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: July 28, 2016 (Date of earliest event reported)

Align Technology, Inc.

(Exact name of registrant as specified in its charter)

DE

0-32259

(State or other jurisdiction of incorporation)

(Commission File Number)

94-3267295 (IRS Employer Identification Number)

95131

(Zip Code)

2560 Orchard Parkway, San Jose, CA

(Address of principal executive offices)

(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:

 \Box 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 9.01. Financial Statements and Exhibits

On July 28, 2016, Align Technology, Inc. ("Align") is issuing a press release and holding a conference call regarding its financial results for its second quarter ended June 30, 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.

(d) Exhibits Press Release of Align Technology, Inc. dated July 28, 2016 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

<u>Exhibit No.</u>

Dated: July 28, 2016

99.1

<u>Description</u> Press Release of Align Technology, Inc. dated July 28, 2016

Align Technology Announces Second Quarter 2016 Results

SAN JOSE, CA -- (Marketwired - July 28, 2016) - Align Technology, Inc. (NASDAQ: ALGN) -

- -- Q2 revenues up 28.6% year-over-year to \$269.4 million
- -- Q2 results driven by Clear aligner revenues up 21.2% year-over-year and
- Scanner revenues up almost 200% year-over-year
- -- Q2 Clear Aligner shipments up 22.4% year-over-year to 177 thousand
- cases, international shipments up 38.3% year-over-year
- -- Diluted EPS \$0.62, up \$0.23 year-over-year

Align Technology, Inc. (NASDAQ: ALGN) today reported financial results for the second quarter ended June 30, 2016. Clear Aligner case shipments in the second quarter of 2016 (Q2'16) were 177 thousand, a 22.4% increase year-over-year. For Q2'16, revenues were \$269.4 million, a 28.6% increase year-over-year, and net profit was \$50.1 million, or \$0.62 per diluted share, up \$0.23 per diluted share compared to the same period in the prior year.

"Q2 was driven by better than expected revenue due to continued strong year-over-year Invisalign volume across our customer base and record utilization, with international case volume up 38.3%, and North America up 15.3%," said Joe Hogan, Align Technology President and CEO. "We also had continued strong demand for our iTero Element with record shipments this quarter resulting in revenue growth of almost 200% year-over-year."

GAAP Summary Financial Comparisons

Second Quarter Fiscal 2016

		Q2'16		Q1'16		Q2'15	Q/Q	Change	Y/Y	Change
Clear Aligner								.0.10		
Shipments Net Revenues		L76,995 269.4M		163,695 238.7M		L44,570 209.5M		+8.1% +12.8%		+22.4% +28.6%
Clear Aligner	-	243.4M		219.7M	-	200.8M		+10.8%		+21.2%
Scanner & Services Net Profit	\$ \$	26.0M 50.1M	\$ \$		\$ \$	8.7M 31.4M		+36.3% +23.7%		+199.0% +60.0%
Diluted EPS	\$	0.62	\$	0.50	\$	0.39	\$	0.12		+\$0.23

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

As of June 30, 2016, Align had \$685.0 million in cash, cash equivalents and marketable securities compared to \$678.7 million as of December 31, 2015. On May 3, 2016, as part of our \$300.0 million April 2014 stock repurchase program, we entered into an Accelerated Stock Repurchase agreement and funded the repurchase of \$50.0 million of our common stock. On that date we received an initial delivery of approximately 0.5 million shares based on current market prices. The final number of shares to be repurchased will be based on our volume-weighted average stock price during the term of the agreement, less an agreed upon discount. Upon completion of this agreement, we will commence repurchasing an additional \$50.0 million of our common stock on the open market. These two actions will complete the April 2014 stock repurchase program. During the quarter the Company also announced a new plan to repurchase up to an additional \$300.0 million of the Company's stock, all of which remains available for repurchase as of June 30, 2016.

Additional Aligners at No Charge Effective July 18, 2015

Align implemented its new Additional Aligners policy on July 18, 2015 in which the Company no longer distinguishes between mid-course corrections and case refinements providing doctors the ability to order additional aligners to address either treatment need at no charge, subject to certain requirements. These changes were effective for all new Invisalign Full, Teen, and Assist treatments shipped worldwide after July 18, 2015, as well as any cases that were open as of this date. While this policy change was largely immaterial to the Company's cash flows, it did impact the timing at which the Company recognizes revenue. The Company estimates Q2'16 revenues and pre-tax income were lower by approximately \$8.3 million due to this change.

Q3 2016 Business Outlook

For the third quarter of 2016 (Q3'16), Align provides the following guidance:

- -- Clear Aligner case shipments in the range of 174.2 thousand to 176.9 thousand, up approximately 18.1% to 19.9% over the same period a year ago.
- -- Net revenues in the range of \$267.2 million to \$273.5 million.
- -- Diluted EPS in the range of \$0.49 to \$0.52.

Align Technology to Supply Non-Invisalign Clear Aligners to SmileDirect Club in North America

In a separate press release today, 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.

Align Web Cast and Conference Call

Align will host a conference call today, July 28, 2016 at 4:30 p.m. ET, 1:30 p.m. PT, to review its second quarter 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 web cast, 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 13640324 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 August 11, 2016.

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 third quarter of 2016, including, but not limited to, anticipated net revenues, gross margin, operating expenses, operating profit, diluted earnings per share, 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, 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, our ability to successfully achieve the anticipated benefits from the scanner and services business, 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 guarter, 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 protect its intellectual property rights, continued compliance with regulatory requirements, competition from existing and new competitors, 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 Ouarterly Report on Form 10-Q for the quarter ended March 31, 2016, which was filed with the SEC on May 5, 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)

	Three Months Ended June 30,				Six Months Ended June 30,			
	 2016		2015		2016		2015	
Net revenues	\$ 269,362	\$	209,488	\$	508,082	\$	407,574	
Cost of net revenues	 64,146		50,854		122,239		97,850	

Gross profit	205,216	158,634	385,843	309,724
Operating expenses: Selling, general and adminstrative Research and development		100,625 15,684		
Total operating expenses	140,080	116,309	267,373	218,475
Income fom operations	65,136	42,325	118,470	91,249
Interest and other income (expense), net	125	174	(302)	(1,278)
Net income before provision for income taxes	65,261	42,499	118,168	89,971
Provision for income taxes	15,113	11,149	27,474	22,444
Net income	\$ 50,148	\$ 31,350	\$ 90,694	\$ 67,527 ======
Net income per share Basic		\$ 0.39		
Diluted	\$ 0.62	\$ 0.39	\$ 1.11	\$ 0.83
Shares used in computing net income per share				
Basic		80,257		
Diluted	81,281	81,394	81,440	81,729

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

	June 30, 2016		De	cember 31, 2015
ASSETS				
Current assets:				
Cash and cash equivalents	\$	167,706	\$	167,714
Marketable securities, short-term		404,107		359,581
Accounts receivable, net		192,660		158,550
Inventories		22,992		19,465
Prepaid expenses and other current				
assets		37,942		26,700
Total current assets		825,407		732,010
Markatahla acquisition long torm		110 100		1 - 1 - 2 - 2 - 2
Marketable securities, long-term		113,158		151,370
Property, plant and equipment, net		161,685		136,473
Goodwill and intangible assets, net Deferred tax assets		83,749		79,162 51,416
Other assets		60,051 7,223		8,202
other assets		1,223		0,202
Total assets	\$	1,251,273	\$	1,158,633
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LIABILITIES AND STOCKHOLDERS' EQUITY				
Current liabilities:				
Accounts payable	\$	30,927	\$	34,354
Accrued liabilities		107,505		107,765

Deferred revenues	160,557	129,553
Total current liabilities	298,989	271,672
Income tax payable Other long term liabilities	41,244 1,182	37,512 1,523
Total liabilities	341,415	310,707
Total stockholders' equity	909,858	847,926
Total liabilities and stockholders' equity	\$ 1,251,273	\$

ALIGN TECHNOLOGY, INC. Q2 2016 FINANCIAL AND BUSINESS METRICS (in thousands except average selling price, utilization and doctors trained)

ALIGN TECHNOLOGY, INC. Q2 2016 FINANCIAL AND BUSINESS METRICS (in thousands except average selling price, utilization and doctors trained)

	Q1 2015	Q2 2015	Q3 2015	Q4 2015	Fiscal 2015	Q1 2016	Q2 2016
Invisalign Clear Aligner Net Revenues by Geography:							
North America International Non-case*	\$118,844 55,920 12,265	61,896	61,265	70,980	250,061	,	\$143,909 83,703 15,824
Total Clear Aligner Net Revenues		\$200,817			\$800,186	\$219,698	\$243,436
YoY % growth QoQ % growth *includes Invisalign training, ancillary products, and retainers	11.2% 0.3%		11.3% -1.3%		12.3%	17.5% 2.6%	21.2% 10.8%
Average Invisalign Selling Price (ASP): Worldwide ASP International ASP	\$ 1,335 \$ 1,410	. ,		\$ 1,250 \$ 1,315		\$ 1,255 \$ 1,315	
Invisalign Clear Aligner Cases Shipped by Geography:							
North America International	91,110 39,670	,	101,260 46,225	,	398,390 184,845	110,500 53,195	114,855 62,140
Total Cases Shipped	130,780	144,570	,	,	583,235	,	176,995
YoY % growth QoQ % growth	16.6% 3.1%	28.9%	23.6%	26.4%	22.0%		22.4% 8.1%
Number of Invisalign Doctors Cases Shipped To:							
North America	20,165	21,335	21,160	21,835	31,710	22,355	22,575

International	9,050	9,790	10,150	10,865	16,460	11,280	12,485
Total Doctors Cases Shipped To				32,700 ======			
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	4.5 9.0 2.9 4.4 4.5	9.5	9.9 2.9 4.6	9.9 3.1 5.0	31.8 7.4	3.0 4.7	10.7 3.1
Number of Invisalign Doctors Trained: North America International	870 1,540	1,120 1,335	1,060 1,200	1,270 1,400	4,320 5,475	875 1,605	1,125 1,760
Total Doctors Trained Worldwide				2,670			
Total to Date Worldwide	96,405 ======			103,790			
Total Net Revenues: Clear Aligner Net Revenues Scanner & Services Net Revenues Total Worldwide Net Revenues	11,057	8,671	9,344	\$214,048 16,228 \$230,276	45,300	19,022	25,926
YoY % growth QoQ % growth	======= 9.7%	======================================	======= 9.4%	=======	======================================		======= 28.6%
Stock-based Compensation (SBC) SBC included in Gross Profit SBC included in Operating Expenses	10,670	11,860	13,677	\$ 1,008 12,799	49,006	11,563	12,767
Total SBC Expense	\$ 11,650 ======	\$ 12,830 ======	\$ 14,661 ======	\$ 13,807 ======	\$ 52,948 ======	\$ 12,524 ======	\$ 13,699 ======

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

ALIGN TECHNOLOGY, INC. BUSINESS OUTLOOK SUMMARY (unaudited)

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

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

	Q3'16 Guidance		
	GAAP		
Net Revenues	\$267.2 - \$273.5		
Gross Margin	74.4% - 74.8%		
Operating Expenses	\$147.1 - \$148.1		
Operating Margin	19.3% - 20.6%		
Net Income per Diluted Share	\$0.49 - \$0.52		

Case Shipments Capital Expenditure Depreciation & Amortization Diluted Shares Outstanding Stock Based Compensation Expense Tax Rate 174.2K - 176.9K \$20M - \$25M \$7.0M - \$7.5M 81.4M* \$14.4M 24.5%

* Excludes any stock repurchases during the quarter

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