays in the future. Additionally, although our operations have not thus far been materially impacted by employee absences, we have employees and consultants in Israel that have been called for military service and may be unavailable for an unknown period of time. Furthermore, while there have been export and import restrictions imposed against Israel, we have not been materially impacted by any trade sanctions yet. We continue to monitor the potential for violence and military actions that may directly or indirectly impact our personnel, manufacturing, supply chain, and sales.

Changing Product Preferences

As the markets for clear aligners and digital processes and workflows used to transform the practice of dentistry continue to mature, we anticipate customer and patient expectations and demands will continue to evolve. We expect to meet customer demands with innovative treatment options that include more choices to address a wider scope of treatment goals and budgets based on our existing and new products. This may result in larger and unpredictable variations in geographic and product mix and selling prices with uncertain implications on our financial statements and business operations.

We strive to manage the challenges from the trends and uncertainties, including the macroeconomic conditions, military conflicts and the evolution of our target markets, by focusing on improving our operations, building flexibility and efficiencies in our processes, adjusting our business models to changing circumstances and offering products that meet market demand. Specifically, we are managing financial impacts through strategic product innovations, introductions and pricing actions, implementing cost saving measures and evaluating hiring needs.

As an example, there was significant adoption of the Invisalign Comprehensive 3in3 product after it was introduced in 2023 that has continued in 2024. The 3in3 configuration offers doctors Invisalign Comprehensive treatment with a three-year treatment expiration date and three additional clear aligners included prior to the treatment expiration date. The 3in3 product allows us to recognize more revenue up front but is offered at a lower price as compared to our traditional Invisalign comprehensive product that has a five-year treatment expiration date with unlimited additional clear aligners prior to the treatment end date.

Further discussion of the impact of these challenges on our business may be found in Part II, Item 1A “Risk Factors.”

Key Financial and Operating Metrics

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

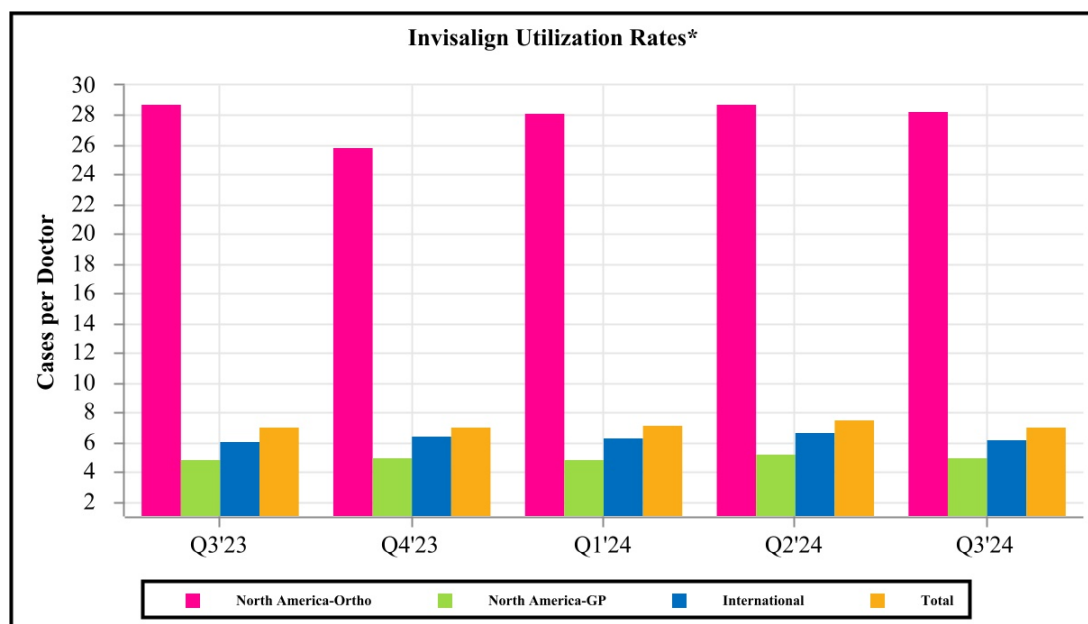
For the three months ended September 30, 2024, our business operations reflect the following:

- Revenues of \$977.9 million, an increase of 1.8% year-over-year;

- Clear Aligner revenues of \$786.8 million, a decrease of 1.0% year-over-year;
 - Americas Clear Aligner revenues of \$349.2 million, a decrease of 4.7% year-over-year;
 - International Clear Aligner revenues of \$361.5 million, an increase of 1.8% year-over-year;
 - Clear Aligner case volume increased 2.5% year-over-year and Clear Aligner case volume for teenage patients increased 6.7% year-over-year;
- Imaging Systems and computer-aided design and computer-aided manufacturing (“CAD/CAM”) Services revenues of \$191.0 million, an increase of 15.6% year-over-year;
- Income from operations of \$162.3 million and operating margin of 16.6%;
- Effective tax rate of 30.1%;
- Net income of \$116.0 million with diluted net income per share of \$1.55;
- Cash and cash equivalents of \$1,041.9 million as of September 30, 2024;
- Cash provided by operating activities of \$263.7 million;
- Capital expenditures of \$29.8 million, primarily related to investments in our manufacturing capacity and facilities; and
- Number of employees was 21,690 as of September 30, 2024, a decrease of 4.4% year-over-year.

Other Statistical Data and Trends

- As of September 30, 2024, approximately 18.9 million people worldwide have been treated with our Invisalign system. Management measures these results by comparing to the millions of people who can benefit from straighter teeth 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.
- For the third quarter of 2024, total Invisalign cases submitted with a digital scanner in the Americas increased to 96.1%, up from 94.6% in the third quarter of 2023 and international scans increased to 89.3%, up from 87.6% in the third quarter of 2023. For the third quarter of 2024, 98.2% of Invisalign cases submitted by North American orthodontists were submitted digitally.
- The total utilization rate in the third quarter of 2024 remained flat at 7.1 cases per doctor compared to the third quarter of 2023. Utilization rates in North America and our International locations were as follows:
 - *North America:* The utilization rate among our North American orthodontist customers decreased to 28.3 cases per doctor in the third quarter of 2024 compared to 28.8 cases per doctor in the third quarter of 2023 and the utilization rate among our North American GP customers increased to 5.0 cases per doctor in the third quarter of 2024 compared to 4.9 cases per doctor in the third quarter of 2023.
 - *International:* International doctor utilization rate was 6.2 cases per doctor in the third quarter of 2024 compared to 6.1 cases per doctor in the third quarter of 2023.



* 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, Invisalign Go and Invisalign Go Plus and Invisalign Palatal Expander.
 - In the U.S., Canada, and EMEA, we also offer a Doctor Subscription Program which is our monthly subscription-based clear aligner program. The program allows doctors the flexibility to order retainers and low-stage “touch-up” clear aligners within their subscribed tier and is designed for a segment of experienced Invisalign trained doctors who are currently not regularly using our retainers or low-stage aligners. The low-stage aligners, the Touch up product, are included as a Non-Comprehensive Product.
 - Non-Case products include, but are not limited to, retention products including retention aligners ordered through the Doctor Subscription Program, Invisalign training, adjusting tools used by dental professionals during the course of treatment and Invisalign Accessory 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 commerce channels in select markets.
- Our Systems and Services segment consists of sales related to our iTero intraoral scanning systems, which includes a single hardware platform and restorative or orthodontic software options, upgrades and leases of scanner systems, sales of pre-owned scanner systems, subscription software, disposables, pay per scan services, as well as exocad’s CAD/CAM software solutions that integrate workflows to dental labs and dental practices.

Net revenues for our Clear Aligner and Systems and Services segments by region for the three and nine months ended September 30, 2024 and 2023 are as follows (in millions):

Net Revenues	Three Months Ended September 30,				Nine Months Ended September 30,			
	2024	2023	Change		2024	2023	Change	
Clear Aligner net revenues:								
Americas	\$ 349.2	\$ 366.6	\$ (17.4)	(4.7)%	\$ 1,093.3	\$ 1,114.3	\$ (20.9)	(1.9)%
International	361.5	355.3	6.2	1.8 %	1,115.2	1,087.9	27.3	2.5 %
Non-case	76.1	73.0	3.1	4.2 %	227.3	215.3	12.0	5.6 %
Total Clear Aligner net revenues	\$ 786.8	\$ 794.9	\$ (8.1)	(1.0)%	\$ 2,435.8	\$ 2,417.4	\$ 18.4	0.8 %
Systems and Services net revenues	191.0	165.3	25.8	15.6 %	568.0	488.1	79.8	16.4 %
Total net revenues	\$ 977.9	\$ 960.2	\$ 17.7	1.8 %	\$ 3,003.8	\$ 2,905.5	\$ 98.3	3.4 %

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

Case volume data which represents Clear Aligner case shipments for the three and nine months ended September 30, 2024 and 2023 is as follows (in thousands):

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2024	2023	Change		2024	2023	Change	
Total case volume	617.2	602.3	14.9	2.5 %	1,865.0	1,815.9	49.1	2.7 %

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

For the three months ended September 30, 2024, total net revenues increased by \$18 million as compared to the same period in 2023, primarily due to an increase in Systems and Services net revenue from higher scanner average selling price ("ASP"), increase in non-system sales, and Clear Aligner net revenues from an increase in volume partially offset lower Clear Aligner ASP.

For the nine months ended September 30, 2024, total net revenues increased by \$98 million as compared to the same period in 2023, primarily due to an increase in Systems and Services net revenues from higher scanner ASP, increase in non-system sales and services revenue and Clear Aligner net revenues from an increase in volume, partially offset by lower Clear Aligner ASP.

Clear Aligner - Americas

For the three months ended September 30, 2024, Americas net revenues decreased by \$17 million as compared to the same period in 2023, primarily due to a 3.9% decrease in ASP, resulting in a decrease of net revenues of \$14 million. The decrease in ASP was driven by unfavorable foreign exchange rates that decreased net revenues by \$6 million, a mix shift to lower priced products and countries which reduced net revenues by \$23 million and higher promotional discounts which decreased net revenues by \$14 million. These decreases were partially offset by lower net deferrals which increased net revenues by \$23 million and price changes which increased net revenues by \$6 million.

For the nine months ended September 30, 2024, Americas net revenues decreased by \$21 million as compared to the same period in 2023, primarily due to a 1.6% decrease in ASP, resulting in a decrease of net revenues of \$18 million. The decrease in ASP was primarily driven by a mix shift to lower priced products and countries which reduced net revenues by \$71 million and higher promotional discounts which decreased net revenues by \$49 million. These decreases were partially offset by lower net deferrals which increased net revenues by \$86 million and price changes which increased net revenues by \$16 million.

Clear Aligner - International

For the three months ended September 30, 2024, International net revenues increased by \$6 million as compared to the same period in 2023, primarily due to a 6.3% increase in case volumes, resulting in increased net revenues by \$22 million. This increase was partially offset by a decrease of 4.3% in ASP which decreased net revenues by \$16 million. Lower ASP was due to unfavorable foreign exchange rates that decreased net revenues by \$5 million and a price reduction we took in the United Kingdom ("UK") to offset VAT on our sales into the UK, which decreased net revenues by \$8 million. ASP was also negatively impacted by a mix shift to lower priced products and countries, which reduced net revenues by \$15 million and

higher promotional discounts which reduced net revenues by \$31 million. The decreases in ASP were partially offset by lower net deferrals and price changes which increased net revenues by \$26 million and \$15 million, respectively.

For the nine months ended September 30, 2024, International net revenues increased by \$27 million as compared to the same period in 2023, primarily due to a 6.1% increase in case volumes, resulting in increased net revenues by \$67 million. This increase was partially offset by a decrease of 3.4% in ASP which decreased net revenues by \$39 million. Lower ASP was due to unfavorable foreign exchange rates that decreased net revenues by \$25 million, a price reduction we took in the UK to offset VAT on our sales into the UK, which decreased net revenues by \$23 million, a mix shift to lower priced products and countries which reduced net revenues by \$47 million and higher promotional discounts which reduced net revenues by \$83 million. The decreases in ASP were partially offset by lower net deferrals and price changes which increased net revenues by \$80 million and \$55 million, respectively.

Clear Aligner - Non-Case

For the three and nine months ended September 30, 2024, non-case net revenues increased by \$3 million and \$12 million, respectively as compared to the same period in 2023 primarily due to increased volume of Vivera retainers which includes retention aligners ordered through our Doctor Subscription Program.

Systems and Services

For the three months ended September 30, 2024, Systems and Services net revenues increased by \$26 million as compared to the same period in 2023 primarily due to higher scanner ASP which increased net revenues by \$20 million, an increase in sales of upgrade scanner systems which increased net revenues by \$7 million, and higher services revenues which increased net revenues by \$7 million. These increases were partially offset by lower volume and unfavorable foreign exchange rates which decreased net revenues by \$10 million and \$3 million, respectively.

For the nine months ended September 30, 2024, Systems and Services net revenues increased by \$80 million as compared to the same period in 2023 primarily due to higher scanner ASP which increased net revenues by \$38 million, an increase in sales of upgrade scanner systems which increased net revenues by \$30 million, and higher services revenue which increased net revenues by \$18 million. Additionally, CAD/CAM software revenues increased net revenues by \$6 million. These increases were partially offset by lower volume and unfavorable foreign exchange rates which decreased net revenues by \$3 million and \$7 million, respectively.

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

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2024	2023	Change	2024	2023	Change
Clear Aligner						
Cost of net revenues	\$ 234.0	\$ 232.6	\$ 1.4	\$ 715.3	\$ 685.7	\$ 29.6
<i>% of net segment revenues</i>	29.7 %	29.3 %		29.4 %	28.4 %	
Gross profit	\$ 552.8	\$ 562.3	\$ (9.5)	\$ 1,720.5	\$ 1,731.7	\$ (11.2)
<i>Gross margin %</i>	70.3 %	70.7 %		70.6 %	71.6 %	
Systems and Services						
Cost of net revenues	\$ 62.1	\$ 64.5	\$ (2.4)	\$ 186.3	\$ 182.5	\$ 3.8
<i>% of net segment revenues</i>	32.5 %	39.0 %		32.8 %	37.4 %	
Gross profit	\$ 128.9	\$ 100.7	\$ 28.2	\$ 381.7	\$ 305.6	\$ 76.1
<i>Gross margin %</i>	67.5 %	61.0 %		67.2 %	62.6 %	
Total cost of net revenues	\$ 296.1	\$ 297.1	\$ (1.0)	\$ 901.6	\$ 868.2	\$ 33.4
<i>% of net revenues</i>	30.3 %	30.9 %		30.0 %	29.9 %	
Gross profit	\$ 681.8	\$ 663.1	\$ 18.7	\$ 2,102.2	\$ 2,037.3	\$ 64.9
<i>Gross margin %</i>	69.7 %	69.1 %		70.0 %	70.1 %	

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

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

Clear Aligner

For the three and nine months ended September 30, 2024, our gross margin percentage decreased as compared to the same periods in 2023 primarily due to lower ASPs.

Systems and Services

For the three months ended September 30, 2024, our gross margin percentage increased as compared to the same period in 2023 primarily due to higher ASPs, partially offset by higher service and freight costs.

For the nine months ended September 30, 2024, our gross margin percentage increased as compared to the same period in 2023 primarily due to higher ASPs, partially offset by lower service revenue mix.

Selling, general and administrative (in millions):

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2024	2023	Change	2024	2023	Change
Selling, general and administrative	\$ 434.1	\$ 408.0	\$ 26.1	\$ 1,338.2	\$ 1,300.9	\$ 37.3
% of net revenues	44.4 %	42.5 %		44.6 %	44.8 %	

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

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

For the three months ended September 30, 2024, selling, general and administrative expense increased compared to the same period in 2023 primarily due to higher employee costs, including higher salary, fringe benefits, stock-based compensation and bonus.

For the nine months ended September 30, 2024, selling, general and administrative expense increased compared to the same period in 2023 primarily due to higher employee costs, including higher salary, fringe benefits, stock-based compensation and bonus partially offset by lower marketing expense.

Research and development (in millions):

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2024	2023	Change	2024	2023	Change
Research and development	\$ 85.3	\$ 88.7	\$ (3.5)	\$ 269.3	\$ 264.7	\$ 4.7
% of net revenues	8.7 %	9.2 %		9.0 %	9.1 %	

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, net of capitalized labor costs related to internal use software, 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 September 30, 2024, research and development expense decreased compared to the same period in 2023 primarily due to capitalization of labor costs related to internal use software, partially offset by higher employee costs.

For the nine months ended September 30, 2024, research and development expense increased compared to the same period in 2023 primarily due to higher employee costs, including salaries, fringe benefits, stock-based compensation, net of capitalized labor costs related to internal use software, and bonus, partially offset by lower outside services expense.

Legal settlement loss (in millions):

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2024	2023	Change	2024	2023	Change
Legal settlement loss	\$ 0.1	\$ —	\$ 0.1	\$ 31.2	\$ —	\$ 31.2
% of net revenues	— %	— %		1.0 %	— %	

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

For the three and nine months ended September 30, 2024, we recorded losses of \$0.1 million and \$31 million, respectively, due to legal settlements. Refer to Note 7 “Legal Proceedings” of the Notes to Condensed Consolidated Financial Statements for more information.

Income from operations (in millions):

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2024	2023	Change	2024	2023	Change
Clear Aligner						
Income from operations	\$ 276.3	\$ 296.3	\$ (20.0)	\$ 862.2	\$ 879.9	\$ (17.8)
Operating margin %	35.1 %	37.3 %		35.4 %	36.4 %	
Systems and Services						
Income from operations	\$ 68.7	\$ 45.0	\$ 23.8	\$ 189.2	\$ 132.6	\$ 56.6
Operating margin %	36.0 %	27.2 %		33.3 %	27.2 %	
Total income from operations ¹	\$ 162.3	\$ 166.3	\$ (4.0)	\$ 463.5	\$ 471.8	\$ (8.3)
Operating margin %	16.6 %	17.3 %		15.4 %	16.2 %	

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

¹ Refer to Note 14 “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.

For the three months ended September 30, 2024, our operating margin percentage decreased compared to the same periods in 2023 primarily due to increased employee costs.

For the nine months ended September 30, 2024, our operating margin percentage decreased compared to the same periods in 2023 primarily due to increased employee costs and legal settlement losses. Refer to Note 7 “Legal Proceedings” of the Notes to Condensed Consolidated Financial Statements for more information.

Clear Aligner

For the three and nine months ended September 30, 2024, our operating margin percentage decreased compared to the same periods in 2023 primarily due to a decrease in gross margin and increased employee costs.

Systems and Services

For the three and nine months ended September 30, 2024, our operating margin percentage increased compared to the same periods in 2023 primarily due to higher gross margin, partially offset by increased employee costs.

Interest income (in millions):

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2024	2023	Change	2024	2023	Change
Interest income	\$ 4.0	\$ 5.5	\$ (1.5)	\$ 11.7	\$ 12.3	\$ (0.6)
% of net revenues	0.4 %	0.6 %		0.4 %	0.4 %	

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

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

For the three months ended September 30, 2024, interest income decreased compared to the same period in 2023 primarily due to lower cash and cash equivalents and lower interest rates.

For the nine months ended September 30, 2024, interest income decreased compared to the same period in 2023 primarily due to lower cash and cash equivalents.

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

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2024	2023	Change	2024	2023	Change
Other income (expense), net	\$ (0.4)	\$ (9.8)	\$ 9.4	\$ (7.0)	\$ (15.7)	\$ 8.8
% of net revenues	— %	(1.0)%		(0.2)%	(0.5)%	

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

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

For the three months ended September 30, 2024, other income (expense), net increased compared to the same period in 2023 primarily due to the favorable impact of foreign exchange rates and losses on equity investments.

For the nine months ended September 30, 2024, other income (expense), net increased compared to the same period in 2023 primarily due to a gain recorded on our equity investments and the favorable impact of foreign exchange rates.

Provision for income taxes (in millions):

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2024	2023	Change	2024	2023	Change
Provision for income taxes	\$ 50.0	\$ 40.7	\$ 9.3	\$ 150.6	\$ 147.3	\$ 3.3
Effective tax rates	30.1 %	25.1 %		32.2 %	31.4 %	

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 and nine month periods ended September 30, 2024 and 2023 primarily due to the recognition of additional tax expense resulting from U.S. taxes on foreign earnings, foreign income taxed at different rates, state income taxes, and non-deductible expense in the U.S.

The increases in our effective tax rate for the three and nine months ended September 30, 2024 compared to the same periods in 2023 are primarily attributable to the change in our jurisdictional mix of income, recognizing a one-time tax benefit related to the application of tax guidance issued during the three months ended September 30, 2023, partially offset by a decrease in U.S. taxes on foreign earnings and remeasurement of Switzerland deferred tax asset due to Swiss tax rate change.

Liquidity and Capital Resources

Liquidity and Trends

As of September 30, 2024 and December 31, 2023, we had the following cash and cash equivalents and short-term and long-term marketable securities (in thousands):

	September 30, 2024	December 31, 2023
Cash and cash equivalents	\$ 1,041,935	\$ 937,438
Marketable securities, short-term	—	35,304
Marketable securities, long-term	—	8,022
Total	<u>\$ 1,041,935</u>	<u>\$ 980,764</u>

As of September 30, 2024 and December 31, 2023, approximately \$756.5 million and \$784.7 million, respectively, of cash, cash equivalents were held by our foreign subsidiaries. We continue to evaluate opportunities to repatriate our foreign earnings if or when needed. We do not expect to incur significant additional costs upon repatriation of these foreign earnings. 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.

Our material cash requirements are as follows:

- Our purchase commitments consist primarily of open purchase orders for goods and services, including manufacturing inventory, supplies and services, sales and marketing, research and development services and technological services, issued in the normal course of business. There have been no material changes to our purchase commitments for goods and services during the nine months ended September 30, 2024 as compared to the year ended December 31, 2023.
- There have been no material changes to our future operating lease payments during the nine months ended September 30, 2024 as compared to the year ended December 31, 2023.
- For 2024, we expect our investments in capital expenditures to be above \$100.0 million. Capital expenditures primarily relate to building construction and improvements as well as manufacturing capacity in support of our continued expansion. Despite the challenging market conditions, 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.
- In January 2023, our Board of Directors authorized a plan to repurchase up to \$1.0 billion of our common stock, \$500.0 million of which had been utilized as of September 30, 2024. We continually evaluate opportunities to repurchase shares of our common stock depending on various factors including our share price and current liquidity requirements. Refer to *Note 10 "Common Stock Repurchase Program" of the Notes to Condensed Consolidated Financial Statements* for details on our stock repurchase programs.

On October 25, 2024, we announced a plan to repurchase \$275.0 million of our common stock through open market repurchases beginning in the fourth quarter of 2024 and continuing through the first quarter of 2025. Refer to *Note 16 "Subsequent Event" of the Notes to Condensed Consolidated Financial Statements* for details on this common stock repurchase.

- As of September 30, 2024, we had no material off-balance sheet arrangements that have or are reasonably likely to have, a current or future material impact on our liquidity or capital resources.
- As of September 30, 2024, we agreed, in principle, to settle certain legal matters for a total of \$31.2 million. We expect to seek final court or administrative approvals, as applicable, in the second half of fiscal year 2024. Settlement payments will be made in accordance with the terms and conditions as set forth in the settlement agreements and/or court approvals. Refer to *Note 7 "Legal Proceedings" of the Notes to Condensed Consolidated Financial Statements* for more information.

- On October 23, 2024, we announced a restructuring plan to reduce costs by adjusting headcount for the existing business environment. We expect to incur between approximately \$25.0 million and \$30.0 million of restructuring charges, primarily related to severance and other one-time post-employment benefits.

Sources and Uses of Cash

The following table summarizes our condensed consolidated cash flows for the nine months ended September 30, 2024 and 2023 (in thousands):

	Nine Months Ended September 30,	
	2024	2023
Net cash flow provided by (used in):		
Operating activities	\$ 452,153	\$ 738,878
Investing activities	(200,996)	(182,619)
Financing activities	(152,703)	(248,059)
Effect of exchange rate changes on cash, cash equivalents, and restricted cash	6,008	(11,205)
Net increase (decrease) in cash, cash equivalents, and restricted cash	\$ 104,462	\$ 296,995

Operating Activities

For the nine months ended September 30, 2024, cash flows from operations of \$452.2 million resulted primarily from our net income of approximately \$317.6 million as well as the following:

Significant adjustments to net income

- Deferred taxes of \$17.5 million related to a decrease in long term deferred tax position;
- Depreciation and amortization of \$106.9 million related to our investments in property, plant and equipment and intangible assets;
- Stock-based compensation of \$134.9 million related to equity awards granted to employees and directors;
- Non-cash operating lease costs of \$28.6 million related to operating lease cost; and
- Other non-cash operating activities of \$6.9 million primarily related to an increase in our bad debt allowance and accounts receivable factoring.

Significant changes in working capital

- Net outflow of \$135.2 million in accounts receivable due to timing of collections and increased revenues; and
- Net inflow of \$47.6 million in accrued and other long-term liabilities primarily due to timing of payments.
- Net outflow of \$60.2 million in deferred revenue.

Investing Activities

Net cash used in investing activities was \$201.0 million for the nine months ended September 30, 2024 and primarily consisted of a \$77.1 million outflow for the Cubicure Acquisition, an outflow of \$75.0 million for our investment in Heartland and purchases of property, plant and equipment in the amount of \$92.6 million. Partially offsetting the cash outflows, is \$43.9 million in proceeds from marketable securities.

Financing Activities

Net cash used in financing activities was \$152.7 million for the nine months ended September 30, 2024 and primarily consisted of an outflow of \$150.0 million for share repurchases and payroll taxes paid for equity awards through share withholdings of \$28.0 million which were partially offset by \$25.3 million of proceeds from the issuance of common stock under our employee stock purchase plan.

Critical Accounting Estimates

Management's discussion and analysis of our financial condition and results of operations is based upon our Condensed Consolidated Financial Statements which have been prepared in accordance with accounting principles generally accepted in the U.S. The preparation of 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 ongoing basis, including those related to revenue recognition, goodwill and finite-lived acquired intangible assets, income taxes and legal proceedings and litigation. We use authoritative pronouncements, historical experience and other assumptions as the basis for making 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 historical prices, changing trends and market conditions, 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 consideration 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 options, 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. For CAD/CAM services, we estimate the SSP of each element, including the initial software license and maintenance and support, using data such as historical prices.

Recent Accounting Pronouncements

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

In the normal course of business, we are exposed to interest rate, foreign currency exchange and inflation risks that could impact our financial position and results of operations. In addition, we are subject to the broad market risk that is created by the global market disruptions and uncertainties resulting from macroeconomic challenges, geopolitical events, trade and other international disputes, including various military conflicts and consumer confidence. Further discussion on these risks may be found in *Part II, Item 1A “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. Fair market value of fixed-rate securities may be adversely impacted due to a rise in interest rates. 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 September 30, 2024, we had no available-for-sale marketable securities.

We do not enter into investments for trading or speculative purposes and have not used any derivative financial instruments to manage our interest rate risk exposure. As of September 30, 2024, we are not subject to risks from immediate interest rate increases on our unsecured revolving line of credit facility.

Currency Rate Risk

As a result of our international business activities, our financial results have been affected by changes in foreign currency exchange rates as well as 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 country. This provides some natural hedging because most of the subsidiaries' operating expenses are generally denominated in their local currencies.

We enter into foreign currency forward contracts for currencies where we have exposures, primarily the Euro, British Pound, Chinese Yuan, Polish Zloty and Canadian Dollar, to minimize the short-term impact of foreign currency exchange rate fluctuations on certain assets and liabilities. These forward contracts are not designated as hedging instruments and are generally one month in original maturity and are marked to market through earnings every period. 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. 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.

Inflation Risk

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

Item 4. Controls and Procedures.

Evaluation of disclosure controls and procedures.

Under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, we have evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of the end of the period covered by this Quarterly Report on Form 10-Q. Based upon that evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that our disclosure controls and procedures are effective as of September 30, 2024, to provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our Chief Executive Officer and our Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure, and that such information is recorded, processed, summarized and reported within the time periods specified in the SEC rules and forms.

Changes in internal control over financial reporting.

There were no changes in our internal control over financial reporting during the quarter ended September 30, 2024 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.

The information required by this item is incorporated herein by reference to the information set forth in *Note 7 "Legal Proceedings" of the Notes to Condensed Consolidated Financial Statements* in Part I, Item 1 of this Quarterly Report on Form 10-Q.

Under the heading "2019 Shareholder Derivative Lawsuit," in Note 7 "Legal Proceedings" of the Notes to Condensed Consolidated Financial Statements, we describe that in the first quarter of 2024, the parties to those derivative lawsuit actions entered into a settlement agreement. On August 2, 2024, the U.S. District Court for the Northern District of California granted preliminary approval of the settlement. A notice approved by the court regarding the final settlement approval hearing and describing the terms of the settlement, as well as a copy of the stipulation of settlement itself, is available on the Company's website at <https://investor.aligntech.com/derivativesettlement>.

Item 1A. Risk Factors.

The following discusses some of the risks and uncertainties that may affect our business, results of operations, financial condition and the price of our common stock. You should carefully review this section, 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 any others. These risk factors should be considered in connection with the forward-looking statements contained in this Quarterly Report on Form 10-Q 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 risks 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.

Macroeconomic and External Risks

Our operations and financial performance depend on global and regional economic conditions. Inflation, fluctuations in foreign currency exchange rates, changes in consumer confidence and demand, general economic weakness, and actual or potential recessions have and could in the future materially affect our business, financial condition, and results of operations.

Macroeconomic conditions impact consumer confidence and discretionary spending, which can adversely affect demand for our products. Consumer spending habits are affected by, among other things, inflation, fluctuations in foreign currency exchange rates, consumer confidence and demand, general economic weakness, actual or potential recessions, pandemics, wars and military actions, employment levels, wages, debt obligations, discretionary income, interest rates, volatility in capital, and perceptions of current and future economic conditions. Macroeconomic conditions can, among other things, reduce or shift spending away from elective procedures, drive patients to pursue less costly orthodontic treatments, decrease the number of orthodontic case starts, reduce patient traffic in dentists' offices, or reduce demand for dental services generally. Further, decreased demand for dental services can cause dentists and labs to postpone investments in capital equipment, such as intraoral scanners and CAD/CAM equipment and software. The declines in, or uncertain economic outlooks for, the U.S., Chinese, European, and certain other international economies have and may continue to adversely affect consumer and dental practice spending. Increases in the cost of fuel and energy, food, and other essential items as well as higher interest rates have and may continue to reduce consumers' disposable income, which could cause a decrease in discretionary spending for products like ours.

Inflation has and may continue to adversely impact spending and trade activities, and may unpredictably impact global and regional economies. Further, we cannot predict the impact of efforts by central banks and federal, state, and local governments to combat inflation, which could result in an economic recession or adversely impact consumer spending for a prolonged period of time. Higher inflation has and may continue to increase domestic and international shipping costs, raw material prices, and labor rates, causing an adverse impact on the costs of producing, procuring, and shipping our products. Our ability to recover these cost increases through price increases may continue to lag, resulting in downward pressure on our operating results. Attempts to offset cost increases with price increases may reduce sales, increase customer dissatisfaction, or otherwise harm our reputation. Any of these events could materially affect our business, financial condition, or results of operations.

We have significant international operations and sales and are therefore exposed to fluctuations in foreign currencies that have and may continue to adversely impact our business, financial condition, or results of operations. Although the U.S. dollar is our reporting currency, a large portion of our net revenues, expenses, and net income are generated in foreign currencies. While we utilize forward contracts to moderate the impact of exchange rate fluctuations on certain assets and liabilities, our hedging strategies may not be successful, and currency exchange rate fluctuations have and may continue to materially adversely affect our operating results and cash flows. In addition, our foreign currency exposure on assets, liabilities, and cash flows that we do not hedge have and could in the future materially impact our financial results in periods when the U.S. dollar significantly fluctuates in relation to foreign currencies.

Our business could be impacted by geopolitical events, trade and other international disputes, war and terrorism, or major public health crises.

Geopolitical events, trade and other international disputes, war and terrorism, or major public health crises have and could in the future harm or disrupt international commerce and the global economy, and could materially affect our business with our customers and consumers, suppliers, contract manufacturers, distributors, and other business partners. Such events have and could result in, among other things, supply chain and trade disruptions, tariffs, trade sanctions, customs inquiries or restrictions, boycotts, reduced consumer spending, government shut downs, cyberattacks, energy shortages or power outages, energy rationing that adversely impacts our manufacturing facilities, rising fuel or rising costs of producing, procuring, and shipping our products, constraints, volatility, or disruption in the financial markets, deaths or injuries to our employees, restrictions and shortages of food, water, shelter, and medical supplies, telecommunications failures, and protests that may impact delivery of our products to customers or destruction of property.

Tariffs, such as those on Chinese goods, and retaliatory trade measures in response may increase the cost of our products and the components and raw materials used to make them. Increased costs could adversely impact our gross margin and reduce demand for our products. Foreign countries may also adopt or rescind other measures, such as controls on the import or export of goods, technology, or data, including personal data, that could adversely impact our operations and supply chains or limit our ability to offer products and services. These measures could require us to take various actions, including changing suppliers or restructuring business relationships. Complying with new or revised trade restrictions may be expensive, time-consuming, and disruptive to our operations. Such restrictions may be announced with little or no advance notice and we may be unable to effectively mitigate any adverse impacts in a timely manner.

Geopolitical events, trade and other international disputes, war, terrorism, or major public health crises involving key commercial, development, or manufacturing markets such as China, Mexico, Israel, Poland, or other countries or regions have and may continue to materially impact our international operations. The impact to us, our employees, and our customers and consumers would be uncertain, particularly if emergency circumstances, armed conflicts, an escalation in political instability or violence, or viral outbreaks disrupt our product development, data or information exchange, payroll or banking operations, or our product or materials distribution. Additionally, our international operations could be impacted if such an event resulted in disruptions, interruptions, and limitations in telecommunication services or critical systems or applications reliant on a stable and uninterrupted communications infrastructure.

Military conflicts and global pandemics have and may in the future materially adversely impact the economies in which we operate. For example, our commercial operations and research and development in Russia have been impacted by the conflict in Ukraine and we were affected by the COVID-19 pandemic. Our iTero operations, headquartered in Israel, are close to areas that have been affected by ongoing violence and military action in the Middle East, which may impact our employees as well as our iTero business and operations. Some employees and consultants in Israel have been called for military service in the current conflict in the Middle East and they may be absent for an unknown period of time. Furthermore, our facilities may be damaged. Our supply chains have been and may continue to be impaired as a result of hostilities, trade restrictions, sanctions, or boycotts. These events could disrupt ongoing operations and may materially impact the timing and cost of shipping of our products or our ability to operate out of Israel. Additionally, China's territorial conflicts with other neighboring countries may impact our operations and sales in China. We cannot predict the progress or outcome of these events or the reactions by governments, businesses, or consumers and each event could, individually or in the aggregate, materially adversely affect our business, financial condition, and results of operations.

Our operations may be impacted by natural disasters, which may become more frequent or severe as a result of climate change, and may adversely impact our business, financial condition, and results of operations as well as those of our customers and suppliers.

Natural disasters can impact our operations and those of our customers and suppliers. Natural disasters such as earthquakes, tsunamis, floods, droughts, hurricanes, wildfires, and extreme weather conditions can cause deaths, injuries, and critical health crises, power outages, property damage, restrictions and shortages of food, water, shelter, and medical supplies, telecommunications failures, materials scarcity, price volatility, and other adverse consequences. Climate change is likely to increase the frequency and severity of natural disasters and, consequently, the risks to our business, operating results, and financial condition. Our digital dental modeling and certain of our customer facing operations are primarily processed in our facilities in Costa Rica; our iTero scanners are primarily manufactured in China and Israel; our aligner molds and finished aligners are fabricated in China, Mexico and Poland; and we have other treatment planning operations and customer facing support in Poland, China, Spain, Germany, France, and Japan. These regions are susceptible to natural disasters. If a natural disaster occurs in a region where one of these facilities or those of our customers or suppliers are located, our employees could be impacted, we could lose valuable research, and our ability to create treatment plans, respond to customer inquiries, or manufacture and ship our aligners or intraoral scanners could be compromised, causing significant product and services delays and reputational harm.

The effects of climate change 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.

Business and Industry Risks

Demand for our products may not increase or may decrease for many reasons, including resistance to the innovative and business-model-disruptive nature of some of our products and services, which could have a material impact on our business, financial condition, and results of operations.

Our products require our customers to forego traditional treatment methods. For example, Invisalign treatment is a significant change from traditional orthodontic wires and brackets, and customers and consumers may not find it cost-effective or preferable. A number of dental professionals believe Invisalign treatment is only appropriate for a limited percentage of patients. Additionally, our clear aligners and iTero products utilize digital technology and some dental professionals have and may continue to resist moving to a digital platform. Increased acceptance of our products depends in part on the recommendations of dental professionals, professional associations, societies, and organizations, as well as other factors including efficacy, safety, ease of use, reliability, aesthetics, and price compared to competing products and traditional treatment methods. If demand for our products fails to increase, or decreases, our business, financial condition, and results of operations may be harmed.

Our net revenues depend primarily on our Invisalign treatment plans and iTero scanners and declines in sales or average selling price of these products may adversely affect net revenues, gross profit, and net income.

Our net revenues are largely dependent on sales of our Invisalign treatment plans with clear aligners and iTero intraoral scanners. Of the two, we expect the Invisalign treatment plans will continue to account for the majority of our net revenues, making the widespread acceptance of the Invisalign system by orthodontists, GPs, and consumers critical to our success.

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

- we introduce new promotions, change existing promotions, or offer general or volume-based discount programs, product or services bundles, large account sales, or consumer rebate programs;
- participation in promotions or programs unexpectedly increases, decreases, or changes demand in material ways;
- our geographic, channel, or product mix shifts to lower priced products or to products with 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;
- governments impose pricing regulations such as volume-based procurement regulations in China; or
- our critical accounting estimates materially differ from actual results.

To stimulate product and services demand, we have a history of offering volume discounts, price reductions, and other promotions to targeted customers and consumers and releasing lower priced products. These promotional campaigns and lower priced products have had, and may in the future have, unexpected and unintended consequences, including reduced net revenues, gross margins, operating margin, net income, average selling prices, and volume.

Competition in the markets for our products is increasing and we expect aggressive competition from existing competitors, other companies that 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 experiencing immense and rapid digital transformation. While solutions such as our Invisalign treatment plans, iTero scanners and CAD/CAM software facilitate this transition, we face competition from companies that also seek to introduce new technologies and products and companies that remain dedicated to traditional products. We may be unable to compete with these competitors or they may render our technology or products obsolete or economically unattractive, in particular as competitors incorporate artificial intelligence (“AI”) and machine learning into new or existing services and technologies that facilitate changes in doctor-patient interactions, expectations, and treatment workflows.

The number and types of competitors are diverse and growing rapidly. Invisalign aligners compete primarily with traditional wires and brackets and increasingly against clear aligners which are manufactured and distributed by new market entrants and existing competitors, including traditional medical device companies, laboratories, startups and, in some cases, doctors and dental support organizations (“DSOs”). Our competitors also include direct-to-consumer companies that provide clear aligners using a business model requiring little or no in-office care from trained and licensed doctors, and doctors and DSOs who manufacture custom aligners in their offices using 3D printing technology. Large consumer product companies may also start supplying orthodontic products. Orthodontists, GPs, and DSOs have and may continue to sample competitive and alternative products and take advantage of competitive promotions and sale opportunities.

Our iTero scanners are also facing increased competition from new and existing competitors. Our iTero scanners compete with polyvinyl siloxane impressions and numerous new or existing intraoral scanners, as well as traditional bite wing 2D dental

x-rays for detecting interproximal caries. We have and may continue to experience competition with our iTero scanners by competitors who introduce products at lower prices or with functionality that better meets customer demand.

If we are unable to compete effectively with existing products, existing competitors, new market entrants, or respond effectively to new technologies, our business, financial condition, and results of operations could be materially adversely impacted.

Our success depends on our ability to successfully develop, introduce, achieve market acceptance of, and manage new products and services.

Our success depends on our ability to quickly and profitably develop, manufacture, market, and obtain and maintain regulatory approval or clearance of new products and services along with improvements to, or refurbishing of, existing products and services. We cannot assure successful development, sales, or acceptance of our new or improved products and services. The extent and rate at which new products or services achieve market acceptance and penetration is a function of many variables, including our ability to:

- successfully predict, timely innovate, develop, and launch new technologies, applications, features, and products to meet market needs and keep pace with changes in technology, customers' demands, and industry standards;
- successfully, and in a timely fashion, obtain regulatory approval or clearance of new and improved products or services from government agencies such as the FDA and analogous agencies in other countries;
- cost-effectively and efficiently develop, manufacture, quality test, market, dispose of, and sell new or improved products and services offerings, including localized versions for international markets;
- properly forecast the amount and timing of new or improved product and services demand;
- allocate our research and development funding to products and services with higher growth prospects;
- ensure the compatibility of our technology, services, and systems with those of our customers;
- anticipate and rapidly innovate in response to new competitive products and services offerings and technologies;
- differentiate our products and services from those of our competitors as well as other products and services in our own portfolio and successfully articulate the benefits to potential customers;
- manage the impact of nationalism or initiatives encouraging consumer purchases from domestic vendors;
- qualify for third-party reimbursement for procedures involving our products or services;
- offer attractive and competitive products and service and subscription plans;
- encourage customers to adopt new technologies and provide the needed technical, sales, and marketing support to make new product and services launches successful;
- manage government procurement program restrictions; and
- source and receive quality raw materials or parts from our suppliers.

If we fail to accurately predict the needs and preferences of customers and their patients, or fail to offer viable products or services, we may invest heavily in research and development that does not lead to significant revenues. Even if we successfully innovate and develop new products and product improvements, we may incur substantial costs doing so and our profitability may suffer. Introduction and acceptance of any products and services may take significant time and effort, particularly if they require doctor education and training to understand their benefits or doctors choose to withhold judgment on a product until patients complete their treatments.

In addition, we periodically introduce new business and sales initiatives to meet customers' needs and demands. In general, our internal resources support these initiatives without clear indications they will prove successful or be without short-term execution challenges. Should these initiatives fail, our business, financial condition, and results of operations could be materially adversely impacted.

We may invest in or acquire other businesses, products, technologies, or other assets which may require significant management attention, disrupt our business, dilute stockholder value, or adversely affect our results of operations.

Periodically, we have and may in the future acquire, or make investments in, companies, technologies, or other assets. Alternatively, we may be unable to find suitable investment or acquisition opportunities or be unable to complete investments or acquisitions on favorable terms. If we make investments or complete acquisitions, we may not ultimately strengthen our competitive position or achieve desired synergies and integration, and investments or acquisitions we complete could be viewed negatively by our customers, securities analysts, and investors. Opposition to acquisitions may lead to negative ratings by analysts or investors, give rise to stockholder objections, or result in stockholder activism, any of which could disrupt our operations or harm our stock price. 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 unable to control or have significant influence over critical issues that could harm the value of our investment.

We are subject to various risks when making a strategic investment or acquisition and integrating the operations and cultures of acquired businesses within our own, which could materially impact our business, financial condition, or results of operations, including that we may:

- fail to perform proper due diligence and inherit unexpected material issues or assets, including intellectual property (“IP”) or other litigation or ongoing investigations, accounting irregularities, or compliance liabilities;
- fail to comply with regulations, governmental orders, or decrees;
- experience IT security and privacy compliance issues;
- invest in companies that generate net losses or are slow or fail to develop;
- not realize a positive return on investment or determine that our investments have declined in value, which could require recording potential impairments;
- need 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;
- find it difficult to implement and harmonize company-wide financial reporting, forecasting and budgeting, accounting, billing, IT, and other systems due to inconsistencies in standards, internal controls, procedures, and policies;
- require significant time and resources to effectuate the integration;
- fail to retain key personnel or harm our existing culture or the culture of an acquired entity;
- not realize material portions of the expected synergies and benefits of the investment or acquisition; or
- unsuccessfully evaluate or utilize the acquired technology or acquired company’s know-how or fail to successfully integrate the technologies acquired.

Operational Risks

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

Our quarterly and annual operating results have and will continue to fluctuate for a variety of reasons. Some of the factors that have historically, and could in the future, cause our operating results to fluctuate include:

- changes in consumer and doctor demand;
- changes in manufacturing, packaging, delivery, and inventory costs;
- the creditworthiness, liquidity, and solvency of our customers and their ability to timely make payments when due;
- our ability to collect payments;
- our acceptance of longer customer payment cycles;
- changes in the timing of revenue recognition and our average selling prices;
- seasonal fluctuations;
- geographic, channel, or product mix shifts to lower priced products or to products with a higher percentage of deferred revenue;
- improvements to or changes in our 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;
- changes in costs and expenditures, including in connection with new treatment planning and fabrication facilities and the hiring and deployment of personnel;
- the timing of clear aligner treatment order submissions, acceptance, processing, and fulfillment, which can cause fluctuations in our backlog; and
- timing and fluctuation of spending around marketing and brand awareness campaigns and industry trade shows.

If we underestimate product demand, it may exceed our manufacturing capacity or that of one or more of our suppliers, we may be understaffed, and we may not have sufficient materials for production. Specifically, our manufacturing process relies on sophisticated computer software and requires new technicians to undergo a long training process, often 120 days or longer. Additionally, production levels for our iTero scanners are generally based on forecasts and historic product demand and we often place orders with suppliers for materials, components, sub-assemblies, and finished products weeks or more in advance of projected customer orders. In addition, we may be required to purchase or lease additional or larger facilities and equipment to manage demand. As a result, if we fail to accurately predict demand, we may have an insufficient number of trained technicians, or an inadequate amount of materials, components, space, or equipment to timely manufacture and deliver products to meet demand, which could damage our relationships with existing customers or harm our ability to attract new customers.

Conversely, if we overestimate customer demand, we may have excess staffing, materials, components, finished products, or capacity. If we hire and train too many technicians in anticipation of demand that does not materialize or materializes slower than anticipated, our costs and expenditures may outpace revenues or revenue growth, harming our gross margin and financial results. Additionally, to secure supplies for production of products, we periodically enter into non-cancelable minimum purchase commitments with vendors, which could impact our ability to adjust inventory for declining demand. If product demand decreases, we may have excess space for manufacturing or insufficient space to store excess materials, components, or finished products. Responding to decreased demand may take time, and could lower our gross margin.

We may make business decisions that adversely affect our operating results such as modifications to our pricing policies 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 are below expectations, we may be unable to timely or effectively reduce spending to offset any net revenues shortfall. This variability

and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period.

We are subject to operating risks, including excess or constrained capacity and operational inefficiencies, which could adversely affect our results of operations.

We are subject to operating risks, including excess or constrained capacity and pressure on our internal systems, personnel, and suppliers. To manage current and anticipated future operations effectively, we must continually implement and improve our operational, financial, and management information systems, hire, train, motivate, manage, and retain employees, and ensure our suppliers remain diverse and capable of meeting demand for the systems, raw materials, parts, and components essential to product manufacturing and delivery. We may fail to balance near-term efforts to meet existing demand with future demand, including adding personnel, creating scalable, secure, and robust systems and operations, and automating processes for long-term efficiencies. Production of our Invisalign aligners and iTero scanners could also be 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, the quality of or changes in product components, and limited production yields. Any such failure could materially impact our business, financial condition, and results of operations.

Additionally, we have established treatment planning and manufacturing facilities closer to our international customers to provide better experiences, create efficiencies, and provide redundancy should other facilities become unavailable. If one of these facilities is temporarily, partially, or fully shut down, we may be unable to timely fulfill orders, which may negatively impact our financial results, reputation and overall business.

Our products and IT systems are critical to our business. Issues with product development or enhancements, IT system and software integration, implementation, updates, and upgrades, or third-party software have previously and could again in the future disrupt our operations and have a material impact on our business, our reputation, and operating results.

We rely on the efficient, uninterrupted, and secure operation of our complex IT systems and are dependent on key third-party software embedded in our products and IT systems as well as third-party hosted IT systems to support our operations, including third-party cloud platforms. All software and IT systems are vulnerable to damage, cybersecurity attacks, or interruption from a variety of sources, including rapidly developing AI technologies. To effectively manage and improve our operations, our IT systems and applications require an ongoing commitment of significant expenditures and resources to maintain, protect, upgrade, 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 cybersecurity threats, and changing customer preferences. Usage of online and hosted technology platforms by us, our customers, and suppliers, including remote working, teledentistry, and new or expanded use of online service platforms, products, and solutions such as doctor, consumer, and patient apps 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, product development, manufacturing, and other software and IT systems which entails certain risks, including disruption of our operations, such as our ability to continue developing and updating products that are safe and secure, track orders and timely ship products, manage our supply chain, and aggregate financial and operational data. Failure to adequately protect and maintain the integrity of our products and our IT systems and those of our suppliers and customers may materially impact our business, financial condition, and results of operations.

We have a complex, global iTero scanner installed base of older and newer models. These models are continually updated to add, expand, or improve features with new hardware, or to provide repair or replacement parts. 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 continue to be unable to ensure that third party components or changes to them will be compatible with, or will not have a negative impact on the functionality of, our iTero scanners. As a result, there have been and may be widespread failures of our iTero scanners or we may experience epidemic failures of our iTero scanners to perform as anticipated. We may not be fully prepared for, or have the infrastructure to, timely and adequately remediate or implement corrective measures for such failures, including due to our dependency on third-party providers or suppliers. Consequently, any remediation may be time-consuming and difficult to achieve, which may materially impact our customers and business partners, damage our reputation, and result in lost business and revenue opportunities, and could be materially costly.

A significant portion of our clear aligner production is dependent on digital scans from our globally dispersed and decentralized installed base of iTero and third-party intraoral scanners. Failures of all or any portion of our 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 materially and adversely affect our ability to accept scans, manufacture clear aligners or restorative procedures or treatments and services, or otherwise service our customers. Any of these events could harm our sales, damage our reputation, adversely impact our strategic partners, or result in litigation.

Additionally, we continuously upgrade and issue new releases of software applications upon which customer facing manufacturing and treatment planning operations depend. Software applications and products containing software frequently contain errors or defects, especially when first introduced or 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 applications and models of our iTero 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, which we are unable to cure in a timely fashion, 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 effect on our business, financial condition or results of our operations and the operations of our customers or our business partners.

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 materially 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 iTero scanners. We maintain single supply relationships for many of these machines and materials. By using single suppliers in limited locations for materials and manufacturing, we are exposed to multiple supply chain vulnerabilities. We are reliant upon manufacturers that we contract with for quality and stability and any failures on their part may have an impact on our ability to supply our products.

Because of our dependence on our suppliers, changes in key relationships can materially disrupt our supply chain. 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 significant interruptions in the supply of one or more products, product retesting, or additional product registration causing us to lose revenues and damage customer relationships. Technology changes by our service providers, vendors, and other third parties 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 increases in price for these items, sales may decrease and our business and prospects may be harmed.

We use distributors for a portion of the importation, marketing, and sales of our products and services, which exposes us to risks to our sales, operations, and reputation, including the risk that these distributors do not comply with applicable laws or our internal procedures.

In addition to our direct sales force, we have and expect to continue to use distributors to import, market, sell, service, and support our products. Our distribution agreements are generally non-exclusive and terminable by either party with customary notice. If alternative distributors cannot 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 key markets 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, safety, data privacy, false advertising or unfair and deceptive trade practices, and marketing and sales activities. The conduct of these distributors also impacts our reputation and our brand. If our distributors fail to satisfy customers, our reputation and brand loyalty could be harmed. 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.

A disruption in the operations of a primary freight carrier, higher shipping costs, or shipping delays could disrupt our supply chain and impact our operating and financial results.

We are dependent on commercial freight carriers, primarily United Parcel Service, Inc. ("UPS"), to deliver our products. If the operations of carriers are disrupted or we fail to mitigate any disruptions, we may be unable to timely deliver products to our customers who may choose alternative products, causing our net revenues and gross margin to decline, possibly materially. 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, which carry higher shipping costs that 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 increases along to our customers, or we cannot otherwise offset such increases, our gross margin and financial results could be materially affected.

Our success depends on our personnel. If we cannot attract, motivate, train or retain personnel, it may be difficult to achieve our strategic priorities, materially affecting our results of operations.

We are highly dependent on the talent and efforts of our personnel. We strive to retain our personnel by providing competitive compensation and benefits, development opportunities and training, flexible work options, and an inclusive corporate culture. However, competition for highly-skilled personnel, particularly technical and digital talent, is intense, and our competitors have and are likely to continue to recruit our personnel. Our compensation and benefit arrangements may not successfully attract new personnel or retain and motivate existing personnel. In addition, other internal and external factors can impact our ability to hire and retain talent, including insufficient advancement or career opportunities, in-office or hybrid work policies, and restrictive immigration policies. The loss of any key personnel, particularly executive management, research and development personnel, or sales personnel, could harm our business and prospects and impede the achievement of our research and development, operational or strategic objectives.

We provide significant training to our personnel and our business will be harmed if our training fails to properly prepare them 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 are not cost-effective. Moreover, for certain roles, this training and experience can make key personnel, such as our sales personnel, highly desirable to competitors and lead to increased attrition. 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. The loss of the services and knowledge of our highly-skilled personnel may significantly delay or prevent the achievement of our development and business objectives.

Additionally, seamless leadership transitions for key positions are critical to sustaining our culture and organizational success. If our succession planning is ineffective, it could adversely impact our business. We continually assess key personnel that we believe are essential to our long-term success. Moreover, future organizational changes may cause attrition rates to increase. If we fail to effectively manage any organizational or strategic changes, our financial condition, results of operations, and reputation, as well as our ability to successfully attract, motivate, and retain key personnel, may be harmed.

We have adopted a hybrid work schedule in many of our offices, allowing employees to collaborate and connect with others several days each week while providing the option to work remotely other days. This hybrid work approach may create challenges with maintaining our corporate culture, employee satisfaction, and hiring, promotion, and retention.

We believe a key to our success has been the culture we have created that emphasizes a shared vision and core values of agility, customer success, and accountability. We have experienced and may continue to experience in the future, difficulties attracting and retaining personnel that meet the qualifications, experience, compliance mindset, and values we expect. If we cannot attract and retain personnel that meet our selection criteria or relax our standards, our corporate culture, ability to achieve our strategic objectives, and our compliance with obligations under our internal controls and other requirements may be harmed. This could have a material adverse effect on our results of operations and our ability to maintain market share.

We have personnel represented by works councils and trade unions in certain countries and others that may be or may become eligible to be represented by works councils, trade unions and other employee associations. Labor disputes and work stoppages involving our personnel may disrupt our operations and could materially impact our results or operations.

We depend on our marketing activities to deepen our market penetration and raise awareness of our brands and products, which may prove unsuccessful 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, and social media and alliances with professional sports teams, social media influencers, and other strategic partners. There is no assurance our advertising campaigns will achieve the returns on advertising spend desired, increase brand or product awareness sufficiently, 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 are perceived by a portion of society negatively, our sponsorships or support of these entities or individuals may be questioned, our products boycotted, and our reputation harmed, any of which could materially affect our financial results 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 have in the past and may again in the future be alleged to violate marketing restrictions and be ordered to stop certain marketing activities or prevented from selling our products. Moreover, competitors do not always follow these restrictions, creating an unfair advantage and making it more difficult and costly 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 we do not control, such as the Android and iOS operating systems, and mobile browsers. Changes in such systems that degrade or eliminate our ability to target or measure the results of ads or increase costs to target audiences could adversely affect our campaigns. Operating systems could also include data privacy settings that may limit our ability to interpret, target and measure ads effectively.

Legal, Regulatory and Compliance Risks

We are subject to antitrust and competition regulations, litigation, and enforcement that may result in fines, penalties, restrictions on our business practices, and product or operational changes which could materially impact our business.

We currently are and may in the future be subject to antitrust, competition, or unfair competition related investigations, enforcement actions, or claims by governmental agencies, competitors, consumers, customers, and others which, even if unfounded, could cause us to incur substantial costs, enter into settlements, consents, be subject to judgments, involve negative publicity, and divert management time and attention, which may materially impact our results of operations. Resolving these matters may require us to change our business practices in materially adverse ways. Governments and regulators are actively developing new competition laws and regulations aimed at the technology sector, AI and digital platforms, and global activities and expansion, including in large markets such as the United States, the European Union (“EU”), and China. In Europe, the EU AI Act entered into force on August 1, 2024 and will become fully applicable on August 2, 2026, with some provisions already applying beginning in February 2025. Although we do not engage in developing or providing AI systems that would qualify as “prohibited AI practices,” restrictions and obligations under this regulation, to the extent applicable to us, could increase costs and burdens to us and our customers, and delay or halt deployment of new products and services, which may have a negative impact on our business and financial results. Government regulatory actions and court decisions may result in fines or hinder our ability to provide certain benefits to our consumers, reducing the attractiveness of our products and the revenue derived from them. These actions and decisions may also hinder our ability to pursue certain mergers, acquisitions, business combinations, or other transactions.

Failure to obtain or maintain approvals or comply with regulations regarding our products or services or those of our suppliers could materially harm our sales, result in substantial penalties and fines, interrupt our supply chain, and cause harm to our reputation.

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, processing, and disclosure of personal, financial, and medical information as well as healthcare records;
- processing and use of children’s personal and health data;
- websites and application advertising that collect and use personal data for marketing purposes;
- prohibitions against the offer, payment, or receipt of remuneration to induce referrals to entities providing healthcare services or goods or to induce the order, purchase, or recommendation of our products; and
- the design, manufacture, marketing, and advertising of our products.

The healthcare and technology markets are also highly regulated and subject to changing political, economic, and regulatory influences. Global regulators are expanding and changing regulations and guidance for products, which can limit the potential benefits of products and cause protracted review timelines for new products. Our critical third-party vendors and service providers are similarly subject to various regulations. Our failure or the failure of our suppliers, customers, advertisers, consultants, 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 allegations of false or misleading advertising or violations of laws or regulations, which may result in costly investigations, fines, penalties, as well as material judgments, settlements or decrees. We are also subject to complex, new and changing environmental, health and safety regulations. There can be no assurance we will adequately address the business risks associated with the implementation and compliance with such laws and our internal processes and procedures to comply with such laws or that we will be able to take advantage of any resulting business opportunities.

Furthermore, before we can sell a new medical device or market a new use of, or claim for, an existing product, we frequently must obtain clearance or approval to do so. For instance, in the United States, FDA regulations are wide ranging and govern, among other things, product design, product materials, development, manufacturing and testing, product labeling, and product storage. It takes significant time, effort, and expense to obtain and maintain clearances and approvals of products and services, and there is no guarantee we will timely succeed, if at all, in the countries in which we do business. In other countries, the requirements, time, effort, and expense to obtain and maintain clearances may differ materially from those of the FDA. Moreover, these laws may change, resulting in additional time, expense, or loss of market access. If requirements to market our products or services are delayed, we may be unable to offer them in markets we deem important. Additionally, failure to comply with applicable regulatory requirements could result in enforcement actions with sanctions including, among other things, fines, civil penalties, and criminal prosecution. Delays or failures to obtain or maintain regulatory approvals, clearances or to comply with regulatory requirements may materially harm our domestic or international operations, and adversely impact our business.

We and certain of our third-party vendors must also comply with and adhere to facility registration and product listing requirements for Quality System regulations. The FDA enforces its Quality System regulations through periodic unannounced inspections. Failure to satisfactorily correct an adverse inspection finding or to comply with applicable manufacturing

regulations can result in enforcement actions, or require us to find alternative manufacturers, which could be a long and costly process and may cause reputational harm. Enforcement actions by regulators could have a material effect on our business.

We are also subject to anti-corruption and anti-bribery (“ABAC”) laws such as the Foreign Corrupt Practices Act (“FCPA”) and the U.K. Bribery Act of 2010, which generally prohibit payments to foreign officials for the purpose of obtaining or maintaining business, securing an advantage, and directing business to another. To comply with ABAC laws, regulators require that we maintain accurate books and records and a system of internal accounting controls. Under the FCPA, we may be held liable for corruption by directors, officers, employees, agents, or other strategic or local partners or representatives.

In addition, while we have policies requiring compliance with applicable laws and regulations and we provide significant training to foster compliance, our employees, third parties acting on our behalf, and customers may not properly adhere to our policies or applicable laws or regulations, including the use of certain electronic communications and maintaining accurate books and records. If our personnel or the personnel of our agents or suppliers fail to comply with any laws, regulations, policies, or procedures, or we fail to audit and enforce compliance, our reputation may be harmed, we may lose customers or revenues, or we may face regulatory investigations, actions, and fines.

In June 2024, the U.S. Supreme Court reversed its longstanding approach under the Chevron doctrine, which provided for judicial deference to regulatory agencies, including the FDA. We cannot be sure whether there will be increased challenges to existing agency regulations or how lower courts will apply the decision in the context of other regulatory schemes without more specific guidance from the U.S. Supreme Court as a result of this decision. For example, this decision may result in more companies bringing lawsuits against the FDA to challenge longstanding decisions and policies of the FDA, which could undermine the FDA's authority, lead to uncertainties in the industry, and disrupt the FDA's normal operations, which could impact the timely review of any regulatory filings or applications we submit to the FDA.

Security breaches, data breaches, cybersecurity attacks, other cybersecurity incidents, or the failure to comply with privacy, security, and data protection laws could materially adversely impact our operations and patient care, and we could be liable for damages, and our business, operations, and reputation could be harmed.

We retain confidential employee, applicant, and customer personal, health and financial, and our own proprietary information and data essential to our business operations. We rely on the effectiveness of our IT systems, our policies and contracts and policies of our third-party vendors, and the IT systems of our service providers and other third parties to safeguard the information and data. Additionally, our cybersecurity controls depend on our healthcare providers, many of whom are individual or small operations with limited IT experience and inadequate or untested security protocols, to successfully manage data privacy and security requirements. It is critical that the facilities, infrastructure, and IT systems on which we depend and the products we develop remain secure and be perceived by the marketplace and our customers as secure. Despite the implementation of security features in our products and security measures in our IT systems, we and our service providers, third-party vendors, and other third parties could be targeted by or subject to physical break-ins, computer viruses and other malicious code, unauthorized or fraudulent access, programming errors or other technical malfunctions, hacking or phishing attacks, malware, ransomware, employee error or malfeasance, cybersecurity attacks, malicious code from common open source code, and other breaches of IT systems or similar disruptive actions, including by organized groups and nation-state actors, which may limit the availability of our systems and result in the unauthorized disclosure of confidential information. For example, we have experienced, and may again experience in the future, cybersecurity incidents, data incidents, and unauthorized internal employee exfiltration of company information. This risk is exacerbated with the advancement of technologies like AI, which malicious third parties are using to create new, more sophisticated and more frequent attacks.

Further, the frequency and sophistication of third-party cybersecurity attacks is increasing. 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 management, and require significant time and resources to address. Legal or regulatory action against us could prevent us from resolving issues quickly or force us to resolve them in unanticipated ways, cause us to incur significant expense and damages, or result in orders forcing us to cease operations or modify our business practices in ways that materially limit or restrict the capabilities of our products and services. Concerns over our privacy practices could adversely affect others' perception of us and deter customers and patients from using our products. In addition, patient care could suffer, and we could be liable if our products or IT systems fail to timely deliver accurate and complete information. We have cybersecurity and other forms of insurance coverage related to cyberattacks, breaches, and other incidents or security problems. However, damages and claims arising from specific incidents may not be covered, 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 material. The costs to eliminate, mitigate, or recover from security problems and cybersecurity attacks and incidents could be material 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 impact on our operations, net revenues, and operating results.

Additionally, our iTero scanners sold to customers globally, strategic business partners, or other locations may be independently or collectively the target of cybersecurity incidents or attacks or subject to viruses, bugs, or other similar negative intruders. Due to the large and growing number of these decentralized devices, we may be unable, or not have the capacity,

knowledge, or infrastructure, to respond to or remedy a cybersecurity issue in a timely manner, which may cause loss or damage to us, 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.

We are also subject to federal, state, and foreign laws and regulations respecting the security and privacy of patient healthcare information applicable to healthcare providers and their business associates, such as the Health Insurance Portability and Accountability Act of 1996, as well as those relating to privacy, data security, content regulation, and consumer protection. We are subject to various national and regional data localization or data residency laws, including U.S. state law, the EU General Data Protection Regulation and analogous laws in China which generally require certain types of data collected within a country be stored and processed only within that country or approved countries. Other countries are considering 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. These laws and regulations are constantly evolving and may be created, interpreted, applied, or amended in ways that adversely affect our business.

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, materials, 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 individual customers or companies, including hospitals and clinics, and how we train and support doctors, their staffs and patients who 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 our products or services cause injury or are 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 (“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 material legal defense costs and damage our reputation, increase our expenses, and divert management’s attention.

Increased focus on current and anticipated environmental, social and governance (“ESG”) laws and scrutiny of our ESG policies and practices may materially increase our costs, expose us to liability, and adversely impact our reputation, employee retention, willingness of customers and suppliers to do business with us and willingness of investors to invest in us.

Our operations are subject to a variety of existing local, regional and global ESG laws and regulations, and we are and may be required to comply with new, broader, more complex and more costly ESG laws and regulations, such as the E.U.’s Corporate Sustainability Reporting Directive. Our compliance obligations span all aspects of our business and operations, including product design and development, materials sourcing and other procurement activities, product packaging, product safety, energy and natural resources usage, facilities design and utilization, recycling and collection, transportation, disposal activities and workers’ rights.

Environmental regulations related to greenhouse gases, hazardous materials, sustainability, and reduction of waste are expected to have an increasingly larger impact on us or our suppliers. Many U.S. and foreign regulators have or are considering enacting new or additional disclosure requirements or limits on the emissions of greenhouse gases, including carbon dioxide and methane, from power generated using fossil fuels. The effects of greenhouse gas emission limits on power generation are subject to significant uncertainties, including the timing of new requirements, levels of emissions reductions and the scope and types of emissions regulated. Additionally, laws on sustainability and waste reduction are increasing and consumers may demand our products, packaging and operations be more sustainable, affect how we manufacture and package our products, increase our costs and those of our suppliers, and which may result in manufacturing, transportation, and supply chain disruptions if clean energy or sustainable alternatives are not readily available in adequate amounts when required. Moreover, alternative clean energy sources, coupled with reduced investments in traditional energy production and infrastructure, may not provide the predictable, reliable, and consistent energy that we, our suppliers and other businesses require.

Additionally, the sourcing and availability of metals used in the manufacture of, or contained in, our products may be affected by laws and regulations governing the use of minerals obtained from certain regions of the world like the Democratic Republic of Congo and adjoining countries. Our expanding geographic operations may increase the risk of purchasing “conflict minerals” and our efforts to identify whether any of our products contain minerals impacted by these laws and regulations may not be adequate or complete. Other restrictions apply to the substances incorporated into our products, including the chemical compounds in our clear aligners, the electronics in our iTero scanners, and the packaging in which they are shipped. These laws are proliferating and new substances subject to restrictions are regularly being added each year. We may be forced to re-design

our products or identify new suppliers to maintain our compliance with these laws. Further, these laws and regulations may decrease the number of suppliers capable of supplying our needs, thereby negatively affecting our ability to manufacture products in sufficient quantities at competitive prices, leading customers to potentially choose competitive goods and services.

Meeting our obligations under existing ESG laws and regulations is costly for us and our suppliers, and we expect these regulations and costs to increase materially. Additionally, regulators may perform investigations, inspections and periodically audit our compliance with these laws and regulations, and our efforts or operations may not 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 materially more costly processes and procedures. Even if we successfully comply with these laws and regulations, our suppliers may not. We may also suffer financial and reputational harm if customers require, and we are unable to deliver, certification that our products are complaint. In all of these situations, customers may stop purchasing products from us, and may take legal action against us, which could harm our reputation, revenues, and results of operations.

Investor advocacy groups, institutional investors, investment funds, proxy advisory services, stockholders, and customers are also increasingly focused on corporate ESG practices. Additionally, public interest and legislative pressure related to companies' ESG practices continues to grow. If our ESG practices fail to meet investor or other industry stakeholders' frequently evolving expectations and standards, our brand, reputation and employee retention may be harmed, customers and suppliers may be unwilling to do business with us and investors may be unwilling to invest in us. If we fail to adopt ESG standards or practices as quickly as stakeholders desire, comply with or timely report on our ESG efforts or practices accurately, or satisfy the disclosure and other expectations of stakeholders, our reputation, business, financial performance, growth, and stock price may be adversely impacted.

We have been incorporating and continue to work to further incorporate AI into our products, services and internal operations. Implementation of AI and machine learning technologies may result in legal and regulatory risks, reputational harm or have other adverse consequences to our business.

We have and are continuing to incorporate AI, including machine learning and independent algorithms, in certain of our products, services and internal operations, which is intended to enhance their operation and effectiveness internally and for our customers, suppliers, and consumers. There can be no assurance that we or our customers will realize the expected benefits from these investments. AI innovation presents risks and challenges that could impact our business. Our, or our vendors', AI algorithms may be flawed. Our datasets or AI training algorithms may be insufficient or contain biased information. Additionally, many countries and regions, including the EU, have proposed new and evolving regulations related to the use of AI and machine learning technologies. The regulations may impose onerous obligations and may require us to unexpectedly rework or reevaluate improvements to be compliant, which may result in the development of products that are subsequently unacceptable under new or revised regulatory frameworks. Use of AI technologies may expose us to an increased risk of regulatory enforcement and litigation. Moreover, some AI features involve the processing of personal data and may be subject to laws, policies, legal obligations, and codes of conduct related to privacy and data protection. AI development and deployment practices could subject us to competitive harm, regulatory enforcement, increased cybersecurity risks, reputational harm, and legal liability.

Intellectual Property Risks

Our success depends in part on our proprietary technology, and if we fail to successfully obtain or enforce our IP rights, our competitive position may be harmed.

Our success depends in part on our ability to maintain existing IP rights and obtain, maintain and enforce further IP protections 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 United States, and other countries to protect a large part of our IP and our competitive position; however, these patents may not prevent third parties from producing competing products similar in design to ours if they are invalidated, held unenforceable, circumvented, or otherwise limited in scope. Furthermore, our foreign patent protections may be more limited in geographic scope than those under U.S. patent and IP laws.

Additionally, any of our patent applications may not result in an issued patent or the scope of the patent ultimately issued may be narrower than initially sought. 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 timely apply for patent protection. We may not apply for a patent if our personnel fail to disclose or recognize new patentable ideas or innovations. 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. Further, third parties may file patents or develop IP strategies that prevent or limit the effectiveness of our patents.

We also protect our IP through copyrights, trademarks, trade secrets, and confidentiality obligations. We generally enter into confidentiality agreements with our employees, consultants, and collaborative partners upon commencement of a relationship with us. However, despite the existence of these protections, we have experienced incidents in which our proprietary information has been misappropriated and believe it will be misappropriated again in the future. If these agreements

do not provide meaningful protection against the unauthorized use or disclosure of our trade secrets or other confidential information, adequate remedies may not exist to prevent unauthorized uses or disclosures.

Enforcement of our IP rights is time-consuming and costly, and could ultimately prove to be unsuccessful. In certain jurisdictions, enforcement of IP rights is more difficult due to legislation and geopolitical circumstances. As we launch our products in different regions at different times, our products may be acquired and reverse engineered by potential competitors in regions where infringement is more difficult to pursue.

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 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 regarding our IP rights, rights claimed by third parties, or IP litigation by any vendors on whose products or services we rely for our products and services may impact our ability to grow our business, adversely impact our results of operations, and adversely impact our reputation.

Extensive litigation over IP rights is common in technologies and industries on which our products and services are based. 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 those claimed by third parties. These proceedings are used 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. We have been sued for infringement of third parties' patents in the past and are currently defending patent infringement lawsuits and other legal claims. In addition, we periodically receive letters from third parties drawing our attention to their IP rights and there may be other third-party IP rights of which we are presently unaware. As dentistry continues to become more digital, competitors may make defense of our IP more challenging. Asserting or defending these proceedings can be unpredictable, protracted, time-consuming, expensive, and distracting to management and technical personnel. Their outcomes may adversely affect our ability to manufacture and market our products, require us to seek licenses for infringing products or technologies, or result in the assessment of significant monetary damages. Unfavorable rulings could include monetary damages, injunctions prohibiting us from selling our products, or exclusion orders preventing us from importing our products in one or more countries. Moreover, independent actions by competitors, customers, or others have alleged that our efforts to enforce our IP rights constitute unfair competition or violations of antitrust laws and investigations and additional litigation based on the same or similar claims may be brought in the future. The potential effects on our business operations resulting from litigation, whether or not ultimately determined in our favor or settled by us, are costly and could materially affect our results of operations and reputation.

Financial, Tax and Accounting Risks

If our goodwill, intangible, or long-lived assets become impaired, we may be required to record a material charge to income.

Under U.S. GAAP, we review our goodwill at least annually, or more frequently, if we identify events or circumstances that indicate it is more likely than not that the fair value of a reporting unit has been reduced below its carrying value. We review finite-lived intangible assets and long-lived assets for impairment when events or changes in circumstances indicate the carrying value of the asset (asset group) may not be recoverable. The qualitative analysis performed by management to identify indicators of impairment or the quantitative analysis used to determine fair value requires management to exercise significant judgement in determining appropriate assumptions and estimates, including revenue growth rates, gross and operating margins, discount rates and future cash flows. Management is responsible for continually assessing qualitative factors that could negatively impact the fair value of goodwill and intangible and long-lived assets and if required, assesses the fair value of each to determine if they have become impaired. Consequently, we may be required to record a material charge to earnings on our financial statements during the period in which any impairment of goodwill intangible assets or long-lived assets is determined.

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 by our regulators could materially affect our current or previously issued financial statements.

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

We are required to furnish in our Annual Report on 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 an assertion by management that our internal control over financial reporting were effective as of our fiscal year end. Our internal controls may become inadequate because of

changes in personnel, updates and upgrades to or migration away from existing software, failure to maintain accurate books and records, changes in accounting standards or interpretations of existing standards, or changes to business models that may require adjustments to our financial reporting 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, and 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 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. This could cause our investors to lose confidence in the accuracy and completeness of our financial reports, which could have an adverse effect on our stock price.

If we fail to manage our exposure to global financial and securities market risks successfully, our operating results and financial statements could be materially impacted.

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 financial condition and results of operations. 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 material realized, unrealized, or impairment losses associated with these investments. Additionally, bank failures could cause or continue to cause volatility in the credit or capital markets, market-wide liquidity issues, bank-runs, and general concern across the global financial industry. These conditions could limit our access to capital or impair the value of assets we hold.

Our effective tax rate may vary significantly from period to period, which could result in volatility of our operating results and adversely affect our financial results.

We are subject to taxes in the United States and foreign countries. Various internal and external factors may affect our future effective tax rate. These factors include changes in the global economic environment, our legal entity structure or activities performed within our entities, our business operations, in tax laws, regulations and/or rates, to existing accounting pronouncements, interpretations of existing tax laws or regulations, in relative proportions of revenues and income before taxes in the various jurisdictions in which we operate that have differing statutory tax rates, and in overall levels of pretax earnings, as well as the settlement of income tax audits and non-deductible goodwill impairments, or changes in the valuation allowance of deferred tax assets. Furthermore, we may continue to experience variation in our effective tax rate related to excess tax benefits or tax expense on stock-based compensation, particularly in the first quarter of each year when the majority of our equity awards vest.

New tax laws and practices, changes to existing tax laws and practices, or disputes regarding the positions we take regarding tax laws, could negatively affect our provision for income taxes as well as our ongoing operations.

Compliance with tax laws requires significant judgment concerning our worldwide provision for income taxes. Changes in tax laws or changes to how those laws are applied to our business could affect the amount of tax which we are subject to and the manner in which we operate. Specifically, in 2016, the Organization for Economic Cooperation and Development (“OECD”) established the Inclusive Framework on Base Erosion and Profit Shifting (“BEPS”) to among other things, allocate greater taxing rights to countries where customers are located and establish a global minimum tax rate. After years of evaluating their respective tax laws, many countries have enacted changes, or are committed to enacting changes, which may increase our tax expense in future years. For example, the EU and other countries have enacted or have committed to enact the OECD/G20 Framework’s Pillar Two 15% global minimum tax. If more countries adopt these changes based on the BEPS guidance, our provision for income taxes or operations may be adversely affected.

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. We are also routinely audited regarding our tax reporting and remissions by local and national governments, and may also be subject to audits in jurisdictions for which we have not accrued tax liabilities. The positions we take regarding taxes as well as the amounts we collect or remit have and may continue to be challenged and we may be liable for failing to collect or remit all taxes deemed owed or the taxes could exceed our estimates. We received a notice and initial assessment from His Majesty’s Revenue and Customs in the United Kingdom for unpaid VAT related to certain clear aligner sales made during various periods between 2019 and 2023. One or more U.S. states or countries may seek to impose incremental or new sales, use, or other tax collection obligations or may determine that such taxes should have, but have not, been paid by us. If we dispute rulings or positions taken by tax authorities, we may incur significant expenses, time, and effort to defend our positions.

The application of existing and new tax laws, and the results of audits 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.

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

The market price of our common stock is subject to rapid and large price fluctuations attributable to various factors, many of which are beyond our control. The factors include:

- quarterly variations in our results of operations and liquidity, our ability to meet or exceed our forecasts and guidance or changes to or withdrawal of our previous forecasts and guidance;
- our ability to regain or sustain our historical growth rates;
- changes in recommendations or valuation models for our stock by the investment community, or speculation in the press or investment community regarding estimates of our net revenues, results of operations, or other key performance indicators;
- announcements by us, 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 inconsistent with macroeconomic, industry, or company-specific fundamentals, including the sentiment of retail investors (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 or purchases of our common stock by us, our officers or directors, credit agreements, and debt issuances;
- announcements of technological innovations or 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;
- short selling or other hedging activity in our stock; and
- general economic market conditions, including rising interest rates, inflationary pressures, recessions, consumer sentiment and demand, global geopolitical conflict, and industry factors unrelated to our actual performance.

In addition, the stock market in general, and the market for technology and medical device companies, in particular, often experience extreme price and volume fluctuations unrelated or disproportionate to corporate operating performance. Any such fluctuations have and may continue to adversely affect the market price of our common stock. 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 U.S. federal funds rate and austerity measures of governments intended to control budget deficits. Securities litigation, including securities class action lawsuits and securities derivative lawsuits, is often brought against an issuer following periods of volatility in the market price of its securities and we have not been exempt from such litigation.

We cannot guarantee that we will continue to repurchase our common stock in the future, and any repurchases 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, market conditions, results of operations, business requirements, and our 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 at historical levels or at all, or that our stock repurchase programs will beneficially impact our stock price. Additionally, effective January 1, 2023, the Inflation Reduction Act imposes a 1% excise tax on our stock repurchases, net of certain stock issuances, which will increase our tax liabilities and the cost to retire stock and may impact if and how much stock we choose to repurchase in the future.

Future sales of significant amounts of our common stock may depress our stock price.

A significant percentage of our outstanding common stock is currently owned by a small number of stockholders. These stockholders have sold in the past, and may sell in the future, large amounts of our stock over relatively short periods of time. Sales of substantial amounts of our stock by existing stockholders may adversely affect the market price of our stock by creating the perception of difficulties or problems with our business, which may depress our stock price.

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

There were no stock repurchases during the three months ended September 30, 2024. As of September 30, 2024, we have \$500.0 million remaining available for repurchases under the January 2023 Repurchase Program authorized by our Board of Directors in January 2023 (Refer to *Note 10 “Common Stock Repurchase Programs”* of the *Notes to Condensed Consolidated Financial Statements* for details on the January 2023 Repurchase Program).

Item 3. Defaults Upon Senior Securities.

Not applicable.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

During the fiscal quarter ended September 30, 2024, no director or officer (as defined in Rule 16a-1(f) of the Exchange Act) adopted or terminated a “Rule 10b5-1 trading arrangement” or a “non-Rule 10b5-1 trading arrangement” (each as defined in Item 408 of Regulation S-K).

Item 6. Exhibits.

(a) Exhibits:

<u>Exhibit Number</u>	<u>Description</u>	<u>Filing</u>	<u>Date</u>	<u>Exhibit Number</u>	<u>Filed herewith</u>
3.1	Amended and Restated Certificate of Incorporation of Align Technology, Inc.	S-1/A (File No. 333-49932)	12/28/2000	3.1	
3.1A	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Align Technology, Inc.	8-K	5/20/2016	3.01	
3.1B	Certificate of Amendment of the Amended and Restated Certificate of Incorporation of Align Technology, Inc.	10-Q	8/04/2023	3.1B	
3.2	Amended and Restated Bylaws of Align Technology, Inc.	8-K	1/17/2024	3.1	
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				X
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				X
32.1†	Certifications pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002				X
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)				X
101.SCH	Inline XBRL Taxonomy Extension Schema Document				X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document				X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document				X
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document				X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document				X
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)				X

† Furnished herewith.

CERTIFICATION

I, Joseph M. Hogan, certify that:

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

Date: November 5, 2024

/s/ JOSEPH M. HOGAN

Joseph M. Hogan

President and Chief Executive Officer

CERTIFICATION

I, John F. Morici, certify that:

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

Date: November 5, 2024

/s/ JOHN F. MORICI

John F. Morici

Chief Financial Officer and Executive Vice President, Global Finance

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

In connection with the Quarterly Report of Align Technology, Inc. (the "Company") on Form 10-Q for the period ending September 30, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

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

Date: November 5, 2024

In connection with the Quarterly Report of Align Technology, Inc. (the "Company") on Form 10-Q for the period ending September 30, 2024 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: November 5, 2024