

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 28, 2016
(Date of earliest event reported)

Align Technology, Inc.
(Exact name of registrant as specified in its charter)

DE
(State or other jurisdiction
of incorporation)

0-32259
(Commission File
Number)

94-3267295
(IRS Employer
Identification Number)

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

95131
(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 28, 2016, 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, 2015. 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

99.1 [Press Release of Align Technology, Inc. dated January 28, 2016](#)

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.

Dated: January 28, 2016

ALIGN TECHNOLOGY, INC.

By: /s/ Roger E. George
Roger E. George

<u>Exhibit No.</u>	Exhibit Index	<u>Description</u>
99.1		Press Release of Align Technology, Inc. dated January 28, 2016

Align Technology Announces Fourth Quarter and 2015 Results

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

- Q4 revenues of \$230.3 million, up 15.9% year-over-year, and diluted EPS of \$0.60
- Q4 Clear Aligner shipments of 160.4 thousand cases, up 26.4% year-over-year
- Q4 international Clear Aligner shipments, up 34.8% year-over-year and 33.7% of total worldwide case shipments
- 2015 revenues of \$845.5 million, up 11.0% year-over-year, and diluted EPS of \$1.77
- 2015 Clear Aligner shipments of 583.2 thousand cases, up 22.0% year-over-year

Align Technology, Inc. (NASDAQ: ALGN) today reported financial results for the fourth quarter and year ended December 31, 2015. Clear Aligner case shipments in the fourth quarter of 2015 (Q4'15) were 160.4 thousand, a 26.4% increase year-over-year. For Q4'15, revenues were \$230.3 million, a 15.9% increase year-over-year, and net profit was \$48.9 million, or \$0.60 per diluted share, up \$0.12 over the prior year.

Clear Aligner case shipments in 2015 were 583.2 thousand, a 22.0% increase year-over-year. For 2015, revenues were \$845.5 million, an 11.0% increase year-over-year and net profit was \$144.0 million, or \$1.77 per diluted share, flat compared with the prior year.

"The fourth quarter was a strong finish to another record year for Align," said Joe Hogan, Align Technology President and CEO. "Better than expected revenue and earnings were driven by record Invisalign volume, which was up 26% year-over-year. These results reflect strong growth across our customer base and geographies -- from both an increase in the number of submitters as well as cases per doctor. In addition, strong scanner revenue growth of 33% year-over-year exceeded expectations as shipments of the new iTero Element began ramping this quarter resulting in record scanner shipments."

Continued Hogan, "For the full year 2015, over half a million patients started Orthodontic treatment with Invisalign, an increase of 22% compared to 13% last year. Our increased growth rate reflects continued adoption and utilization from international doctors and a solid rebound in North America, both driven by investments in territory coverage and sales and marketing programs, including clinical education. Product and technology innovation is also a key growth driver for the Company, and as a result, in 2015 we continued to see increased clinical confidence in Invisalign treatment for our customers worldwide."

GAAP Summary Financial Comparisons Fourth Quarter Fiscal 2015

	Q4 '15	Q3 '15	Q4 '14	Q/Q Change	Y/Y Change
Clear Aligner Shipments	160,400	147,485	126,905	+8.8 %	+26.4 %
Net Revenues	\$ 230.3M	\$ 207.6M	\$ 198.6M	+10.9 %	+15.9 %
Clear Aligner	\$ 214.0M	\$ 198.3M	\$ 186.4M	+7.9 %	+14.8 %
Scanner & Services	\$ 16.2M	\$ 9.3M	\$ 12.2M	+73.7 %	+33.4 %
Net Profit	\$ 48.9M	\$ 27.6M	\$ 39.5M	+77.0 %	+23.6 %
EPS	\$ 0.60	\$ 0.34	\$ 0.48	+\$0.26	+\$0.12

Fiscal 2015

	2015	2014	Y/Y Change
Clear Aligner Shipments	583,235	478,000	+22.0%
Net Revenues	\$ 845.5M	\$ 761.7M	+11.0%
Clear Aligner	\$ 800.2M	\$ 712.5M	+12.3%
Scanner & Services	\$ 45.3M	\$ 49.1M	(7.7)%
Net Profit	\$ 144.0M	\$ 145.8M	(1.2)%
EPS	\$ 1.77	\$ 1.77	0.00

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

As of December 31, 2015, Align had \$678.7 million in cash, cash equivalents and marketable securities compared to \$602.6 million as of December 31, 2014. We repurchased approximately 0.2 million shares of stock for \$11.2 million in Q4'15 and 1.7 million shares for \$101.8 million in 2015. These repurchases were collectively part of a three-year, \$300 million stock repurchase program announced in April 2014, of which there is approximately \$100 million remaining for repurchases through April 2017.

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 Q4'15 and 2015 reported revenues and pre tax income were lower by approximately \$7.0 million and \$14 million, respectively due to this change.

Q1 2016 Business Outlook

For the first quarter of 2016 (Q1'16), Align provides the following guidance:

- Clear Aligner case shipments in the range of 161.3 thousand to 163.7 thousand, up approximately 23% to 25% over the same period a year ago.
- Net revenues in the range of \$232.5 million to \$236.6 million.
- Diluted EPS in the range of \$0.37 to \$0.40.

Align Web Cast and Conference Call

Align will host a conference call today, January 28, 2016 at 4:30 p.m. ET, 1:30 p.m. PT, to review its fourth quarter and 2015 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 approximately fifteen minutes prior to the start of the call. 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 13627358 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 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 first 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, 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 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 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, 2014, which was filed with the Securities and Exchange Commission on February 26, 2015. 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		Year Ended	
	December 31, 2015	December 31, 2014	December 31, 2015	December 31, 2014
Net revenues	\$ 230,276	\$ 198,600	\$ 845,486	\$ 761,653
Cost of revenues	57,466	47,938	205,376	183,210
Gross profit	172,810	150,662	640,110	578,443

Operating expenses:				
Selling, general and administrative	99,582	85,893	390,239	332,068
Research and development	13,889	13,276	61,237	52,799
Total operating expenses	113,471	99,169	451,476	384,867
Operating profit	59,339	51,493	188,634	193,576
Interest and other income (expense), net	313	(1,716)	(2,533)	(3,207)
Profit before income taxes	59,652	49,777	186,101	190,369
Provision for income taxes	10,775	10,236	42,081	44,537
Net profit	\$ 48,877	\$ 39,541	\$ 144,020	\$ 145,832
Net profit per share				
- basic	\$ 0.61	\$ 0.49	\$ 1.80	\$ 1.81
- diluted	\$ 0.60	\$ 0.48	\$ 1.77	\$ 1.77
Shares used in computing net profit per share				
- basic	79,481	80,266	79,998	80,754
- diluted	81,051	81,691	81,521	82,283

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

	December 31, 2015	December 31, 2014
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 167,714	\$ 199,871
Marketable securities, short-term	359,581	254,787
Accounts receivable, net	158,550	129,751
Inventories	19,465	15,928
Prepaid expenses and other current assets	26,700*	56,823
Total current assets	732,010	657,160
Marketable securities, long-term	151,370	147,892
Property, plant and equipment, net	136,473	90,125
Goodwill and intangible assets, net	79,162	82,056
Deferred tax assets	51,416*	3,099
Other assets	8,202	7,665
Total assets	\$ 1,158,633	\$ 987,997
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 34,354	\$ 23,247
Accrued liabilities	107,765	87,880
Deferred revenues	129,553	90,684
Total current liabilities	271,672	201,811
Other long term liabilities	39,035	33,415

Total liabilities	310,707	235,226
Total stockholders' equity	847,926	752,771
Total liabilities and stockholders' equity	\$ 1,158,633	\$ 987,997

* As of December 31, 2015 we early adopted Accounting Standards Update No. 2015-17, Income Taxes (Topic 740), which simplifies the presentation of deferred income taxes. Under the new standard, both deferred tax liabilities and assets are required to be classified as noncurrent in a consolidated balance sheet. The prior reporting period was not retrospectively adjusted.

ALIGN TECHNOLOGY, INC.

Q4 2015 FINANCIAL AND BUSINESS METRICS

(in thousands except average selling price, utilization and doctors trained)

	Q4 2014	Fiscal 2014	Q1 2015	Q2 2015
Invisalign Clear Aligner Net Revenues by Geography:				
North America	\$ 113,670	\$ 446,577	\$ 118,844	\$ 126,137
International	60,467	219,742	55,920	61,896
Non-case*	12,300	46,230	12,265	12,784
Total Clear Aligner Net Revenues	\$ 186,437	\$ 712,549	\$ 187,029	\$ 200,817
YoY % growth	12.2 %	15.9%	11.2%	11.7%
QoQ % growth	4.7 %		0.3%	7.4%

*includes Invisalign training, ancillary products, and retainers

Average Invisalign Selling Price (ASP):				
Worldwide ASP	\$ 1,370	\$ 1,395	\$ 1,335	\$ 1,300
International ASP	\$ 1,510	\$ 1,575	\$ 1,410	\$ 1,380

Invisalign Clear Aligner Cases Shipped by Geography:				
North America	86,855	338,530	91,110	99,630
International	40,050	139,470	39,670	44,940
Total Cases Shipped	126,905	478,000	130,780	144,570

Number of Invisalign Doctors Cases Shipped To:				
North America	19,745	29,890	20,165	21,335
International	8,945	13,450	9,050	9,790
Total Doctors Cases Shipped To	28,690	43,340	29,215	31,125

Invisalign Doctor Utilization Rates*:				
North America	4.4	11.3	4.5	4.7
North American Orthodontists	8.6	27.7	9.0	9.5
North American GP Dentists	2.9	6.9	2.9	3.0
International	4.5	10.4	4.4	4.6
Total Utilization Rates	4.4	11.0	4.5	4.6

* # of cases shipped/# of doctors to whom cases were shipped

Number of Invisalign Doctors Trained:				
North America	1,170	4,145	870	1,120
International	1,255	5,290	1,540	1,335
Total Doctors Trained Worldwide	2,425	9,435	2,410	2,455

Total to Date Worldwide	=====	=====	=====	=====
	93,995	93,995	96,405	98,860
	=====	=====	=====	=====
Total Net Revenues:				
Clear Aligner Net Revenues	\$ 186,437	\$ 712,549	\$ 187,029	\$ 200,817
Scanner & Services Net Revenues	12,163	49,104	11,057	8,671
	-----	-----	-----	-----
Total Worldwide Net Revenues	\$ 198,600	\$ 761,653	\$ 198,086	\$ 209,488
	=====	=====	=====	=====
YoY % growth	11.4 %	15.4%	9.7%	8.8%
QoQ % growth	4.6 %		-0.3%	5.8%
Stock-based Compensation (SBC)				
SBC included in Gross Profit	\$ 965	\$ 3,570	\$ 980	\$ 970
SBC included in Operating Expenses	9,510	36,225	10,670	11,860
	-----	-----	-----	-----
Total SBC Expense	\$ 10,475	\$ 39,795	\$ 11,650	\$ 12,830
	=====	=====	=====	=====

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	Q3	Q4	Fiscal
	2015	2015	2015
Invisalign Clear Aligner Net Revenues by Geography:			
North America	\$ 124,085	\$ 129,663	\$ 498,729
International	61,265	70,980	250,061
Non-case*	12,942	13,405	51,396
	-----	-----	-----
Total Clear Aligner Net Revenues	\$ 198,292	\$ 214,048	\$ 800,186
	=====	=====	=====
YoY % growth	11.3%	14.8%	12.3%
QoQ % growth	-1.3%	7.9%	

*includes Invisalign training, ancillary products, and retainers

Average Invisalign Selling Price (ASP):			
Worldwide ASP	\$ 1,255	\$ 1,250	\$ 1,285
International ASP	\$ 1,325	\$ 1,315	\$ 1,355

Invisalign Clear Aligner Cases Shipped by Geography:			
North America	101,260	106,390	398,390
International	46,225	54,010	184,845
	-----	-----	-----
Total Cases Shipped	147,485	160,400	583,235
	=====	=====	=====

Number of Invisalign Doctors Cases Shipped To:			
North America	21,160	21,835	31,710
International	10,150	10,865	16,460
	-----	-----	-----
Total Doctors Cases Shipped To	31,310	32,700	48,170
	=====	=====	=====

Invisalign Doctor Utilization Rates*:			
North America	4.8	4.9	12.6
North American Orthodontists	9.9	9.9	31.8
North American GP Dentists	2.9	3.1	7.4
International	4.6	5.0	11.2
Total Utilization Rates	4.7	4.9	12.1

* # of cases shipped/# of doctors to whom cases were shipped

Number of Invisalign Doctors Trained:			
North America	1,060	1,270	4,320
International	1,200	1,400	5,475

Total Doctors Trained Worldwide	2,260	2,670	9,795
Total to Date Worldwide	101,120	103,790	103,790
Total Net Revenues:			
Clear Aligner Net Revenues	\$ 198,292	\$ 214,048	\$ 800,186
Scanner & Services Net Revenues	9,344	16,228	45,300
Total Worldwide Net Revenues	\$ 207,636	\$ 230,276	\$ 845,486
YoY % growth	9.4%	15.9%	11.0%
QoQ % growth	-0.9%	10.9%	
Stock-based Compensation (SBC)			
SBC included in Gross Profit	\$ 984	\$ 1,008	\$ 3,942
SBC included in Operating Expenses	13,677	12,799	49,006
Total SBC Expense	\$ 14,661	\$ 13,807	\$ 52,948

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 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)

	Q1'16 Guidance
	GAAP
Net Revenues	\$232.5 - \$236.6
Gross Margin	73.5% - 74.1%
Operating Expenses	\$130.9 - \$132.4
Operating Margin	17.2% - 18.2%
Net Income per Diluted Share	\$0.37 - \$0.40

Business Metrics:	Q1'16
Case Shipments	161.3K - 163.7K
Capital Expenditure	\$20M - \$25M
Depreciation & Amortization	\$5.0M - \$5.5M
Diluted Shares Outstanding	81.1M*
Stock Based Compensation Expense	\$13.5M
Tax Rate	25.0%

* Excludes any stock repurchases during the quarter

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