UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report: January 31, 2017 (Date of earliest event reported)

Align Technology, Inc.

(Exact name of registrant as specified in its charter)

DE 0-32259 94-3267295
(State or other jurisdiction of incorporation) (Commission File Number) (IRS Employer Identification Number)

2560 Orchard Parkway, San Jose, CA 95131
(Address of principal executive offices) (Zip Code)

(408) 470-1000

(Registrant's telephone number, including area code)

Not Applicable

(Former Name or Former Address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 2.02. Results of Operations and Financial Condition

On January 31, 2017, Align Technology, Inc. ("Align") is issuing a press release and holding a conference call regarding its financial results for its fourth quarter and fiscal year ended December 31, 2016. The full text of the press release is furnished as Exhibit 99.1 to this Form 8-K.

This information shall not be deemed "filed" for purposes of Section 18 of the Securities and Exchange Act of 1934, as amended (the "Exchange Act"), or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Align is making reference to non-GAAP financial information in both the press release and the conference call. A reconciliation of non-GAAP financial measures contained in the attached press release to the comparable GAAP financial measures is contained in the attached press release and a reconciliation of these and certain other non-GAAP financial information provided on the conference call (to the extent not reconciled on such call) is contained on the Investor Relations section of our website at investor.aligntech.com.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits

Press Release of Align Technology, Inc. dated January 31, 2017

Signature

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 hereunto duly authorized.

Align Technology, Inc.

By: <u>/s/ Roger E. George</u>
Roger E. George
Vice President, Legal and
Corporate Affairs and
General Counsel

Exhibit Index

Exhibit No.

Dated: January 31, 2017

99.1

Description

Press Release of Align Technology, Inc. dated January 31, 2017

Align Technology Announces Fourth Quarter and Year Ended 2016 Results

SAN JOSE, CA -- (Marketwired - January 31, 2017) - Align Technology, Inc. (NASDAQ: ALGN)

- -- Record 2016 revenues of \$1.1 billion, up 27.7% year-over-year, and diluted EPS of \$2.33
- -- 2016 Invisalign case shipments of 708.5 thousand cases, up 21.5% yearover-year
- -- Q4 revenues up 27.3% year-over-year to \$293.2 million
- -- Q4 Clear Aligner** revenues up 17.5% and Scanner revenues up 156.8% year-over-year
- -- Q4 Invisalign case shipments up 18.5% year-over-year to 190.1 thousand cases, international Invisalign case shipments up 25.0% year-over-year
- -- Q4 diluted EPS \$0.59, down \$0.01 year-over-year

Align Technology, Inc. (NASDAQ: ALGN) today reported financial results for the fourth quarter and year ended December 31, 2016. Invisalign case shipments in the fourth quarter of 2016 (Q4'16) were 190.1 thousand, a 18.5% increase year-over-year. For Q4'16, revenues were \$293.2 million, a 27.3% increase year-over-year, and net profit was \$47.6 million, or \$0.59 per diluted share, down \$0.01 per diluted share compared to the same period in the prior year. Q4'16 EPS was unfavorably impacted by a stronger U.S. dollar, which amounted to approximately \$0.08 per diluted share due to net foreign exchange losses related to the revaluation of certain balance sheet accounts.

For 2016, Invisalign case shipments were 708.5 thousand cases and iTero scanner shipments were 3,970 units, an increase of 21.5% and 229.6%, respectively. For 2016, revenues were \$1.1 billion, a 27.7% increase year-over-year and net profit was \$189.7 million, or \$2.33 per diluted share, up \$0.56 per diluted share compared to the prior year.

Commenting on Align's Q4 and 2016 results, Align Technology President and CEO Joe Hogan said, "Q4 was another record quarter for Align, reflecting continued strong growth across all geographies and customer channels compared to the prior quarter last year. These results helped us to exceed \$1 billion in annual revenue for the first time in our history. In addition, more than 700 thousand patients started orthodontic treatment with Invisalign clear aligners in 2016, helping us to surpass our 4 millionth Invisalign patient. We also saw strong adoption of our new iTero Element scanner this year, which more than tripled our scanner shipments over the prior year."

GAAP Summary Financial Comparisons

Fourth Quarter Fiscal 2016

	Ç	4'16		Q3'16		Q4'15	 Q/Q Change	 Y/Y Change
Invisalign Case Shipments*	19	0,055	-	177,755	1	L60,400	+6.9%	+18.5%
Net Revenues		,		278.6M		,	+5.2%	+27.3%
Clear Aligner**	\$ 2	51.5M	\$	243.7M	\$	214.0M	+3.2%	+17.5%
Scanner & Services	\$	41.7M	\$	34.9M	\$	16.2M	+19.3%	+156.8%
Net Profit	\$	47.6M	\$	51.4M	\$	48.9M	(7.3)%	(2.6)%
Diluted EPS	\$	0.59	\$	0.63	\$	0.60	\$ (0.04)	\$ (0.01)

Fiscal 2016

	 		:	
	2016	2015	Υ/\	/ Change
Invisalign Case Shipments*	 708,500	583,235		+21.5%
Net Revenues	\$ 1,079.9M	\$ 845.5M		+27.7%
Clear Aligner**	\$ 958.3M	\$ 800.2M		+19.8%
Scanner & Services	\$ 121.5M	\$ 45.3M		+168.3%
Net Profit	\$ 189.7M	\$ 144.0M		+31.7%
Diluted EPS	\$ 2.33	\$ 1.77	\$	0.56

Note: Changes and percentages are based on actual values and may effect totals due to rounding

^{*} Invisalign Shipment figures exclude SmileDirectClub aligners

^{**} Clear aligner revenue includes revenues from Invisalign clear aligners and SmileDirectClub aligners

As of December 31, 2016, Align had \$700.0 million in cash, cash equivalents and marketable securities compared to \$678.7 million as of December 31, 2015. We repurchased approximately 0.4 million shares of stock for \$38.0 million in Q4'16 under the April 2014 Repurchase Program. Subsequent to year-end, the Company purchased the remaining shares under this plan for \$3.8 million completing the Align 2014 Repurchase Plan. Align has \$300.0 million available for repurchase under its 2016 Repurchase Plan announced on April 28, 2016.

2016 Business Highlights

The following list highlights Align's key announcements over the past year:

- -- Launched iTero Element 1.4 software and Invisalign Outcome Simulator 4.0 application: Align announced the iTero Element 1.4 new software upgrade which includes color scanning, restorative pre-treatment scanning and optimized orthodontic scanning. In addition, the iTero scanners include the enhanced Invisalign Outcome Simulator 4.0 application now with Invisalign 3D Progress Tracking and Patient Simulation Sharing.
- -- Launched Invisalign G7: Align announced Invisalign G7, a new set of features designed to deliver greater control of tooth movements and improved treatment outcomes. Invisalign G7 builds on earlier Invisalign G-series releases with new features to fine-tune certain tooth movements and deliver treatment outcome quality that Invisalign providers expect, particularly with teenage patients.
- -- Weekly Aligner Wear Recommendation: Align announced one-week aligner wear recommendation for all Invisalign Full, Teen and Assist products instead of two-week aligner wear for each stage of Invisalign treatment. Continued Invisalign product innovation including "G-Series" features, SmartTrack aligner material, and clinically proven treatment predictability, allowed the company to confidently recommend one-week wear.
- -- Launched ClinCheck Pro 5.0: Align announced ClinCheck Pro 5.0, the next generation Invisalign treatment software, with ability to view side-by-side treatment plans, a more realistic 3D visual model, and a new configurable toolbar for even greater flexibility.
- -- 4 Million Patients Milestone: Align announced that 4 million patients started treatment with Invisalign clear aligners. This is a significant accomplishment for the company and the 100,000 Invisalign-trained doctors around the world, demonstrating increased global acceptance of Invisalign treatment as a preferred choice for straightening teeth.
- -- SmileDirectClub Supplier Agreement: Align announced a supply agreement with SmileDirectClub to manufacture non-Invisalign clear aligners for SmileDirectClub's doctor-directed, at-home program for affordable, cosmetic teeth straightening. SmileDirectClub aligners will include up to 20 stages without attachments or interproximal reduction (IPR), and will be manufactured by Align per SmileDirectClub's specifications for minor tooth movement.
- -- Research Awards Program for 2016 and 2017: Align announced the Research Awards Program for 2017. This is an ongoing annually funded program established in 2010 and designed to promote clinical and scientific dental research in universities across the globe. Align also announced that fourteen research awards totaling \$310,000 were awarded to four universities in North America and eight International universities under its 2016 program.
- -- 3Shape Trios Scanner Interoperability: Align announced that 3Shape's TRIOS® Standard, TRIOS Color and TRIOS 3 scanners were qualified in Q4'16 for Invisalign case submission. Align and 3Shape also announced a collaborative agreement to enhance the existing STL export workflow with iTero® scanners and laboratory partners using 3Shape Dental System™ Software which will enable improved consistency for customers using the workflow
- -- Invisalign Commercially Available in India: Align announced commercial availability of the Invisalign system in India in February 2016. Align is offering a comprehensive range of products including Invisalign Full, Invisalign Teen, Invisalign Lite clear aligners, and Vivera Retainers. Align began training doctors in Delhi, Mumbai, Pune, Chandigarh, Chennai, and expanded into Bangalore, Ahmedabad, Hyderabad, Calcutta, and Cochin over the year. Align also launched a consumer marketing campaign.
- -- ERP System Implementation: Align implemented a new ERP system in July, which provides a foundation that enables new capabilities, improves speed of execution, and will be used to improve Align's customers' experience.

Q1 2017 Business Outlook

For the first quarter of 2017 (Q1'17), Align provides the following guidance:

- -- Invisalign case shipments in the range of 200 thousand to 203 thousand, up approximately 22% to 24% over the same period a year ago.
- -- Net revenues in the range of \$295 million to \$298 million.
- -- Diluted EPS in the range of \$0.64 to \$0.67, which includes \$0.14 of excess tax benefits.

Regarding our tax rate: At the start of 2017, we adopted accounting standards update entitled Improvements to Employee Share-Based Payment Accounting. Under this new standard, excess tax benefits and deficiencies associated with employee share-based payments are no longer recognized as additional paid-in capital on the balance sheet but instead recognized directly to income tax expense or benefit in the income statement for the reporting period in which they occur. Under this new standard, we expect our Q1 effective tax rate to be approximately 1% to 2%, which includes \$12 million in excess tax benefits.

Align Web Cast and Conference Call

Align will host a conference call today, January 31, 2017 at 4:30 p.m. ET, 1:30 p.m. PT, to review its fourth quarter and year end 2016 results, discuss future operating trends and the business outlook. The conference call will also be web cast live via the Internet. To access the webcast, go to the "Events & Presentations" section under Company Information on Align's Investor Relations web site at http://investor.aligntech.com. To access the conference call, please dial 201-689-8261. An archived audio web cast will be available beginning approximately one hour after the call's conclusion and will remain available for approximately 12 months. Additionally, a telephonic replay of the call can be accessed by dialing 877-660-6853 with conference number 13652166 followed by #. For international callers, please dial 201-612-7415 and use the same conference number referenced above. The telephonic replay will be available through 5:30 p.m. ET on February 14, 2017.

About Align Technology, Inc.

Align Technology is the leader in modern Clear Aligner orthodontics that designs, manufactures and markets the Invisalign® system, which provides dental professionals with a range of treatment options for adults and teenagers. Align also offers the iTero 3D digital scanning system and services for orthodontic and restorative dentistry. Align was founded in March 1997 and received FDA clearance to market the Invisalign system in 1998. Visit www.aligntech.com for more information.

For additional information about the Invisalign system or to find an Invisalign provider in your area, please visit www.invisalign.com. For additional information about the iTero 3D digital scanning system, please visit www.itero.com.

Forward-Looking Statement

This news release, including the tables below, contains forward-looking statements, including statements regarding certain business metrics for the first quarter of 2017, including, but not limited to, anticipated net revenues, gross margin, operating expenses, operating profit, diluted earnings per share, tax rate and case shipments. Forward-looking statements contained in this news release and the tables below relating to expectations about future events or results are based upon information available to Align as of the date hereof. Readers are cautioned that these forward-looking statements are only predictions and are subject to risks, uncertainties and assumptions that are difficult to predict. As a result, actual results may differ materially and adversely from those expressed in any forward-looking statement. Factors that might cause such a difference include, but are not limited to, difficulties predicting customer and consumer purchasing behavior, Align's ability to protect its intellectual property rights, continued compliance with regulatory requirements, competition from existing and new competitors, the willingness and ability of our customers to maintain and/or increase product utilization in sufficient numbers, the possibility that the development and release of new products does not proceed in accordance with the anticipated timeline, the possibility that the market for the sale of these new products may not develop as expected, or that the expected benefits of new or existing business relationships will not be achieved as anticipated, the risks relating to Align's ability to sustain or increase profitability or revenue growth in future periods while controlling expenses, growth related risks, including capacity constraints and pressure on our internal systems and personnel, continued customer demand for our existing and new products, changes in consumer spending habits as a result of, among other things, prevailing economic conditions, levels of employment, salaries and wages and consumer confidence, the timing of case submissions from our doctors within a quarter, acceptance of our products by consumers and dental professionals, foreign operational, political and other risks relating to Align's international manufacturing operations, Align's ability to develop and successfully introduce new products and product enhancements and the loss of key personnel. These and other risks are detailed from time to time in Align's periodic reports filed with the Securities and Exchange Commission, including, but not limited to, its Annual Report on Form 10-K for the year ended December 31, 2015, which was filed with the Securities and Exchange Commission (SEC) on February 25, 2016, and its Quarterly Report on Form 10-Q for the quarter ended September 30, 2016, which was filed with the SEC on November 8, 2016. Align undertakes no obligation to revise or update publicly any forward-looking statements for any reason.

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

			-		 	-	
Net revenues	\$	293,203	\$	230,276	\$ 1,079,874	9	845,486
Cost of net revenues		72,954	_	57,466	 264,580		205,376
Gross profit		220,249	-	172,810	 815,294		640,110
Operating expenses: Selling, general and administrative Research and development		21,609		13,889	75,720		390,239 61,237
Total operating expenses							451,476
Income from operations		68,372		59,339	248,921		188,634
Interest and other income (expense), net		(7,516)	-	313	 (6,355)		(2,533)
Net income before provision for income taxes and equity in losses of investee		60,856		59,652	242,566		186,101
Provision for income taxes Equity in losses of investee, net of tax				10,775			
Net income		47,621	- \$	48,877	\$ 189,682		144,020
Net income per share: Basic							1.80
Diluted	\$	0.59	\$	0.60	\$ 2.33	9	1.77
Shares used in computing net income per share:							
Basic	==-						79,998
Diluted		81,248		81,051	81,484		81,521 =======

ALIGN TECHNOLOGY, INC. UNAUDITED CONDENSED CONSOLIDATED BALANCE SHEETS (in thousands)

	December 31 2016	December 31, 2015
ASSETS		
Current assets: Cash and cash equivalents Marketable securities, short-term Accounts receivable, net Inventories Prepaid expenses and other current assets Total current assets	\$ 389,275 250,981 247,415 27,131 38,176	359,581 158,550 19,465 26,700
Marketable securities, long-term Property, plant and equipment, net Equity method investments Goodwill and intangible assets, net Deferred tax assets Other assets	59,783 175,167 45,061 81,998 67,844 13,320	136,473 79,162 51,416
Total assets	\$ 1,396,151	1,158,633

LIABILITIES AND STOCKHOLDERS' EQUITY

Current liabilities: Accounts payable Accrued liabilities Deferred revenues	\$ 28,596 134,332 191,407	107,765
Total current liabilities	354,335	271,672
Income tax payable Other long term liabilities	45,133 1,294	,
Total liabilities	400,762	310,707
Total stockholders' equity	995,389	847,926
Total liabilities and stockholders' equity	\$ 1,396,151	\$ 1,158,633

ALIGN TECHNOLOGY, INC. INVISALIGN BUSINESS METRICS*

Invisalign Average Selling Price (ASP): Worldwide ASP International ASP	\$:	915 1,250	\$:	915 1,285	\$		\$	Q2 2016 1,285 1,345
Invisalign Cases Shipped by Geography: North America International	54	4,010	18	4,845	į	53,195		114,855 62,140
Total Cases Shipped								L76,995
YoY% growth QoQ% growth	:	26.4%	:	22.0%		25.2% 8.1%		
Number of Invisalign Doctors Cases Were Shipped To: North America International	2: 10	9,865	10	6,460		11,280		22,575 12,485
Total Doctors Cases Shipped To	3	2,700	48	8,170	;	33,635		35,060
Invisalign Doctor Utilization Rates*: North America North American Orthodontists North American GP Dentists International Total Utilization Rates * # of cases shipped/# of doctors to whom cases were shipped		3.1		31.8		3.0		10.7 3.1 5.0
Number of Invisalign Doctors Trained: North America International	:	1,270 1,400		4,320 5,475		875 1,605		1,125 1,760
Total Doctors Trained Worldwide	:	2,670	9	9,795		2,480		2,885
Total to Date Worldwide	103	3,790	10	3,790	10	 06,270 	1	109,155

		Q3	Q4	F	iscal
		2016	2016		2016
Invisalign Average Selling Price (ASP):				
Worldwide ASP	\$	1,285	\$ 1,230	\$	1,265
International ASP	\$	1,365	\$ 1,315	\$	1,335

Invisalign Cases Shipped by Geography: North America International		122,555 67,500	244,690
Total Cases Shipped	177,755	190,055	708,500
YoY% growth QoQ% growth	20.5% 6.9%	18.5%	21.5%
Number of Invisalign Doctors Cases Were Shipped To:	e		
North America International	12,720	23,265 13,635	34,065 20,415
Total Doctors Cases Shipped To	35,290	36,900 =====	
Invisalign Doctor Utilization Rates*: North America North American Orthodontists North American GP Dentists International Total Utilization Rates * # of cases shipped/# of doctors to whom cases were shipped	11.1 3.0 4.9	5.3 11.3 3.2 5.0 5.2	36.6 7.6 12.0
Number of Invisalign Doctors Trained: North America International	1,300 1,315	1,420 2,280	4,720 6,960
Total Doctors Trained Worldwide		3,700	
Total to Date Worldwide	111,770	115,470 ======	115,470

Note: Historical public data may differ due to rounding. Additionally, rounding may effect totals.

ALIGN TECHNOLOGY, INC. STOCK-BASED COMPENSATION (in thousands)

	Q4 2015	Fiscal 2015	Q1 2016	Q2 2016
Stock-based Compensation (SBC) SBC included in Gross Profit SBC included in Operating Expenses		•		\$ 932 12,767
Total SBC Expense	\$13,807 ======	\$52,948 ======	\$12,524	\$13,699
			-	
	Q3 2016		Q4 016	Fiscal 2016
Stock-based Compensation (SBC)	2010	2	010	2010
SBC included in Gross Profit	\$	995 \$	1,078 \$	3,966
SBC included in Operating Expenses	12,	716	13,136	50,182
Total SBC Expense	\$ 13, =======	711 \$ === ====	14,214 \$ ========	54,148

ALIGN TECHNOLOGY, INC. BUSINESS OUTLOOK SUMMARY (unaudited)

The outlook figures provided below and elsewhere in this press release are

^{*}Invisalign business metrics exclude SmileDirectClub aligners.

approximate in nature since Align's business outlook is difficult to predict. Align's future performance involves numerous risks and uncertainties and the company's results could differ materially from the outlook provided. Some of the factors that could affect Align's future financial performance and business outlook are set forth under "Forward Looking Information" above in this press release.

Financial Outlook (in millions, except per share amounts and percentages)

	Q1'17 Guidance
	GAAP
Net Revenues	\$295.0 - \$298.0
Gross Margin	74.2% - 74.5%
Operating Expenses	\$162.5 - \$164.5
Operating Margin	19.1% - 19.3%
Net Income per Diluted Share	\$0.64 - \$0.67 (1)
Business Metrics:	Q1'17
Case Shipments Capital Expenditure Depreciation & Amortization Diluted Shares Outstanding Stock Based Compensation Expense Tax Rate	200.0K - 203.0K \$70M - \$75M \$8.0M - \$8.5M 81.3M (2) \$14.6M 1% - 2% (1)

- (1) Includes the benefit from the adoption of the new accounting standard update for share-based compensation $\,$
- (2) Excludes any stock repurchases during the quarter

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