ALIGN TECHNOLOGY INC

FORM 10-Q
(Quarterly Report)

Filed 05/08/25 for the Period Ending 03/31/25

Address	410 NORTH SCOTTSDALE ROAD, SUITE 1300 TEMPE, AZ, 85288
Telephone	408-470-1000
CIK	0001097149
Symbol	ALGN
SIC Code	3842 - Orthopedic, Prosthetic, and Surgical Appliances and Supplies
Industry	Medical Equipment, Supplies & Distribution
Sector	Healthcare
Fiscal Year	12/31

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2025

or

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

For the transition period from to

Commission File Number: 000-32259

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

Delaware	**94-3267295**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

410 North Scottsdale Road, Suite 1300
Tempe, Arizona 85288
(Address of principal executive offices) (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	☒	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
Emerging growth company	☐		

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

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

As of May 1, 2025, the number of shares outstanding of the registrant's Common Stock, $0.0001 par value, was 72,484,841.

ALIGN TECHNOLOGY, INC.

TABLE OF CONTENTS

PART I	FINANCIAL INFORMATION	3
Item 1.	Financial Statements (Unaudited):	3
	Condensed Consolidated Statements of Operations	3
	Condensed Consolidated Statements of Comprehensive Income	4
	Condensed Consolidated Balance Sheets	5
	Condensed Consolidated Statements of Stockholders' Equity	6
	Condensed Consolidated Statements of Cash Flows	7
	Notes to Condensed Consolidated Financial Statements	8
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	24
Item 3.	Quantitative and Qualitative Disclosures About Market Risk	33
Item 4.	Controls and Procedures	34
PART II	OTHER INFORMATION	35
Item 1.	Legal Proceedings	35
Item 1A.	Risk Factors	35
Item 2.	Unregistered Sales of Equity Securities and Use of Proceeds	50
Item 3.	Defaults Upon Senior Securities	50
Item 4.	Mine Safety Disclosures	50
Item 5.	Other Information	50
Item 6.	Exhibits	51
Signatures		52

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

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

	Three Months Ended March 31,	
	2025	2024
Net revenues	$ 979,262	$ 997,431
Cost of net revenues	299,154	299,615
Gross profit	680,108	697,816
Operating expenses:		
Selling, general and administrative	447,629	451,822
Research and development	97,201	91,859
Legal settlement loss	4,178	—
Total operating expenses	549,008	543,681
Income from operations	131,100	154,135
Interest income and other income (expense), net:		
Interest income	5,316	4,392
Other income (expense), net	4,026	(141)
Total interest income and other income (expense), net	9,342	4,251
Net income before provision for income taxes	140,442	158,386
Provision for income taxes	47,212	53,358
Net income	$ 93,230	$ 105,028
Net income per share:		
Basic	$ 1.27	$ 1.40
Diluted	$ 1.27	$ 1.39
Shares used in computing net income per share:		
Basic	73,562	75,175
Diluted	73,615	75,322

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

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

	Three Months Ended March 31,	
	2025	**2024**
Net income	$ 93,230	$ 105,028
Other comprehensive income (loss):		
Change in foreign currency translation adjustment, net of tax	12,199	(2,932)
Change in unrealized gains (losses) on investments, net of tax	—	203
Other comprehensive income (loss)	12,199	(2,729)
Comprehensive income	$ 105,429	$ 102,299

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

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

	March 31, 2025	December 31, 2024
ASSETS		
Current assets:		
Cash and cash equivalents	$ 873,012	$ 1,043,887
Accounts receivable, net of allowance for doubtful accounts of $22,469 and $19,131, respectively	1,061,976	995,685
Inventories	246,567	254,287
Prepaid expenses and other current assets	220,474	198,582
Total current assets	2,402,029	2,492,441
Property, plant and equipment, net	1,264,847	1,271,134
Operating lease right-of-use assets, net	113,179	113,376
Goodwill	457,611	442,630
Intangible assets, net	102,750	103,488
Deferred tax assets	1,523,479	1,557,372
Other assets	238,925	234,159
Total assets	$ 6,102,820	$ 6,214,600
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 125,382	$ 108,693
Accrued liabilities	546,173	598,188
Deferred revenues	1,319,393	1,331,146
Total current liabilities	1,990,948	2,038,027
Income tax payable	99,781	96,466
Operating lease liabilities	86,487	88,214
Other long-term liabilities	131,361	139,908
Total liabilities	2,308,577	2,362,615
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; 73,057 and 73,849 issued and outstanding, respectively)	7	7
Additional paid-in capital	1,386,807	1,362,234
Accumulated other comprehensive income (loss), net	18,177	5,978
Retained earnings	2,389,252	2,483,766
Total stockholders' equity	3,794,243	3,851,985
Total liabilities and stockholders' equity	$ 6,102,820	$ 6,214,600

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

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

Three Months Ended March 31, 2025	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss), Net	Retained Earnings	Total
Balance as of December 31, 2024	73,849	$ 7	$ 1,362,234	$ 5,978	$ 2,483,766	$ 3,851,985
Net income	—	—	—	—	93,230	93,230
Net change in foreign currency translation adjustment	—	—	—	12,199	—	12,199
Issuance of common stock relating to employee equity compensation plans	393	—	13,909	—	—	13,909
Tax withholdings related to net share settlements of equity awards	(99)	—	(19,577)	—	—	(19,577)
Common stock repurchased and retired	(1,086)	—	(14,756)	—	(187,744)	(202,500)
Stock-based compensation	—	—	44,997	—	—	44,997
Balance as of March 31, 2025	73,057	$ 7	$ 1,386,807	$ 18,177	$ 2,389,252	$ 3,794,243

Three Months Ended March 31, 2024	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss), Net	Retained Earnings	Total
Balance as of December 31, 2023	75,075	$ 7	$ 1,162,140	$ 21,168	$ 2,447,174	$ 3,630,489
Net income	—	—	—	—	105,028	105,028
Net change in unrealized gains (losses) from investments	—	—	—	203	—	203
Net change in foreign currency translation adjustment	—	—	—	(2,932)	—	(2,932)
Issuance of common stock relating to employee equity compensation plans	328	—	14,339	—	—	14,339
Tax withholdings related to net share settlements of equity awards	(86)	—	(26,055)	—	—	(26,055)
Common stock repurchased and retired	(36)	—	—	—	—	—
Equity forward contract related to accelerated stock repurchase	—	—	49,527	—	(49,527)	—
Stock-based compensation	—	—	38,788	—	—	38,788
Balance as of March 31, 2024	75,281	$ 7	$ 1,238,739	$ 18,439	$ 2,502,675	$ 3,759,860

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

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

	Three Months Ended March 31, 2025	Three Months Ended March 31, 2024
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net income	$ 93,230	$ 105,028
Adjustments to reconcile net income to net cash provided by operating activities:		
Deferred taxes	33,683	18,047
Depreciation and amortization	39,148	32,946
Stock-based compensation	44,997	38,788
Non-cash operating lease cost	9,457	9,612
Other non-cash operating activities	2,950	(2,359)
Changes in assets and liabilities, net of effects of acquisitions:		
Accounts receivable	(65,302)	(69,589)
Inventories	7,396	15,573
Prepaid expenses and other assets	(21,970)	(79,160)
Accounts payable	8,575	4,100
Accrued and other long-term liabilities	(67,877)	(34,473)
Long-term income tax payable	3,316	4,570
Deferred revenues	(34,927)	(14,419)
Net cash provided by operating activities	52,676	28,664
CASH FLOWS FROM INVESTING ACTIVITIES:		
Acquisitions, net of cash acquired	—	(77,075)
Purchase of property, plant and equipment	(25,289)	(9,369)
Proceeds from maturities of marketable securities	—	6,035
Proceeds from sales of marketable securities	—	831
Other investing activities	—	(6)
Net cash used in investing activities	(25,289)	(79,584)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock	13,909	14,339
Common stock repurchases, net of excise tax	(201,088)	—
Payroll taxes paid upon the vesting of equity awards	(19,577)	(26,055)
Net cash used in financing activities	(206,756)	(11,716)
Effect of foreign exchange rate changes on cash, cash equivalents, and restricted cash	8,480	(9,004)
Net decrease in cash, cash equivalents, and restricted cash	(170,889)	(71,640)
Cash, cash equivalents and restricted cash at beginning of the period	1,044,963	938,519
Cash, cash equivalents and restricted cash at end of the period	$ 874,074	$ 866,879

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, 2024, 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, 2024 as filed with the SEC on February 28, 2025. The results of operations for the three months ended March 31, 2025 are not necessarily indicative of the results that may be expected for the year ending December 31, 2025 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 our consolidated financial statements and accompanying notes. Actual results could differ materially from those estimates. On an ongoing basis, we evaluate our estimates, including those related to revenue recognition and deferred revenues, useful lives of intangible assets and property, plant and equipment, goodwill, income taxes, contingent liabilities, the fair values of financial instruments, stock-based compensation and the valuation of investments in privately held companies among others. We base our estimates on historical experience and on various other assumptions that are believed to be reasonable, the results of which form the basis for making judgments about the carrying values of assets and liabilities.

Certain Risks and Uncertainties

Financial instruments which potentially expose the Company to concentration of credit risk, consist principally of cash and cash equivalents. These instruments have minimal credit risk exposures. Management regularly monitors their compositions and maturities. The Company maintains its cash and cash equivalents in bank accounts that exceed federally insured FDIC limits. Through March 31, 2025, the Company has not experienced any material credit losses on such deposits.

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

(i) New Accounting Pronouncements Recently Adopted

On November 27, 2023, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) 2023-07 (“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 and other 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. We adopted this standard in the fiscal year ended December 31, 2024. See *Note 14 “Segments and Geographical Information.”*

(ii) Recent Accounting Pronouncements Not Yet Effective

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. There will be no impact to our consolidated balance sheets or statements of operations; however, the Company is evaluating the effect of this pronouncement on our consolidated financial statement disclosures.

On November 4, 2024, the FASB issued ASU 2024-03, *"Income Statement-Reporting Comprehensive Income-Expense Disaggregation Disclosures."* The amendments in this ASU require a public entity to disclose, in the notes to the financial statements, specified information about certain costs and expenses, including the amounts of inventory purchases, employee compensation, depreciation and intangible asset amortization. For public business entities, the provisions of ASU 2024-03 are effective for fiscal years beginning after December 15, 2026, and interim periods within fiscal years beginning after December 15, 2027. Early adoption is permitted. There will be no impact to our consolidated balance sheets or statements of operations; however, the Company is evaluating the effect of this pronouncement on our consolidated financial statement disclosures.

Note 2. Financial Instruments

Cash, Cash Equivalents and Marketable Securities

The following tables summarize our cash, cash equivalents and marketable securities balances in our Condensed Consolidated Balance Sheets as of March 31, 2025 and Consolidated Balance Sheets as of December 31, 2024 (in thousands):

					Reported as:		
March 31, 2025	**Amortized Cost**	**Gross Unrealized Gains**	**Gross Unrealized Losses**	**Fair Value**	**Cash and Cash Equivalents**	**Marketable securities, short-term**	**Marketable securities, long-term**
Cash	$ 757,327	$ —	$ —	$ 757,327	$ 757,327	$ —	$ —
Money market funds	100,608	—	—	100,608	100,608	—	—
Certificate of deposits	15,077	—	—	15,077	15,077	—	—
Total	$ 873,012	$ —	$ —	$ 873,012	$ 873,012	$ —	$ —

					Reported as:		
December 31, 2024	**Amortized Cost**	**Gross Unrealized Gains**	**Gross Unrealized Losses**	**Fair Value**	**Cash and Cash Equivalents**	**Marketable securities, short-term**	**Marketable securities, long-term**
Cash	$ 752,423	$ —	$ —	$ 752,423	$ 752,423	$ —	$ —
Money market funds	291,464	—	—	291,464	291,464	—	—
Total	$ 1,043,887	$ —	$ —	$ 1,043,887	$ 1,043,887	$ —	$ —

We had no short-term or long-term marketable securities as of March 31, 2025 or December 31, 2024.

Fair Value Measurements

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

Level 1 — 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 March 31, 2025 and December 31, 2024 (in thousands):

Description	Balance as of March 31, 2025	Level 1	Level 2
Cash equivalents:			
Money market funds	$ 100,608	$ 100,608	$ —
Certificate of deposits	15,077	15,077	—
	$ 115,685	$ 115,685	$ —

Description	Balance as of December 31, 2024	Level 1	Level 2
Cash equivalents:			
Money market funds	$ 291,464	$ 291,464	$ —
	$ 291,464	$ 291,464	$ —

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 $6.4 million and $14.6 million during the three months ended March 31, 2025 and 2024, respectively. Factoring fees on the sales of receivables were recorded in other income (expense), net in our Condensed Consolidated Statements 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 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 in Heartland through the purchase of Class A Common Stock for $150 million in total. In the fourth quarter of 2024 we recorded a $6 million increase to the carrying value of our investment, which increased the total carrying value of our investment in Heartland to $156 million.

On December 19, 2024, we entered into a Subscription Agreement (the "Smile Doctors Subscription Agreement") with New SD Holding Company, L.P. ("SD Holding Company"). Pursuant to the Smile Doctors Subscription Agreement we acquired less than a 3% equity interest in SD Holding Company through the purchase of Class A Common Units for $30 million. SD Holding Company owns a controlling interest, through intermediary entities, in Smile Doctors, LLC.

We account for our investments in Heartland and SD Holding Company as investments in equity securities, utilizing the measurement alternative. Based on a review of the relevant facts and circumstances, primarily observable transactions for identical investments, we determined that no adjustments to the carrying values of our investments were necessary for the three months ended March 31, 2025.

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 in our Condensed Consolidated Balance Sheets as Other assets and any price adjustments or impairment, if any, are recorded in Other income (expense), net in our Condensed Consolidated Statements 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 $11.5 million and a net gain of $19.7 million, during the three months ended March 31, 2025 and 2024, respectively. 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 March 31, 2025 and December 31, 2024, the fair value of outstanding foreign exchange forward contracts was not material.

The following tables present the gross notional value of all our foreign exchange forward contracts outstanding as of March 31, 2025 and December 31, 2024 (in thousands):

	March 31, 2025	
	Local Currency Amount	Notional Contract Amount (USD)
Euro	€166,020	$ 179,590
Canadian Dollar	C$95,300	66,393
Polish Zloty	PLN199,200	51,328
British Pound	£34,500	44,598
Chinese Yuan	¥260,000	35,862
Japanese Yen	¥3,300,000	22,105
Israeli Shekel	ILS80,600	21,646
Brazilian Real	R$101,800	17,605
Swiss Franc	CHF9,300	10,567
Australian Dollar	A$5,400	3,369
Czech Koruna	Kč76,800	3,321
New Taiwan Dollar	NT$66,000	1,991
New Zealand Dollar	NZ$3,000	1,700
Korean Won	₩2,430,000	1,654
		$ 461,729

	December 31, 2024	
	Local Currency Amount	Notional Contract Amount (USD)
Euro	€176,080	$ 183,172
Polish Zloty	PLN283,000	68,633
Canadian Dollar	C$97,000	67,446
British Pound	£37,600	47,090
Israeli Shekel	ILS90,055	24,740
Chinese Yuan	¥164,500	22,417
Brazilian Real	R$83,100	13,327
Japanese Yen	¥2,000,000	12,778
Swiss Franc	CHF5,700	6,314
New Zealand Dollar	NZ$7,000	3,924
Czech Koruna	Kč72,800	3,004
Australian Dollar	A$3,800	2,355
New Taiwan Dollar	NT$58,700	1,786
Korean Won	₩2,000,000	1,361
		$ 458,347

Note 3. Balance Sheet Components

Inventories consist of the following (in thousands):

	March 31, 2025	December 31, 2024
Raw materials	$ 118,333	$ 124,377
Work in process	69,432	73,660
Finished goods	58,802	56,250
Total inventories	$ 246,567	$ 254,287

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

	March 31, 2025	December 31, 2024
Value added tax receivables	$ 33,168	$ 34,028
Prepaid expenses	104,081	82,978
Other current assets	83,225	81,576
Total prepaid expenses and other current assets	$ 220,474	$ 198,582

Accrued liabilities consist of the following (in thousands):

	March 31, 2025	December 31, 2024
Accrued payroll and benefits	$ 192,101	$ 248,003
Accrued expenses	73,120	66,391
Accrued income taxes	47,838	48,808
Accrued sales and marketing expenses	43,086	37,617
Current operating lease liabilities	32,048	31,063
Accrued property, plant and equipment	10,023	13,462
Other accrued liabilities	147,957	152,844
Total accrued liabilities	$ 546,173	$ 598,188

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

	Three Months Ended March 31,	
	2025	2024
Balance at beginning of period	$ 31,211	$ 22,426
Charged to cost of net revenues	4,719	5,449
Actual warranty expenditures	(3,332)	(3,312)
Balance at end of period	$ 32,598	$ 24,563

Deferred revenues consist of the following (in thousands):

	March 31, 2025	December 31, 2024
Deferred revenues - current	$ 1,319,393	$ 1,331,146
Deferred revenues - long-term [1]	$ 93,317	$ 102,164

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

During the three months ended March 31, 2025 and 2024, we recognized $979.3 million and $997.4 million of net revenues, respectively, of which $246.0 million and $236.8 million was included in the deferred revenues balance at December 31, 2024 and 2023, respectively.

Our unfulfilled performance obligations, including deferred revenues and backlog, as of March 31, 2025 were $1,418.6 million. These performance obligations are expected to be fulfilled over a period up 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	$	85,794

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 Statements 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 purchase price to 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	$	85,794

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, the projected future cash flows associated with the technology, the asset's life cycle and a 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 three months ended March 31, 2025, categorized by reportable segment, is as follows (in thousands):

	Clear Aligner	Systems and Services	Total
Balance as of December 31, 2024	$ 152,645	$ 289,985	$ 442,630
Foreign currency translation adjustments	3,534	11,447	14,981
Balance as of March 31, 2025	$ 156,179	$ 301,432	$ 457,611

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 March 31, 2025	Accumulated Amortization	Accumulated Impairment Loss	Net Carrying Value as of March 31, 2025
Existing technology	11	$ 146,651	$ (56,004)	$ —	$ 90,647
Customer relationships	10	21,500	(10,750)	—	10,750
Trademarks and tradenames[1]	7	9,800	(7,000)	—	2,800
Patents	12	480	(290)	—	190
		$ 178,431	$ (74,044)	$ —	104,387
Foreign currency translation adjustments					(1,637)
Total intangible assets, net					$ 102,750

[1] The Weighted Average Amortization Period decreased from 10 years to 7 years due an intangible asset with a useful life of 15 years becoming fully amortized during the current quarter.

	Weighted Average Amortization Period (in years)	Gross Carrying Amount as of December 31, 2024	Accumulated Amortization	Accumulated Impairment Loss	Net Carrying Value as of December 31, 2024
Existing technology	11	$ 146,651	$ (52,238)	$ —	$ 94,413
Customer relationships	10	21,500	(10,079)	—	11,421
Trademarks and tradenames	10	16,600	(9,255)	(4,122)	3,223
Patents	12	480	(280)	—	200
		$ 185,231	$ (71,852)	$ (4,122)	109,257
Foreign currency translation adjustments					(5,769)
Total intangible assets, net					$ 103,488

The total estimated future amortization expense for these acquired finite-lived intangible assets as of March 31, 2025, is as follows (in thousands):

Fiscal Year Ending December 31,		Amortization
Remainder of 2025	$	13,827
2026		17,923
2027		15,607
2028		14,505
2029		14,505
2030		6,328
Thereafter		21,692
Total	$	104,387

Amortization expense for the three months ended March 31, 2025 and 2024 was $4.6 million and $5.0 million, respectively.

Note 6. Credit Facility

We have a credit facility, as amended in December 2022, that provides for a $300.0 million unsecured revolving line of credit, along with a $50.0 million letter of credit. Our credit facility has a maturity date of December 23, 2027 and bears 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. The credit facility requires us to comply with specific financial conditions and performance requirements. As of March 31, 2025, we had no outstanding borrowings under the credit facility and were in compliance with the conditions and performance requirements in all material respects.

Note 7. Legal Proceedings

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. Plaintiffs have appealed the district court's summary judgment ruling to the United States Court of Appeals for the Ninth Circuit. Oral argument was held on April 10, 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. Oral argument was held on April 10, 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 to resolve all remaining claims in the Section 1 lawsuit. In March, 2025, Align and plaintiffs agreed to a revised settlement to resolve all Section 1 claims for a $31.75 million cash payment. On April 24, 2025 Plaintiffs filed a motion requesting the court approve the revised settlement. A hearing on the motion is scheduled for May 22, 2025. 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.

For the quarter ended March 31, 2025, Align accrued a total loss of $31.75 million, $27.5 million as of December 31, 2024 and an additional loss accrual of $4.25 million in the first quarter of 2025, for 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 ("Defendants"). 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 Defendants' infringement of multiple Align multilayer material patents through Defendants' manufacture, sale and offer for sale of aligners made with Zendura FLX/ClearQuartz materials. Defendants filed motions to dismiss the complaint, which are pending. Defendants are also seeking to invalidate all of Align's asserted patents at the district court and United States Patent and Trial Appeal Board.

On July 9, 2024, Defendants filed counterclaims against Align for alleged antitrust violations, false advertising, unfair competition and breach of contract. Among other things, the counterclaims seek to stop Align's accused business practices and money damages. On September 13, 2024, we filed a motion to dismiss defendants' counterclaims. On February 7, 2025, the magistrate judge recommended denial of the motion to dismiss. On February 21, 2025, we filed objections to the recommendation, which are pending before the district court judge. A trial is scheduled for February 16, 2026.

We believe Defendants' counterclaims are without merit and intend to vigorously defend ourselves. We are 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 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 were required to pay these assessments prior to contesting or litigating the matter 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 for the period of October 2019 through May 2023 and withdraw any potential assessments for the period from June 2023 through mid-October 2023. HMRC has refunded to the Company all assessed amounts, approximately $100 million.

The Company has remaining exposure in the amount of approximately $6.0 million for periods up to December 2023. A statutory appeal (before the First-tier Tribunal - "Tax Tribunal") was held on January 27th through January 30th, 2025. On April 24, 2025, the Tax Tribunal issued a ruling in Align's favor indicating that clear aligners are "dental prostheses for the purposes of VAT", which is a key condition for the VAT exemption. HMRC has until June 19, 2025 to appeal the Tax Tribunal decision. HMRC may also attempt to challenge the applicability of VAT on a different basis.

It is not possible at this stage to accurately evaluate the likelihood of an unfavorable outcome from the Tax Tribunal statutory appeal. 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 March 31, 2025, we did not have any material indemnification claims that were probable or reasonably possible.

Note 9. Stockholders' Equity

As of March 31, 2025, the Align Technology, Inc. 2005 Incentive Plan, as amended, has a total reserve of 32,168,895 shares, of which 1,877,934 shares are available for issuance.

Summary of Stock-Based Compensation Expense

The stock-based compensation related to our stock-based awards and employee stock purchase plan for the three months ended March 31, 2025 and 2024 is as follows (in thousands):

	Three Months Ended March 31,	
	2025	2024
Cost of net revenues	$ 1,538	$ 2,064
Selling, general and administrative	30,866	28,494
Research and development	12,593	8,230
Total stock-based compensation	$ 44,997	$ 38,788

Restricted Stock Units ("RSUs")

The fair value of RSUs is based on our closing stock price on the date of grant. RSUs granted generally vest over a period of four years. A summary for the three months ended March 31, 2025 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, 2024	1,019	$ 331.10		
Granted	650	197.93		
Vested and released	(286)	362.30		
Forfeited	(32)	318.19		
Unvested as of March 31, 2025	1,351	$ 260.72	2.0	$ 214,594

As of March 31, 2025, we expect to recognize $293.0 million of total unamortized compensation costs, net of estimated forfeitures, related to RSUs over a weighted average period of 3.1 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 three months ended March 31, 2025:

	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, 2024	193	$ 679.14		
Granted	127	362.98		
Vested and released [1]	(26)	915.22		
Forfeited	(10)	915.22		
Unvested as of March 31, 2025	284	$ 506.66	2.1	$ 45,057

[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 March 31, 2025, we expect to recognize $78.6 million of total unamortized compensation costs, net of estimated forfeitures, related to MSUs over a weighted average period of 2.1 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 three months ended March 31, 2025:

	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, 2024	11	$ 204.33		
Granted	—	—		
Vested and released	(5)	201.63		
Forfeited	—	—		
Unvested as of March 31, 2025	6	$ 206.36	1.8	$ 1,001

As of March 31, 2025, we expect to recognize $0.9 million of total unamortized compensation costs, net of estimated forfeitures, related to PSUs over a weighted average period of 1.8 years.

Employee Stock Purchase Plan

As of March 31, 2025, we have 1,800,725 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:

	Three Months Ended March 31,	
	2025	2024
Expected term (in years)	1.1	0.9
Expected volatility	40.9 %	56.0 %
Risk-free interest rate	4.2 %	4.8 %
Expected dividends	—	—
Weighted average fair value at grant date	$ 70.62	$ 100.10

As of March 31, 2025, we expect to recognize $13.4 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 January 2023, our Board of Directors authorized a 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.

The following tables summarize the total repurchases of our common stock pursuant to Accelerated Share Repurchase ("ASR") agreements and open market common stock repurchases under the January 2023 Repurchase Program:

Accelerated Share Repurchase Agreements

Agreement Date	Repurchase Program	Amount Paid (in millions)	Completion Date	Total Shares Received	Average Price per Share
Q4 2023	January 2023	$ 250.0	Q1 2024	1,086,334	$ 230.13

Open Market Common Stock Repurchases

Agreement Date	Repurchase Program	Amount Paid (in millions)	Completion Date	Total Shares Received	Average Price per Share
Q4 2023	January 2023	$ 100.0	Q4 2023	465,518	$ 214.81
Q2 2024	January 2023	$ 150.0	Q2 2024	598,302	$ 250.73
Q4 2024	January 2023	$ 275.0	Q1 2025	1,241,509	$ 221.50
Q1 2025	January 2023	$ 129.0	N/A[1]	753,993	$ 171.03

[1] In May 2025, we completed the open market repurchase program initiated in Q1 2025. In total we repurchased approximately 1.3 million shares of our common stock at an average price of $168 per share for an aggregate purchase price of approximately $225.0 million.

As of March 31, 2025 we had $96.0 million available for repurchase under the January 2023 Repurchase Program, which was used to repurchase shares through May 2, 2025. These subsequent repurchases completed the January 2023 Repurchase Program.

In April 2025, our Board of Directors authorized a plan to repurchase up to $1.0 billion of our common stock ("April 2025 Repurchase Program"), none of which has been utilized.

Note 11. Accounting for Income Taxes

Our provision for income taxes was $47.2 million and $53.4 million for the three months ended March 31, 2025 and 2024, respectively, representing effective tax rates of 33.6% and 33.7%, respectively. Our effective tax rate differs from the statutory federal income tax rate of 21% for the three months ended March 31, 2025 and 2024 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 regard 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 $147.4 million and $145.5 million as of March 31, 2025 and December 31, 2024, 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 months ended March 31, 2025.

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 March 31,	
	2025	2024
Numerator:		
Net income	$ 93,230	$ 105,028
Denominator:		
Weighted average common shares outstanding, basic	73,562	75,175
Dilutive effect of potential common stock	53	147
Total shares, diluted	73,615	75,322
Net income per share, basic	$ 1.27	$ 1.40
Net income per share, diluted	$ 1.27	$ 1.39
Anti-dilutive potential common shares [1]	964	571

[1] Represents approximately 964 thousand RSU weighted average outstanding common stock equivalent shares for the three months ended March 31, 2025 and approximately 569 thousand RSU and 2 thousand ESPP weighted average outstanding common stock equivalent shares for the three months ended March 31, 2024 that are excluded from the calculation of diluted net income per share as the effect would have been anti-dilutive.

Note 13. Supplemental Cash Flow Information

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

	Three Months Ended March 31,	
	2025	2024
Non-cash investing and financing activities:		
Acquisition of property, plant and equipment in accounts payable and accrued liabilities	$ 13,851	$ 21,284
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	$ 9,592	$ 9,998
Right-of-use assets obtained in exchange for lease obligations:		
Operating leases	$ 5,024	$ 10,568

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. We group our operations into two reportable segments; Clear Aligner segment and Imaging Systems and CAD/CAM services ("Systems and Services") segment, which are based on our predominant product lines.

Our CODM uses gross profit and income from operations to assess each reportable segments performance, by reviewing each measure against internal forecasts and historical performance. Our CODM may also benchmark each segments performance against our competitors and external expectations.

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

	Three Months Ended March 31,	
	2025	2024
Net revenues		
Clear Aligner	$ 796,843	$ 817,251
Systems and Services	182,419	180,180
Total net revenues	$ 979,262	$ 997,431
Cost of net revenues[1]		
Clear Aligner	$ 234,754	$ 238,105
Systems and Services	64,400	61,510
Total cost of goods sold	$ 299,154	$ 299,615
Gross profit		
Clear Aligner	$ 562,089	$ 579,146
Systems and Services	118,019	118,670
Total gross profit	$ 680,108	$ 697,816
Other Segment expenses		
Clear Aligner	$ 301,865	$ 292,908
Systems and Services	59,556	68,977
Unallocated corporate expenses	187,587	181,796
Total operating expenses	$ 549,008	$ 543,681
Segment income from operations		
Clear Aligner	$ 260,224	$ 286,238
Systems and Services	58,463	49,693
Total segment income from operations	$ 318,687	$ 335,931

[1] Management has identified cost of net revenues as a significant expense for our Clear Aligner and Systems and Services reportable segments.

Other segment expenses typically include employee related costs, marketing and advertising costs and depreciation and amortization expense incurred by various functions including selling, marketing, general and administrative and research and development. Our CODM does not regularly receive these operating expenses at the reportable segment level.

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 information technology ("IT"), facilities, human resources, accounting and finance, legal and regulatory, other separately managed general and administrative costs outside the reportable segments and restructuring costs.

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

	Three Months Ended March 31,	
	2025	2024
Total segment income from operations	$ 318,687	$ 335,931
Unallocated corporate expenses	(187,587)	(181,796)
Total income from operations	131,100	154,135
Interest income	5,316	4,392
Other income (expense), net	4,026	(141)
Net income before provision for income taxes	$ 140,442	$ 158,386

The following table includes certain non-cash expenses for each reportable segment (in thousands):

	Three Months Ended March 31,	
	2025	2024
Stock-based compensation		
Clear Aligner	$ 5,818	$ 3,764
Systems and Services	403	359
Unallocated corporate expenses	38,776	34,665
Total stock-based compensation	$ 44,997	$ 38,788
Depreciation and amortization		
Clear Aligner	$ 18,904	$ 14,433
Systems and Services	8,469	6,838
Unallocated corporate expenses	11,775	11,675
Total depreciation and amortization	$ 39,148	$ 32,946

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 March 31,	
	2025	2024
Net revenues [1]:		
U.S.	$ 423,318	$ 432,101
Switzerland	224,132	251,758
Other International	331,812	313,572
Total net revenues	$ 979,262	$ 997,431

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

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

	March 31, 2025	December 31, 2024
Long-lived assets [1]:		
Switzerland	$ 568,693	$ 571,628
U.S.	203,140	207,689
Other International	606,193	605,193
Total long-lived assets	$ 1,378,026	$ 1,384,510

[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

2023 Restructuring

During the fourth quarter of 2023, we 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. During the first quarter of 2024, we reduced our December 31, 2023 restructuring liability by approximately $3.9 million, primarily due to cash payments.

2024 Restructuring

During the fourth quarter of 2024, we initiated a restructuring plan to increase efficiencies across the organization which is expected to be completed in the second half of 2025. We incurred approximately $37.0 million in restructuring expenses, of which $13.0 million remained unpaid and were included in Accrued liabilities as of December 31, 2024. During the first quarter of 2025, we reduced our December 31, 2024 restructuring liability by approximately $11.0 million primarily due to cash payments, offset by approximately $2.1 million of additional restructuring expense recorded in Cost of net revenues.

The 2023 and 2024 restructuring activities were primarily related to employee severance and other one-time post-employment benefits.

Activity related to the restructuring liabilities associated with our restructuring initiatives consist of the following (in thousands):

	Three Months Ended March 31,	
	2025	**2024**
Balance at beginning of period[1]	$ 13,001	$ 5,299
Restructuring charges	2,056	(152)
Cash payments and adjustments	(11,018)	(3,752)
Balance at end of period [1]	$ 4,039	$ 1,395

[1] Included in “Accrued liabilities” within our Condensed Consolidated Balance Sheets.

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

Forward-Looking Statements

In addition to historical information, this Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, 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 fluctuations in currency exchange rates, inflation, higher interest rates, market volatility, threats or actual imposition of tariffs, customs duties and fees by nations and retaliatory actions, threats of or actual economic slowdowns or recessions, or escalating trade wars and geopolitical tensions, our expectations and beliefs regarding customer and consumer purchasing behavior and changes in consumer spending habits, our expectations regarding implemented or proposed tariffs and retaliatory actions or other trade restrictions or measures taken by the United States and other countries that have or could impact our products and product sales, our expectations regarding product mix, product launches, product pilots 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 increased geopolitical tensions involving Taiwan and the South China Sea 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 and potential collaboration opportunities, 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 impacts or 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 and ability to repatriate foreign earnings, 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, 2024 as filed with the Securities and Exchange Commission (the "SEC").

Executive Overview of Results

Trends and Uncertainties

Our 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, Trade Impediments and Geopolitical Tensions

Our revenues are susceptible to fluctuations resulting from events and circumstances, including macroeconomic conditions, fluctuations in foreign currency exchange rates, inflation, threats or actual imposition of tariffs, customs duties and fees by nations and retaliatory actions, threats of or actual slowdowns or recessions, supply chain challenges, market volatility, higher interest rates, employment levels, health insurance coverage, wages, debt obligations, discretionary income and other factors, each of which impacts customer confidence, consumer sentiment and demand. Many of these same factors also impact the availability of certain raw materials, parts and components used in our products as well as our costs and those of our suppliers through higher raw material prices, transportation costs, labor costs, supply and distribution operations. In the first quarter of 2025, we believe sales of our products were adversely impacted by macroeconomic conditions that negatively affected disposable income and consumer demand. We believe this will continue for the remainder of 2025, particularly if tariffs or the threat of tariffs and retaliatory actions impair discretionary spending. We also expect the geopolitical conflicts involving Ukraine, the Middle East, China and other regions to continue to create market uncertainties and dampen consumer sentiment and demand.

Specifically, government actions in key strategic countries or regions relating to implemented or proposed tariffs and retaliatory actions, particularly in the United States, China, Europe, Israel and Mexico are expected to adversely impact our revenue and cost of goods sold. Additionally, the escalating trade war and geopolitical tensions between the United States and China may result in the limitation or prohibition of the availability of certain raw materials, components and parts necessary for our products or the products of our suppliers. The degree of our exposure is dependent on, among other things, the type of goods subject to any tariffs or trade restrictions enacted, the tariff rates or limits imposed, the timing of the tariffs or restrictions and any other retaliatory measures enacted. The impact may vary by time and region, making operational results uncertain and difficult to predict. These events may also cause a shift in public opinion about companies based in the United States and this may have an adverse impact on our reputation and business. We continue to closely monitor the foregoing issues, assess their potential impact on our operations and financial results, and implement plans to mitigate the impact of any adverse events.

Additionally, a material amount of our revenues are derived internationally and many of our international operations are denominated in currencies other than the U.S. dollar. In the first quarter of 2025, the U.S. dollar strengthened against major currencies, 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.

We continue to monitor the potential for violence and military actions that may directly or indirectly impact our personnel, manufacturing, supply chain, and sales. For instance, ongoing conflicts in Ukraine and the Middle East as well as increased geopolitical tensions involving Taiwan and the South China Sea may further exacerbate general and regional macroeconomic instability, particularly if fighting erupts, intensifies, spreads to other locations, creates shipping and logistical challenges or cost increases, leads to sanctions or boycotts, or otherwise materially impacts our operations or consumer spending. Our iTero business is headquartered in Israel and, although the sales, delivery times and cost of shipping our products have not been materially impacted and we have put measures in place to help reduce the future risks, it remains uncertain if there will be impacts on our sales, delivery times or cost of shipping our products. While there have been export and import restrictions imposed against products originating from and businesses operating in Israel, they have not materially impacted our sales or operations to date although we continue to monitor the risk.

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 continue to 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, tariffs and retaliatory measures, military conflicts and the evolution of our target markets, by focusing on improving our operations, further increasing 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 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 also allows us to recognize more revenue up front while doing so 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 the foregoing strategic priorities by the achievement of key financial and operating metrics. For the three months ended March 31, 2025, our business operations reflect the following:

- Revenues of $979 million, a decrease of 1.8% year-over-year;
- Clear Aligner revenues of $797 million, a decrease of 2.5% year-over-year;
- Clear Aligner case volume increased 6.2% year-over-year and Clear Aligner case volume for teens and growing patients increased from 199.2 thousand shipments to 225.8 thousand or 13.3% year-over-year;
- Imaging Systems and computer-aided design and computer-aided manufacturing ("CAD/CAM") Services revenues of $182 million, an increase of 1.2% year-over-year;
- Income from operations of $131 million and operating margin of 13.4%;
- Effective tax rate of 33.6%;
- Net income of $93 million with diluted net income per share of $1.27;
- Cash and cash equivalents of $873 million as of March 31, 2025;
- Cash provided by operating activities of $53 million;
- Capital expenditures of $25 million, primarily related to investments in our manufacturing capacity and facilities; and
- Number of employees was 21,200 as of March 31, 2025, a decrease of 2.2% year-over-year.

Other Statistical Data and Trends

- As of March 31, 2025, approximately 20 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 first quarter of 2025, the total number of Invisalign trained doctors cases were shipped to (doctor submitters) was 85.3 thousand compared to 83.5 thousand in first quarter of 2024, a 2.1% increase.

- The total utilization rate in the first quarter of 2025 increased to 7.5 cases per doctor compared to 7.2 in the first quarter of 2024. This increase was primarily driven by improved utilization in our international markets.

- The clear aligner revenue per case shipment (clear aligner revenues divided by case shipments) decreased from $1,350 in the first quarter of 2024 to $1,240 in the first quarter of 2025, an 8.1% decrease.

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, Invisalign First and Invisalign Comprehensive 3in3.

    - 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 United States, 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 revenues 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, scanner wand upgrades, and non-system revenues from 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 for the three months ended March 31, 2025 and 2024 are as follows (in millions)[1]:

	Three Months Ended March 31,			
Net Revenues	**2025**	**2024**	**Change**	
Clear Aligner net revenues	$ 796.8	$ 817.3	$ (20.4)	(2.5)%
Systems and Services net revenues	182.4	180.2	2.2	1.2 %
Total net revenues	$ 979.3	$ 997.4	$ (18.2)	(1.8)%

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

[1] Beginning with this quarterly report on Form 10-Q for the quarter ended March 31, 2025, we are no longer disclosing Clear Aligner net revenues for Americas, International and Non-case. Rather our disclosure will align with our Clear Aligner reportable segment in total.

Clear Aligner Case Volume

Case volume data which represents Clear Aligner case shipments for the three months ended March 31, 2025 and 2024 is as follows (in thousands):

	Three Months Ended March 31,			
	2025	**2024**	**Change**	
Total case volume	642.3	605.1	37.2	6.2 %

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

For the three months ended March 31, 2025, total net revenues decreased by $18 million as compared to the same period in 2024, primarily due to a decrease in Clear Aligner net revenues from lower average selling prices ("ASP"). The decrease in Clear Aligner net revenues was partially offset by an increase in Systems and Services net revenue primarily due to an increase in sales of scanner wands.

Clear Aligner

For the three months ended March 31, 2025, Clear Aligner net revenues decreased by $20 million as compared to the same period in 2024, primarily due to a decrease in ASP, driven by higher discounts and a product mix shift to lower priced products, resulting in a decrease of net revenues of $40 million and a net revenue decrease of $26 million from unfavorable foreign exchange rates. These decreases were partially offset by an increase in volume which increased net revenue by $46 million.

Systems and Services

For the three months ended March 31, 2025, Systems and Services net revenues increased by $2 million as compared to the same period in 2024, primarily due to an increase of $12 million in sales of scanner wands, driven by strong volume partially offset by lower ASP, and a $4 million increase from non-system sales. These increases were partially offset by lower scanner system sales of $9 million, driven by lower volume and ASP, and $5 million lower net revenues from unfavorable foreign exchange rates.

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

	Three Months Ended March 31, 2025	Three Months Ended March 31, 2024	Change
Clear Aligner			
Cost of net revenues	$ 234.8	$ 238.1	$ (3.4)
% of net segment revenues	*29.5 %*	*29.1 %*	
Gross profit	$ 562.1	$ 579.1	$ (17.1)
Gross margin %	*70.5 %*	*70.9 %*	
Systems and Services			
Cost of net revenues	$ 64.4	$ 61.5	$ 2.9
% of net segment revenues	*35.3 %*	*34.1 %*	
Gross profit	$ 118.0	$ 118.7	$ (0.7)
Gross margin %	*64.7 %*	*65.9 %*	
Total cost of net revenues	$ 299.2	$ 299.6	$ (0.5)
% of net revenues	*30.5 %*	*30.0 %*	
Gross profit	$ 680.1	$ 697.8	$ (17.7)
Gross margin %	*69.5 %*	*70.0 %*	

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

Clear Aligner

For the three months ended March 31, 2025, our gross margin percentage decreased as compared to the same period in 2024 primarily due to lower ASPs partially offset by lower manufacturing spend.

Systems and Services

For the three months ended March 31, 2025, our gross margin percentage decreased as compared to the same period in 2024 primarily due to a decrease in scanner wand and scanner system ASPs, partially offset by lower manufacturing spend and services efficiency.

Selling, general and administrative (in millions):

	Three Months Ended March 31,		
	2025	2024	Change
Selling, general and administrative	$ 447.6	$ 451.8	$ (4.2)
% of net revenues	*45.7 %*	*45.3 %*	

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

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

For the three months ended March 31, 2025, selling, general and administrative expense decreased compared to the same period in 2024 primarily due to lower employee costs, including salaries, fringe benefits, stock-based compensation and bonus and lower outside services, partially offset by higher marketing expense.

Research and development (in millions):

	Three Months Ended March 31,		
	2025	2024	Change
Research and development	$ 97.2	$ 91.9	$ 5.3
% of net revenues	*9.9 %*	*9.2 %*	

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

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

For the three months ended March 31, 2025, research and development expense increased compared to the same period in 2024 primarily due to higher employee costs, including salaries, fringe benefits, bonus, stock-based compensation, net of capitalized labor costs related to internal use software.

Legal settlement loss (in millions):

	Three Months Ended March 31,		
	2025	2024	Change
Legal settlement loss	$ 4.2	$ —	$ 4.2
% of net revenues	*0.4 %*	*— %*	

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

For the three months ended March 31, 2025, we recorded losses of $4.2 million 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 March 31, 2025	Three Months Ended March 31, 2024	Change
Clear Aligner			
Income from operations	$ 260.2	$ 286.2	$ (26.0)
Operating margin %	*32.7 %*	*35.0 %*	
Systems and Services			
Income from operations	$ 58.5	$ 49.7	$ 8.8
Operating margin %	*32.0 %*	*27.6 %*	
Total income from operations [1]	$ 131.1	$ 154.1	$ (23.0)
Operating margin %	*13.4 %*	*15.5 %*	

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 March 31, 2025, our operating margin percentage decreased compared to the same period in 2024 primarily due to lower gross margin from our clear aligner reportable segment and an increase in 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 months ended March 31, 2025, our operating margin percentage decreased compared to the same period in 2024 primarily due to a decrease in gross margin and a decrease in operating leverage primarily due to higher marketing spend.

Systems and Services

For the three months ended March 31, 2025, our operating margin percentage increased compared to the same period in 2024 primarily due to operating leverage partially offset by lower gross margin.

Interest income (in millions):

	Three Months Ended March 31, 2025	Three Months Ended March 31, 2024	Change
Interest income	$ 5.3	$ 4.4	$ 0.9
% of net revenues	*0.5 %*	*0.4 %*	

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

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

For the three months ended March 31, 2025, interest income increased compared to the same period in 2024 primarily due to higher cash and cash equivalents.

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

	Three Months Ended March 31, 2025	Three Months Ended March 31, 2024	Change
Other income (expense), net	$ 4.0	$ (0.1)	$ 4.2
% of net revenues	*0.4 %*	*— %*	

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

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

For the three months ended March 31, 2025, other income (expense), net increased compared to the same period in 2024 primarily due to the favorable impact of foreign exchange rates partially offset by a gain recorded on our equity investments in the first quarter of 2024.

Provision for income taxes (in millions):

	Three Months Ended March 31,		
	2025	2024	Change
Provision for income taxes	$ 47.2	$ 53.4	$ (6.1)
Effective tax rates	*33.6 %*	*33.7 %*	

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 month periods ended March 31, 2025 and 2024 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 decrease in our effective tax rate for the three months ended March 31, 2025 compared to the same period in 2024 is primarily attributable to the change in our jurisdictional mix of income, a decrease in U.S. taxes on foreign earnings, partially offset by remeasurement of Switzerland deferred tax asset due to Swiss tax rate change in 2024 and lower excess tax benefits from stock-based compensation.

Liquidity and Capital Resources

Liquidity and Trends

As of March 31, 2025 and December 31, 2024, we had cash and cash equivalents of $873 million and $1,044 million, respectively, of which approximately $740 million and $855 million, respectively, 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 operating cash flow from our domestic operations and have access to $300 million under our 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 as of March 31, 2025 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 three months ended March 31, 2025 as compared to the year ended December 31, 2024.

- There have been no material changes to our future operating lease payments during the three months ended March 31, 2025 as compared to the year ended December 31, 2024.

- We expect our investments in capital expenditures for fiscal year 2025 to be between $100 million and $150 million. Capital expenditures primarily relate to technology upgrades as well as additional manufacturing capacity in support of our continued expansion. Despite the challenging market conditions, we intend to continue to invest in research and development, manufacturing and treatment planning to meet actual and anticipated demand.

- In April 2025, our Board of Directors authorized a plan to repurchase up to $1.0 billion of our common stock, none of which has been utilized. 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.

- As of March 31, 2025, 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 March 31, 2025, we agreed, in principle, to settle a legal matter for a total of $31.75 million. We expect to seek court or administrative approvals, as applicable, in the second quarter of 2025. 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.

Sources and Uses of Cash

The following table summarizes our Condensed Consolidated Statements of Cash Flows for the three months ended March 31, 2025 and 2024 (in thousands):

	Three Months Ended March 31,	
	2025	**2024**
Net cash flow provided by (used in):		
Operating activities	$ 52,676	$ 28,664
Investing activities	(25,289)	(79,584)
Financing activities	(206,756)	(11,716)
Effect of exchange rate changes on cash, cash equivalents and restricted cash	8,480	(9,004)
Net decrease in cash, cash equivalents and restricted cash	$ (170,889)	$ (71,640)

Operating Activities

For the three months ended March 31, 2025, cash flows from operations of $53 million resulted primarily from our net income of approximately $93 million as well as the following:

Significant adjustments to net income

- Deferred taxes of $34 million related to a decrease in our long term deferred tax position;
- Depreciation and amortization of $39 million related to our investments in property, plant and equipment and intangible assets;
- Stock-based compensation of $45 million related to equity awards granted to employees and directors;
- Non-cash operating lease costs of $9 million related to operating lease cost; and
- Other non-cash operating activities of $3 million primarily related to an increase in our bad debt allowance.

Significant changes in working capital

- Net outflow of $65 million in accounts receivable due to timing of collections;
- Net outflow of $68 million in accrued and other long-term liabilities primarily due to the payment of fiscal year 2024 bonuses; and
- Net outflow of $35 million in deferred revenue.

Investing Activities

Net cash used in investing activities was $25 million for the three months ended March 31, 2025 which was solely related to purchases of property, plant and equipment.

Financing Activities

Net cash used in financing activities was $207 million for the three months ended March 31, 2025 and primarily consisted of an outflow of $201 million for share repurchases and payroll taxes paid for equity awards through share withholdings of $20 million which were partially offset by $14 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 earned on our cash and cash equivalents balance. As of March 31, 2025, we are not exposed to interest rate risk on our unsecured revolving line of credit. An immediate 10% change in interest rates would not have a material adverse impact on our future operating results and cash flows. As of March 31, 2025, we had no short term or long-term marketable securities.

We have not historically used derivative financial instruments to manage our exposure to changes in interest rates.

Foreign Currency Exchange 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 adversely impact our results of operations or financial condition in the future. We generally sell our products in the local currency of the respective countries. This provides some natural hedging because most of the subsidiaries' operating expenses are also 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.

Although we will continue to monitor our exposure to currency fluctuations, and, where appropriate, 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. If our costs become subject to significant inflationary pressures, we may not be able to fully offset such higher costs through price increases. There is no assurance that our results of operations and financial condition will not be adversely impacted by inflation in the future.

Investment Risk

We hold equity securities in privately held companies, which are subject to equity price risks and exposures from the evolving macroeconomic environment, including uncertainty and volatility in financial markets and other changes in economic conditions, such as an increase in trade tensions and related tariffs, that could have a material impact on the carrying value of our investments.

Our investments in privately held companies primarily consist of equity securities without readily determinable fair values. We elected to account for our investments in privately held companies using the measurement alternative, which is cost, less any impairment, adjusted for changes in fair value resulting from observable transactions for identical or similar investments of the same issuer. We perform a qualitative assessment at each reporting date to determine whether there are triggering events for impairment. The qualitative assessment considers factors such as but not limited to, the investee's financial performance and business prospects; industry performance; economic environment; and other relevant events and factors affecting the investee. Valuations of our equity investments are complex due to the lack of readily available market data and observable transactions. The carrying value of our investments in privately held companies was $188.2 million at March 31, 2025 and December 31, 2024.

Item 4. Controls and Procedures.

Evaluation of disclosure controls and procedures.

Our management, under the supervision and with the participation of our Chief Executive Officer and our Chief Financial Officer, has evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of the end of the period covered by this Quarterly Report on Form 10-Q. Based upon that evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that our disclosure controls and procedures are effective as of March 31, 2025, 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's rules and forms.

Changes in internal control over financial reporting.

There have been no changes in our internal control over financial reporting during the quarter ended March 31, 2025 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.

Item 1A. Risk Factors.

The following discusses some of the risks and uncertainties that may affect our business, reputation, results of operations, financial condition, cash flows, 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 business, financial condition and results of operations 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 slowdowns or 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, threats or actual imposition of tariffs, customs duties and fees by nations and retaliatory actions, general economic weakness, actual or potential slowdowns or recessions, pandemics, wars and military actions, employment levels, health insurance coverage, wages, debt obligations, discretionary income, interest rates, market volatility 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. Uncertain economic outlooks for, or declines in the economic outlooks of, the United States, Chinese, European and other international economies have and could in the future materially adversely affect consumer demand 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 could in the future reduce consumers' disposable income, which could cause a decrease in discretionary spending for our products.

Inflation has and may continue to adversely impact spending and trade activities and may unpredictably impact global and regional economies. Efforts by central banks and federal, state and local governments to combat inflation could result in an economic recession or slowdown 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, which could adversely impact the costs of producing, procuring and shipping our products. Our products or one or more of the materials or components of our products may also be subject to tariffs imposed by the United States or other countries. We may not be able to fully mitigate the impact of the increased costs or pass price increases on to our customers, 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 and expenses are generated in foreign currencies. While we forecast our balance sheet exposures to foreign currency fluctuations and utilize foreign currency forward contracts to moderate the impact of exchange rate fluctuations on certain assets and liabilities, these contracts may not eliminate our exposure to fluctuations in foreign currency. Currency exchange rate fluctuations have and may continue to materially adversely affect our results of operations and cash flows.

Our business, financial condition and results of operations could be impacted by geopolitical events, new, proposed or retaliatory tariffs, trade and international disputes, wars, military actions and terrorism, or major public health crises.

Geopolitical events, tariffs, trade and international disputes, wars, military actions 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 adversely 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, changes in diplomatic and trade relationships, new tariffs and retaliatory tariffs, trade protection measures, quotas, embargoes, safeguards, trade sanctions and countersanctions, 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, data or information exchange, disruptions, interruptions or limitations in telecommunication services, critical systems or applications reliant on a stable and uninterrupted communications infrastructure, and protests that may impact delivery of our products to customers or destruction of property. Such events may also cause a shift in public opinion about companies based in the United States, which could adversely impact on our reputation and business.

Tariffs or proposed tariffs, such as those recently announced on China, Mexico, Canada, Israel and other foreign countries not previously subject to tariffs, and any retaliatory trade measures taken in response to such tariffs may increase the cost of our products and components and raw materials used to make them. A significant portion of the products we sell, and the components and raw materials used in our products are originally manufactured or sourced outside the United States. For example, we manufacture clear aligners in our facility in Mexico and ship them to the United States, primarily for our United States customers with the remainder eventually shipping to other international locations. Tariffs would result in additional costs for our products, which may reduce demand for our products and adversely impact our gross margin and results of operations, and we may not be able to fully or substantially mitigate the impact of any new or increased tariffs or pass price increases on to our customers. Trade policies and disputes could result in increased tariffs and other trade restrictions and protectionist measures, which could increase our manufacturing costs, increase prices of and reduce demand for our products, limit our ability to sell to certain customers, limit or prohibit the availability of certain raw materials, components and parts necessary for our products or the products of our suppliers, or impede or slow the movement of our goods across borders. The extent and duration of the tariffs and the resulting impact on general economic conditions and on our business are uncertain.

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, which could adversely impact our operations and supply chains or limit our ability to offer certain products and services. These measures could require us to take various actions, including changing suppliers, where we manufacture our products, or restructuring business relationships. Complying with new or revised trade restrictions may be expensive, time-consuming, disruptive to our logistics and operations, and more costly for us and our customers. 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 or at all.

Military conflicts have and may in the future materially adversely impact the economies in which we operate. Our iTero operations, headquartered in Israel, are close to areas that have been affected by ongoing violence and military action, which may impact our employees and our iTero business and operations. Some employees and consultants in Israel have been called for military service in the current conflict and they may be absent for certain periods of time. Furthermore, our facilities may be damaged or our manufacturing capability or delivery schedules may be impacted as a result of the ongoing conflict. Our supply chains and demand for our products could be impaired as a result of hostilities, export and import restrictions, sanctions or boycotts. These events could disrupt ongoing operations and may materially impact the logistics, timing and cost of shipping of our products and materials or our ability to operate out of impacted areas. 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 consumers, suppliers, contract manufacturers, distributors and other business partners.

Natural disasters such as earthquakes, tsunamis, floods, droughts, hurricanes, wildfires, urban fires, volcanic eruptions and other extreme weather conditions can cause deaths, injuries and major public 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. If a natural disaster occurs in a region where one of our facilities or those of our customers or suppliers are located, our or their employees or facilities could be impacted, valuable research could be lost, and our ability to create treatment plans, respond to customer inquiries or manufacture and ship our products could be compromised, causing significant delays and reputational harm. Climate change could increase the frequency and severity of natural disasters and could change the supply, demand or availability of sources of energy or resources material to manufacturing our products and operations. It could also affect the availability or cost of materials, goods, and services on which we and our suppliers, contract manufacturers, distributors and other business partners rely, which could materially adversely impact our business, financial condition and results of operations.

Business and Industry Risks

Demand for our products and services 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 and services require our customers and consumers to forego traditional treatment methods. For example, Invisalign treatment is a significant departure from traditional orthodontic wires and brackets, and our 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 and services 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, third-party reimbursement and price compared to competing products and traditional treatment methods. If demand for our products or services fails to increase, or decreases, our business, financial condition and results of operations may be materially adversely affected.

Our net revenues depend primarily on sales of the Invisalign System and iTero intraoral scanners and declines in sales or ASP may adversely affect net revenues, gross profit and net income.

Our net revenues are primarily dependent on sales of the Invisalign System and iTero intraoral scanners. Of the two, we expect the Invisalign System to continue to represent the majority of our net revenues, making sales of it critical to our success.

The ASPs of our products, particularly the Invisalign System, are influenced by numerous factors, including the mix of product treatment packages, geographical mix, channel mix and timing of products sold (particularly the timing and quantity of orders for additional clear aligners for certain Invisalign products) and foreign currency exchange rates. In addition, we sell our products at different prices and with varying shipping and handling charges or processing fees that may differ by country. Our ASPs for the Invisalign System and iTero intraoral scanners have been and could in the future be adversely affected if:

- we offer promotions or 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 or are unable to increase 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;
- we modify our pricing strategies for certain products or adjust pricing for certain items based on cancellation fees, shipping and handling charges or processing fees;
- we participate in government tenders, such as volume-based procurement 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 and net income, ASPs and volume.

Competition in the markets for our products and services is increasing and we expect aggressive competition from existing competitors and emerging companies that introduce new technologies, products or services 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, and we face competition from a variety of competitors including companies that specialize in our products or systems and services. While solutions such as the Invisalign System, iTero intraoral scanners, CAD/CAM software and digital platform facilitate this transition, we face competition from companies that seek to introduce new technologies and products and companies that remain dedicated to traditional products. As we continue to expand globally, we may see new competition in different geographic regions. We have experienced price-focused competition from competitors in various markets we serve and we anticipate this will continue. We may be unable to compete with these competitors or they may render our technology or products obsolete or economically unattractive, particularly 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. We may be unable to devote adequate financial resources to develop or acquire new AI technologies and systems in the future and sufficiently meet evolving industry trends and consumer demands.

The number and types of competitors we face are diverse and growing rapidly. The Invisalign System competes primarily against traditional wires and brackets and increasingly with clear aligners manufactured and distributed by new market entrants and existing competitors, including traditional medical device companies, laboratories, startups and, in some cases, doctors and dental service 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 or procure from third-party white-label providers. 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 intraoral scanners are also facing increased competition from new and existing competitors. Our scanners compete with polyvinyl siloxane impressions and numerous new or existing intraoral scanners, as well as traditional bite wing 2D dental x-rays and dental imaging systems that leverage near infrared imaging technology for detecting interproximal caries. We experience and may continue to experience competition with our scanners and software solutions by competitors who introduce products at lower prices or with functionality that better meets customer demand, including expansion of their portfolios in the digital ecosystem.

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 or improved 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, improved or refurbished products and services. We cannot ensure successful development, sales or acceptance of our products and services. The extent and rate at which our new, improved or refurbished products or services achieve market acceptance and penetration depends on many factors, including our ability to:

- successfully predict, timely innovate, develop, and launch new or improved technologies, applications, features, products and services to meet market demand and keep pace with changes in technology, customers' demands and industry standards;
- successfully and timely obtain regulatory approval or clearance of new or improved products or services from government agencies such as the U.S. Food and Drug Administration ("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, 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 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;
- design and manufacture products that achieve the clinical and practice outcomes we believe necessary for market acceptance;
- 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, services and subscription plans;
- encourage customers to adopt new or improved technologies and provide the needed technical, sales and marketing support to make new or improved 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 or improved products and services, 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 business, financial condition and results of operations.

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 such investments or complete acquisitions, we may not ultimately strengthen our competitive position or achieve desired synergies and integration. Investments or acquisitions we complete could be viewed negatively and may lead to negative ratings by analysts or investors, or give rise to stockholder objections or activism, 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 actions, orders or decrees;
- experience information technology ("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 our investment or determine that investments have declined in value, which could potentially require recording impairments;
- need to pay cash, incur debt or issue equity securities to pay for an acquisition, adversely affecting our liquidity, financial condition or the trading price 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 and could in the future cause our operating results to fluctuate include:

- changes in consumer, customer and industry 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 ASPs;
- 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 fail to accurately predict product demand, we may not have the appropriate level of our manufacturing capacity or that of one or more of our suppliers, staffing, materials, components, space, equipment or finished products. 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 intraoral scanners are generally based on forecasts and historic demand and we often place orders with suppliers for materials, components, sub-assemblies and finished products weeks or more in advance of projected orders. If we do not hire and train the appropriate number of technicians in anticipation of demand, our costs and expenditures may not align with our revenues or revenue growth. 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. In addition, we may be required to purchase or lease additional or larger facilities and equipment to manage demand. If we fail to timely manufacture and deliver products to meet demand, this could damage our relationships with existing customers or harm our ability to attract new customers and adversely affect our business, financial condition and results of operations.

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. The majority 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 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 shortfalls. This variability and unpredictability could also result in our failing to meet the expectations of industry, financial analysts or investors.

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, operational inefficiencies 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 the Invisalign System and iTero intraoral 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 reputation, business, financial condition and results of operations.

Our IT systems are critical to our business. Issues with 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 complex IT systems and are dependent on key third-party software embedded in 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 interruptions or other disruptions 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, including privacy, security and data protection laws, regulations and actions, 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 business processes, extend established processes to new subsidiaries, and implement additional functionality in our enterprise resource planning, product development, manufacturing, and other software and IT systems. This entails certain risks, including operational disruptions, such as our ability to continue developing and updating products while addressing safety and security, 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 IT systems and those of our suppliers and customers may materially impact our business, financial condition, and results of operations.

Additionally, we continuously upgrade and issue new software releases upon which customer facing manufacturing and treatment planning operations depend. Software applications and products containing software may contain errors or defects, especially when first introduced or released. The discovery of a defect, error, or security vulnerability in our products, software applications or IT systems, incompatibility with customers' computer operating systems and hardware configurations with a new release or upgraded version or the failure of our products or primary IT systems, which we are unable to cure in a timely fashion, may cause adverse consequences. These may include delays or loss of revenues, significant remediation costs, market acceptance delays, data damage, loss, or unavailability, unintended disclosure or other processing of financial, health or other information relating to individuals, product recalls, loss of market share or increased service costs, any of which could have a material effect on our reputation, business, financial condition or results of our operations and the operations of our customers or our business partners.

Products in our Systems and Services segment, such as our iTero intraoral scanners, are subject to software and hardware risks that, if improperly managed, could have a material adverse impact on our business and financial results.

The success of our Systems and Services segment depends on the quality and reliability of our products. We face software and hardware risks related to the manufacturing, design, quality and safety of our complex, global installed base of iTero intraoral scanners, which are continually updated to add, expand, or improve features with new hardware we manufacture or components that we source, to integrate new or existing software or other components manufactured by third parties, or to provide repair or replacement parts, any of which may contain errors or exhibit failures, especially when products are first introduced. We may be unable to ensure that third party components or changes to them will be completely compatible with our iTero intraoral scanners, which could result in failures of our iTero intraoral scanners to perform as anticipated. Additionally, the third-party software integrated into or interoperable with our iTero intraoral scanners will routinely reach end of life, and as a consequence, certain applications and models may be exposed to additional vulnerabilities, including security risks, errors, and malfunctions that may be irreparable or difficult to repair. We may not timely and adequately remediate or implement corrective measures for such failures, including due to reliance 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. If our products experience component aging, errors, or performance problems, or do not otherwise satisfy our stringent quality processes and controls we may choose to or be compelled to recall certain products, which may include, product withdrawals from the market, labeling changes, design changes, customer notifications, and notifications to global regulatory bodies.

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 intraoral scanners, termination of interoperability with third-party intraoral 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 system outages, regardless of cause, 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 claims, demands, litigation, and liabilities, which could have a material effect on our reputation, business, financial condition or results of our operations and the operations of our customers or 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, financial condition and results of operations could be materially adversely affected if supply is restricted or ends or the price materially increases.

We are highly dependent on our supply chain, particularly manufacturers of specialized and customized scanning equipment, rapid prototyping machines, resin and other advanced materials, as well as the optics, electronic and other mechanical components of our iTero intraoral scanners. We maintain single and sole supply relationships for many of these machines and materials. By using single and sole 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, which could create 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 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, resellers and other agents or sales intermediaries to import, market, sell, service and support our products and services. 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 and services 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, their employees and agents for compliance with laws and regulations, including fair competition, bribery and corruption, import and export compliance, safety, data privacy, false advertising or unfair and deceptive trade practices, and marketing and sales activities. The conduct of these distributors may impact our reputation and brand and if they 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 depend on commercial freight carriers, primarily United Parcel Service, Inc., to deliver our products. If the operations of commercial freight 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 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 will be difficult to achieve our strategic priorities, which could materially adversely affect our business, financial condition and 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, 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 12 months or more to train sales representatives to successfully market and sell our products and services 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, operational or strategic 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 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 adversely affected.

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 and Accountability. We have experienced and may continue to experience 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, products, and services, 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, social media and alliances with professional sports teams, athletes, social media influencers and other strategic partners. There is no assurance our advertising campaigns will achieve the desired returns on advertising spend, increase brand, product or services awareness sufficiently or generate goodwill and positive reputational goals, or that we will be able to maintain commercial relationships with social media influencers and other strategic partners. Moreover, should any entity or individual endorsing us, our products or services 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 and services boycotted and our brand image and reputation harmed, any of which could materially affect our business, financial condition and results of operations.

In addition, many countries prohibit certain types of marketing activities. For example, some countries restrict direct to consumer advertising of medical devices. We have and may in the future be alleged to violate marketing restrictions and be ordered to stop certain marketing activities or prevented from selling our products and services. Moreover, competitors do not always follow these restrictions, which can create an unfair advantage and make 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, services or operational changes which could materially impact our business, financial condition and results of operations.

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, consent decrees, be subject to judgments, involve negative publicity and divert management time and attention, which may materially impact our business, financial condition and 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, regulations and actions 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, and China. Government regulatory actions and court decisions may result in fines or hinder our ability to provide certain benefits to our customers and consumers, reducing the attractiveness of our products, services and the net revenue derived from them. These actions and decisions may also hinder our ability to pursue certain mergers, acquisitions, business combinations, investments or other transactions.

Failure to obtain or maintain approvals or comply with regulations and government actions 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 and government actions under numerous federal, state, local, and foreign laws, including those regulating:

- the storage, transmission, disclosure, and other processing of, and security measures with respect to, personal, financial and medical information as well as healthcare records;
- processing and use of children’s personal and health data;
- websites and application advertising, including that involving the use of cookies or involving the collection, use, disclosure, or other processing of data relating to individuals 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 services; and
- the design, manufacture, marketing and advertising of our products and services.

The healthcare and technology markets are also highly regulated and subject to evolving political, economic and regulatory influences and government actions. Global regulators are expanding and changing regulations and guidance for products and services, which can limit their potential benefits and cause protracted review timelines for new products and services. Our critical third-party vendors and service providers are subject to similar 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 evolving environmental, health and safety regulations. There can be no assurance we will adequately address the 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 regulatory clearance or approval. 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. Moreover, these laws may change, resulting in additional time, expense or loss of market access. If the 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 fines, civil penalties and criminal prosecution. Delays or failures to obtain or maintain regulatory approvals, clearances or to comply with regulatory requirements may materially adversely affect 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 comply with applicable 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, financial condition and results of operations.

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 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, intermediaries or representatives acting on our behalf.

While we have policies and procedures requiring compliance with applicable laws and regulations and we provide training to foster compliance, our employees, third parties acting on our behalf, and customers may not adhere to our policies and procedures 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 to evaluating administrative rulemaking under the *Chevron* doctrine, which provided for judicial deference to regulatory agencies, including the FDA. There may 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 courts. For example, this decision may result in more companies suing the FDA to challenge its longstanding decisions and policies, 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.

In 2025, there have been significant and wide-ranging reforms to federal policy and the federal government including significant workforce reductions across federal agencies. We may be impacted by the reduction in federal agencies including obtaining and maintaining clearances and approvals of our products and services. The rapid increase in new or changed government regulations could result in significant costs and expenses, including those related to compliance, and require modifications in the way we and our customers conduct business. If we are unable to respond to changing regulations in a timely and effective manner, our business, financial condition and results of operations could materially adversely be impacted.

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 reputation, business, financial condition and results of operations could be harmed.

We retain confidential employee, applicant and customer personal, health and financial, and our own proprietary information and data essential to our operations. We rely on the effectiveness of our IT systems, policies and contracts and the policies of our third-party vendors, and their IT systems to safeguard information and data. Additionally, our cybersecurity controls depend on our customers, many of whom are individual or small healthcare providers 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 and services we develop remain secure and be perceived as secure. Despite the implementation of security features in our products and services 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 attacks, phishing, vishing, deepfakes, and other social engineering attacks, malware, ransomware, employee noncompliance, error or malfeasance, cybersecurity attacks, malicious code, and other breaches of, or incidents impacting, IT systems or similar malicious or otherwise disruptive actions, including by organized groups and nation-state actors, which may disrupt or limit the availability of, or result in damage to, our IT systems and result in loss or unavailability of, damage to, or the unauthorized acquisition, use, disclosure, or other processing 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 information. This risk is exacerbated with the advancement of technologies like AI, which malicious third parties can use to create new, more sophisticated and more frequent or other attacks. There can be no assurance our cybersecurity risk management program and processes, including our policies, controls or procedures, will be fully implemented, complied with or effective in protecting our systems and information or any other information we maintain or otherwise process.

Further, the frequency and sophistication of third-party cybersecurity attacks are increasing. Significant service disruptions, breaches, incidents, interruptions or other disruptive events impacting our infrastructure and IT systems, or other cybersecurity incidents, or any belief or reporting that any of the foregoing has occurred, could expose us to regulatory investigations, or other proceedings, private claims, demands, and litigation, impair our reputation and competitive position, distract 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 our products and services. Concerns over our practices with respect to privacy, data protection, data governance, and cybersecurity could adversely affect our reputation and deter customers and consumers from using our products and services. In addition, patient care could suffer, and we could be liable if our products, services 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, but we cannot guarantee applicable insurance will be available to us in the future on economically reasonable terms or at all. Damages and claims arising from incidents may not be covered, may exceed coverage limits, and may not cover the time and effort we incur investigating and responding to any incidents, or other costs or liabilities, which may be material. The costs to eliminate, mitigate, or recover from security problems and cybersecurity attacks and incidents could be material and require us to implement additional or different security controls or other measures and, depending on the nature and extent of the problem and the products, services or IT systems impacted, such security problems and cybersecurity attacks and incidents may result in network, IT system interruptions or other disruptions, decreased product sales, data loss, damage, unavailability, or other liabilities, any of which may have a material impact on our operations, net revenues and operating results. The costs associated with cybersecurity tools and infrastructure and competition for scarce cybersecurity and IT resources could limit our ability to identify, eliminate or remediate cybersecurity or other security vulnerabilities or problems or enact changes to minimize the attack surface of our network.

Additionally, our iTero intraoral scanners may be independently or collectively the target of cybersecurity incidents or attacks or subject to security vulnerabilities, bugs, errors, defects, or viruses or other malicious code. 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 incident in a timely manner. Any such cybersecurity incident may cause loss or damage to us, our customers or strategic business partners or may cause further malfunctions in, or damage to, our products, services, or IT systems, damage to, or loss, unavailability, or unauthorized acquisition, use, or other processing of our data, or disruption, interruption or temporary cessation of our operations. Further, any such security breach or incident, or other cybersecurity incident, or any belief or reporting that any of the foregoing has occurred, may otherwise have a negative impact upon our business or reputation.

We also are or may become, or alleged to be or become, subject to certain 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 ("HIPAA"), the HIPAA Standards for Privacy of Individually Identifiable Health Information and the Security Standards for the Protection of Electronic Protected Health Information under HIPAA and the Health Information Technology for Economic and Clinical Health Act of 2009 , as well as those relating to privacy, data security, content regulation and consumer protection, such as the California Consumer Protection Act, as amended by the California Privacy Rights Act (as amended, the "CCPA"). The CCPA requires covered businesses that process personal information of California residents to disclose certain practices, provides California residents with data privacy rights, imposes operational requirements, and provides for significant civil penalties for violations as well as a private right of action for certain data breaches and statutory damages. There are limited exemptions under the CCPA for protected health information covered by HIPAA and certain other state laws, but the CCPA and other new and evolving state laws could impact our business activities. Numerous other states have enacted, or plan to enact, laws relating to privacy, data protection, data governance and cybersecurity, with such enacted laws either in operation or slated to go into operation over the next several years. Many of these laws are comprehensive privacy laws similar to the CCPA. States also are enacting laws addressing specific subject matter, such as Washington's My Health, My Data Act, which includes a private right of action. Laws in all 50 U.S. states have required notice to individuals whose personal data has been disclosed as a result of a data breach. Outside of the U.S., relevant legal requirements continue to evolve. For example, the collection and use of health data and other personal information is governed in the EU by the General Data Protection Regulation, which imposes significant obligations upon companies and rights for individuals, with substantial penalties for noncompliance up to the greater of €20,000,000 or 4% of the total worldwide annual turnover of the preceding financial year, and by certain EU member state-level legislation. Numerous other jurisdictions maintain similar legislation or other laws or regulations addressing privacy, data protection, data governance, or cybersecurity.

We are also subject to data export restrictions and international transfer laws and regulations that prohibit or impose conditions upon certain data transfers. The mechanisms upon which we and many other companies rely for European data transfers have been the subject of legal challenge, regulatory interpretation and judicial decisions by the EU courts and regulators, and may be subject to significant changes. Several jurisdictions, including the EU, the United States, China, Australia, and Japan, have established legal requirements for cross-border transfers of all or certain personal information and certain jurisdictions have also established legal requirements for data localization, which may require us to maintain separate servers located in those countries so that all or certain personal information are maintained locally. These laws and regulations addressing cross-border data transfers and data localization are constantly evolving and may be created, interpreted, applied or amended in ways that could restrict our activities in certain jurisdictions, limit our ability to provide our products and services in those jurisdictions, require us to modify our policies and practices and to engage in additional contractual negotiations, or increase our costs and obligations and impose limitations upon our ability to efficiently transfer personal data across borders. We have and likely will again in the future be required to implement new or expand existing data storage protocols, build new storage facilities, devote additional resources, and modify relevant policies or procedures to comply with the foregoing laws and regulations, any of which could be costly and which may adversely affect our business and our customers' businesses, our financial condition and our results of operations in those jurisdictions.

With laws, regulations and other obligations relating to privacy, data protection, data governance and cybersecurity imposing new and relatively burdensome obligations, and with substantial uncertainty over the interpretation and application of these and other obligations, we may face challenges in addressing their requirements and making necessary changes to our policies and practices and may incur significant costs and expenses in an effort to do so. Further, any failure or perceived failure by us or our vendors, customers, or service providers to comply with our applicable policies or notices relating to privacy, data protection, data governance or cybersecurity, our contractual or other obligations to third parties, or any of our other legal obligations, laws, rules, regulations, government actions or standards relating to privacy, data protection, data governance or cybersecurity, may result in governmental investigations or enforcement actions, litigation, claims and other proceedings, harm our reputation, and could result in significant liability.

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 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 and services. 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 and services 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.

Current and anticipated sustainability and social ("Sustainability") laws and scrutiny of our Sustainability 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 Sustainability laws and regulations, and we are and may be required to comply with new, broader, more complex and more costly Sustainability laws and regulations, such as the EU'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, workers' and human rights.

Sustainability regulations 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 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, as Sustainability laws are increasing, customers 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 may result in manufacturing, transportation and supply chain disruptions if sustainable clean energy is not readily available in adequate amounts when required. Moreover, clean energy sources, coupled with reduced investments in traditional energy production and infrastructure, may not provide the predictable, reliable and consistent energy we, our suppliers and other business partners 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 diligence efforts to identify whether any of our products contain minerals impacted by these laws and regulations may not be accurate, 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 intraoral scanners and the packaging in which they are shipped. These laws are proliferating and new substances subject to restrictions are added regularly and may require additional reporting or phasing out of certain chemicals and compounds such as per- and polyfluoroalkyl substances (PFAS). We may be required 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 Sustainability laws and regulations is costly for us and our suppliers, and we expect these regulations and costs to increase, in particular as the regulatory frameworks in each jurisdiction in which we operate become more complex and distinct. 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 compliant. In all of these situations, customers may stop purchasing products from us, and may take legal action against us, which could harm our reputation, business, financial condition and results of operations.

Investor advocacy groups, institutional investors, investment funds, proxy advisory services, stockholders and customers have and could in the future focus on corporate Sustainability practices. Additionally, public interest and legislative pressure related to companies' Sustainability practices has been evolving in recent years. If we fail to adopt Sustainability standards or practices as quickly as stakeholders desire, comply with or timely report on our Sustainability efforts or practices accurately, or satisfy the disclosure and other expectations of stakeholders, our brand, reputation, employee retention, business, financial performance, growth, and stock price may be adversely impacted.

We have been incorporating and continue to work to further incorporate AI technologies into our products, services and IT systems. 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 IT systems, which is intended to enhance their operation and effectiveness internally and for our customers, consumers and suppliers. 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. In Europe, the EU AI Act entered into force on August 1, 2024 which will become fully effective on August 2, 2026, with some provisions effective in February 2025. Other jurisdictions are considering similarly focused legislation. Although we do not engage in developing or providing AI systems for which their placement on the market, putting into service, or use would qualify as "prohibited AI practices," restrictions and obligations under this regulation, to the extent applicable to us, could have a negative impact on our business, financial condition and results of operations. Additionally, other jurisdictions have proposed, and in certain cases enacted, laws and regulations addressing aspects of the use and development of AI. The evolving AI regulatory environment may, among other impacts, result in:

- inconsistencies among AI regulations and frameworks across jurisdictions;
- onerous compliance, governance, research and development obligations that may require us to rework or reevaluate improvements to be compliant or result in the development of products that are unacceptable under new or revised regulatory frameworks;
- increased risk of regulatory enforcement and litigation related to our AI models;
- increased liability related to the use of AI by our customers, consumers or suppliers that are beyond our control;
- delays in the deployment of new products and services;
- competitive and reputational harm; and
- increased cybersecurity risks.

The input of confidential information or trade secrets into AI systems may result in the loss of intellectual property, proprietary rights or attorney-client privilege in such information or trade secrets. The use of AI technologies for developing products or services may adversely affect or preclude our intellectual property rights in such products or services, or may expose us to liability related to the infringement, misappropriation or other violation of third-party intellectual property. Further, particularly given the nascent stage of the technology, the use of AI can lead to unintended consequences, including the generation of outputs that appear correct but are factually inaccurate, misleading, or that result in unintended biases and discriminatory outcomes, or are otherwise flawed, which could harm our reputation and business and expose us to risks related to such inaccuracies or errors in these outputs.

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 could be misappropriated 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 and adversely impact our reputation and results of operations.

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 and may in the future be sued for. and defend lawsuits and other legal claims challenging, infringement of third parties' patents. 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 and services, 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 reputation, business, financial condition and results of operations.

Financial, Tax and Accounting Risks

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

Under U.S. GAAP, we review our goodwill 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 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, and discount rates. 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 material charges to income 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 principles. A change in these principles or in the way these principles 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 the end of our fiscal year. Our internal controls may become ineffective 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, 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.

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 impact our future effective tax rate. These include changes in the global economic environment, our legal entity structure or activities performed within our entities, our business operations, tax laws, regulations and/or rates, changes to existing accounting pronouncements, changes in interpretations of existing tax laws or regulations, the relative proportions of revenues and income before taxes in the various jurisdictions in which we operate that have differing statutory tax rates, overall levels of pretax earnings, settlements of income tax audits, non-deductible goodwill impairments, and changes in the valuation allowance offsetting 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, the Organization for Economic Cooperation and Development ("OECD") established the Inclusive Framework on Base Erosion and Profit Shifting to among other things, allocate greater taxing rights to countries where customers are located and establish a global minimum tax rate. Countries including EU member countries have enacted, are considering enacting, or have committed to enact the OECD/G20 Framework's Pillar Two 15% global minimum tax, including Switzerland which is a significant jurisdiction for us. We continue to monitor the enactment of legislation to evaluate the impact of changing global tax laws, which could adversely affect our provision for income taxes or operations.

Moreover, the application of indirect taxes (such as sales and use tax ("SUT"), value-added tax ("VAT"), goods and services tax ("GST"), and other indirect taxes) to our operations is complex and evolving. U.S. states, local and foreign taxing jurisdictions have differing rules and regulations governing differing types of taxes, and these rules and regulations are subject to varying interpretations and exemptions that may change over time. We collect and remit SUT, VAT, GST and other taxes in many jurisdictions and we are routinely subject to audits. The positions we take regarding taxes as well as the amounts we collect or remit 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 have and may continue to dispute rulings or positions taken by tax authorities, which have and may continue to 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;
- stockholder activism or securities class action litigation;
- 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, new, proposed or retaliatory tariffs, 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, 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 repurchase 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.

Unregistered Sales of Equity Securities

None.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

The following table summarizes the stock repurchase activity for the three months ended March 31, 2025.

Period	Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Approximate Dollar Value of Shares that May Yet Be Purchased Under the Plans or Programs[1]
January 1, 2025 through January 31, 2025	331,542	$ 217.57	331,542	$ 225,000,000
February 1, 2025 through February 28, 2025	83,348	$ 189.12	83,348	$ 209,200,000
March 1, 2025 through March 31, 2025	670,645	$ 168.78	670,645	$ 96,000,000
Total	1,085,535		1,085,535	

[1] *January 2023 Repurchase Program.* In January 2023, we announced that our Board of Directors had authorized a plan to repurchase up to $1,000,000,000 of our common stock ("January 2023 Repurchase Program"). See Note 10 "*Common Stock Repurchase Programs" of the Notes to Condensed Consolidated Financial Statements* for details on the January 2023 Repurchase Program.

In April 2025, our Board of Directors authorized a plan to repurchase up to $1.0 billion of our common stock ("April 2025 Repurchase Program"), none of which has been utilized.

Item 3. Defaults Upon Senior Securities.

Not applicable.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

During the fiscal quarter ended March 31, 2025, 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:

Exhibit Number	Description	Filing	Date	Exhibit Number	Filed herewith
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.

SIGNATURES

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

ALIGN TECHNOLOGY, INC.

May 8, 2025	By: /s/ JOSEPH M. HOGAN **Joseph M. Hogan** **President and Chief Executive Officer** **(Principal Executive Officer)**
May 8, 2025	By: /s/ JOHN F. MORICI **John F. Morici** **Chief Financial Officer and Executive Vice President, Global Finance (Principal Financial Officer and Principal Accounting Officer)**

Exhibit 31.1

CERTIFICATION

I, Joseph M. Hogan, certify that:

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

Date: May 8, 2025

/s/ JOSEPH M. HOGAN

Joseph M. Hogan
President and Chief Executive Officer

Exhibit 31.2

CERTIFICATION

I, John F. Morici, certify that:

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

Date: May 8, 2025

/s/ JOHN F. MORICI

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

Exhibit 32.1

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

In connection with the Quarterly Report of Align Technology, Inc. (the “Company”) on Form 10-Q for the period ending March 31, 2025 as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

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

Date: May 8, 2025

In connection with the Quarterly Report of Align Technology, Inc. (the “Company”) on Form 10-Q for the period ending March 31, 2025 as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

By:	/s/ JOHN F. MORICI
Name:	**John F. Morici**
Title:	**Chief Financial Officer and Executive Vice President, Global Finance**

Date: May 8, 2025