

# ALIGN TECHNOLOGY INC

## **FORM 8-K** (Current report filing)

Filed 01/30/18 for the Period Ending 01/30/18

Address	2560 ORCHARD PARKWAY SAN JOSE, CA, 95131
Telephone	4087381500
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, DC 20549

FORM 8-K

CURRENT REPORT PURSUANT  
TO SECTION 13 OR 15(D) OF THE  
SECURITIES EXCHANGE ACT OF 1934

Date of report (Date of earliest event reported) January 30, 2018

**ALIGN TECHNOLOGY, INC .**

(Exact Name of Registrant as Specified in Its Charter)

**Delaware**

(State or Other Jurisdiction of Incorporation)

**0-32259**

(Commission File Number)

**94-3267295**

(IRS Employer Identification No.)

**2820 Orchard Parkway, San Jose, California**

(Address of Principal Executive Offices)

**95134**

(Zip Code)

**2820 Orchard Parkway, San Jose, California95134**

(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 ( see General Instruction A.2. below):

- 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))
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**ITEM 2.02 RESULTS OF OPERATIONS AND FINANCIAL CONDITIONS**

On January 30, 2018, Align Technology, Inc. ("Align") is issuing a press release and holding a conference call regarding its financial results for its fourth quarter and year ended December 31, 2017. 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.

**ITEM 9.01 Financial Statements and Exhibits**

(d) Exhibits

<b>Exhibit No.</b>	<b>Description</b>
99.1	Press Release of Align Technology, Inc. announcing fourth quarter and year ended 2017 financial results dated January 30, 2018

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**SIGNATURES**

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

Dated: January 30, 2018

**ALIGN TECHNOLOGY , INC.**

By: /s/Roger E. George

Roger E. George

Vice President, Legal and Corporate Affairs and General Counsel

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**INDEX TO EXHIBITS**

**Exhibit No.**  
99.1

**Description**  
Press Release of Align Technology, Inc. announcing fourth quarter and year ended 2017 financial results dated January 30, 2018



Align Technology

Yin Cantor  
(408) 470-1044  
ycantor@aligntech.com

Ethos Communication:

Shannon Mangum Henderson  
(678) 261-7803  
align@ethoscommunication.com

**ALIGN TECHNOLOGY ANNOUNCES FOURTH QUARTER AND 2017 FINANCIAL RESULTS**

- Q4 revenues up 43.7% year-over-year to a record \$421.3 million, and diluted EPS of \$0.13, includes \$86.6 million tax expense, or \$1.06 per diluted share negative impact due to the new U.S. Tax Cut and Jobs Act
- Q4 operating income up 60.3% year-over-year to a record \$109.6 million or operating margin of 26.0%
- Q4 total Invisalign case shipments up 34.2% year-over-year to 255.0 thousand
- Q4 Invisalign cases for teenage patients up 44.1% year-over-year to 63.5 thousand
- Q4 scanner and services revenues up 37.0% year-over-year to \$57.1 million
- Record 2017 Invisalign revenues up 34.1% year-over-year to \$1.3 billion with Invisalign case shipments up 31.4% year-over-year to 931.0 thousand
- Record 2017 iTero scanner volume up 37.5%

SAN JOSE, Calif., January 30, 2018 -- Align Technology, Inc. (Nasdaq: ALGN) today reported financial results for the fourth quarter and year ended December 31, 2017. Invisalign case shipments in the fourth quarter of 2017 (Q4'17) were 255.0 thousand, up 34.2% year-over-year. North America and International case shipments were up year-over-year 24.2% and 52.3%, respectively. Q4'17 Invisalign cases for teenage patients were 63.5 thousand, up 44.1% year-over-year. Q4'17 revenues were \$421.3 million, up 43.7% year-over-year with Q4'17 operating income a record \$109.6 million, up 60.3% year-over-year resulting in an operating margin of 26.0%. Q4'17 net profit was \$10.3 million, or \$0.13 per diluted share, which includes an \$86.6 million tax expense, or \$1.06 per diluted share negative impact due to the new U.S. Tax Cut and Jobs Act, comprised of a \$10.0 million non-cash write-down of our deferred tax assets and a mandatory deemed repatriation tax of \$76.6 million.

For 2017, record Invisalign revenues were \$1.3 billion, up 34.1% year-over-year with Invisalign case shipments of 931.0 thousand, up 31.4% year-over-year. 2017 iTero revenues were \$164.2 million, up 35.1% with record volumes, up 37.5% year-over-year. 2017 Invisalign cases for teenage patients were 237.5 thousand, up 40.4% year-over-year. For 2017, revenues were \$1.5 billion, up 36.4% year-over-year and net profit was \$231.4 million, or \$2.83 per diluted share, which includes an \$86.6 million tax expense, or \$1.06 per diluted share negative impact due to the new U.S. Tax Cut and Jobs Act, comprised of a \$10.0 million non-cash write-down of our deferred tax assets and a mandatory deemed repatriation tax of \$76.6 million.

Align Technology, Inc. 2820 Orchard Pkwy, San Jose, CA 95134  
Tel: (408) 470-1000 Fax: (408) 470-1010  
[WWW.ALIGNTECH.COM](http://WWW.ALIGNTECH.COM)

Commenting on Align's Q4 and 2017 results, Align Technology President and CEO Joe Hogan said, "Overall, the fourth quarter was a strong finish to another outstanding year for Align, with better than expected revenues, volumes and operating income. Record Q4 revenues were up 43.7% year-over-year driven by increased Invisalign volumes across all geographies and customer channels, as well as by record iTero scanner revenue. Q4 Invisalign volume was up 34.2% year-over-year reflecting strong international growth from increased utilization and expansion of our customer base which included over 4,000 new customers for the third consecutive quarter. Notwithstanding this strong performance, our Q4 results were impacted by the new U.S. Tax Cut and Jobs Act which reduced our reported net income and EPS. However, Q4 operating income was a record \$109.6M or 26.0%."

Hogan continued, "For the full year, revenues of \$1.5 billion increased 36.4% year-over-year driven by both record Invisalign revenue which surpassed the \$1 billion mark for the first time ever and record iTero scanner revenues. These results reflect continued progress and execution of our four strategic growth drivers which focus on: driving international expansion; increasing Orthodontists utilization of Invisalign, especially with teenagers; enabling GP dentists to treat or refer more Invisalign cases; and generating consumer demand from millions of people worldwide and connecting them with an Invisalign doctor."

#### GAAP Summary Financial Comparisons Fourth Quarter Fiscal 2017

	Q4'17	Q3'17	Q4'16	Q/Q Change	Y/Y Change
Invisalign Case Shipments <sup>1</sup>	255.0K	236.1K	190.1K	+8.0%	+34.2%
Net Revenues	\$ 421.3M	\$ 385.3M	\$ 293.2M	+9.4%	+43.7%
Clear Aligner <sup>2</sup>	\$ 364.2M	\$ 341.6M	\$ 251.5M	+6.6%	+44.8%
Scanner & Services	\$ 57.1M	\$ 43.7M	\$ 41.7M	+30.8%	+37.0%
Net Profit <sup>3</sup>	\$ 10.3M	\$ 82.6M	\$ 47.6M	(87.6)%	(78.4)%
Diluted EPS <sup>3</sup>	\$ 0.13	\$ 1.01	\$ 0.59	(0.88)	(0.46)

#### Fiscal 2017

	2017	2016	Y/Y Change
Invisalign Case Shipments <sup>1</sup>	931,045	708,500	+31.4%
Net Revenues	\$ 1,473.4M	\$ 1,079.9M	+36.4%
Clear Aligner <sup>2</sup>	\$ 1,309.3M	\$ 958.3M	+36.6%
Scanner & Services	\$ 164.2M	\$ 121.5M	+35.1%
Net Profit <sup>3</sup>	\$ 231.4M	\$ 189.7M	+22.0%
Diluted EPS <sup>3</sup>	\$ 2.83	\$ 2.33	+\$0.50

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

<sup>1</sup> Invisalign Shipment figures do not include SmileDirectClub aligners

<sup>2</sup> Clear aligner revenue includes revenues from Invisalign clear aligners and SmileDirectClub aligners

<sup>3</sup> Q4'17 and 2017 net profit and diluted EPS includes \$86.6 million tax expense, or \$1.06 per diluted share negative impact due to the new U.S. Tax Cut and Jobs Act

As of December 31, 2017, Align had \$761.5 million in cash, cash equivalents and marketable securities compared to \$700.0 million as of December 31, 2016. We repurchased approximately 0.2 million shares of stock for \$50.0 million in Q4'17 under the April 2016 Repurchase Program. We have \$200.0 million remaining available for repurchases under the existing stock repurchase authorization.

### **2017 Business Highlights**

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

- Expanded restorative digital workflow solutions for iTero Element® scanner to include iTero Chairsides CAD, a chairside prosthetics design software application that will support same-day dentistry as part of collaboration with Exocad GmbH.
- Celebrated the 5 millionth Invisalign® patient, a 12-year old Canadian teenager starting Invisalign treatment with mandibular advancement.
- Signed distribution agreement with Glidewell Dental for the iTero Element® intraoral scanning system in North America with glidewell.io™ In-Office Solution, a chairside restorative ecosystem designed to simplify the process of prescribing and delivering laboratory-quality dental restorations.
- Opened the first Invisalign® store pilot in San Francisco to help consumers connect with an Invisalign® provider to improve their smile with Invisalign® treatment.
- Awarded nearly \$300,000 to researchers at universities in North America, Europe and Asia Pacific as part of the Company's Research Award Program to support clinical and scientific dental research.
- Signed distribution agreement Patterson Dental for iTero Element® intraoral scanning system in U.S. and Canada.
- Opened first Invisalign® Treatment Planning Facility in Chengdu, China.
- Launched TimeLapse technology for digital scan comparisons and ability to complete a scan in as little as 1 minute as part of a software upgrade for its iTero Element® intraoral scanners.
- Received U.S. Patents for SmartTrack material, an innovative multi-layer polymer that delivers more gentle, constant force to improve control of tooth movements with Invisalign® clear aligners.
- Celebrated the 1 millionth Invisalign® Teen patient, an 11 year-old boy from the U.S. starting Invisalign treatment.
- Launched first global, multi-million dollar Invisalign brand platform and marketing campaign.
- Achieved over 1 million scans submitted with iTero Element® scanner since its introduction in 2015.
- Introduced of Invisalign® Teen with mandibular advancement feature, the first clear aligner solution for Class II correction in growing tween and teen patients. (Not yet available in the U.S., pending FDA approval.)
- Expanded digital implant workflow options for the iTero® intraoral scanner with Nobel Biocare implants and ELOS Medtech scan bodies.



**Q1 2018 Business Outlook**

For the first quarter of 2018 (Q1'18), Align provides the following guidance:

- Net revenues in the range of \$400 million to \$410 million, up approximately 29% to 32% over the same period a year ago.
- Invisalign case shipments in the range of 264 thousand to 269 thousand, up approximately 27% to 29% over the same period a year ago.
- Operating margin in the range of 18.5% to 19.5%
- Diluted EPS in the range of \$0.94 to \$0.98.

**Align Web Cast and Conference Call**

Align will host a conference call today, January 30, 2018 at 4:30 p.m. ET, 1:30 p.m. PT, to review its fourth quarter and year ended 2017 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 13674959 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 13, 2018.

**About Align Technology, Inc.**

Align Technology designs and manufactures the Invisalign® system, the most advanced clear aligner system in the world, and iTero® intraoral scanners and services. Align's products help dental professionals achieve the clinical results they expect and deliver effective, cutting-edge dental options to their patients. Visit [www.aligntech.com](http://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](http://www.invisalign.com). For additional information about iTero digital scanning system, please visit [www.itero.com](http://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 2018 year end, 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, the security of customer and/or patient data is compromised for any reason, 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, 2016, which was filed with the Securities and Exchange Commission (SEC) on February 28, 2017, and its latest Quarterly Report on Form 10-Q for the quarter ended September 30, 2017, which was filed with the SEC on November 2, 2017. 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)

	<b>Three Months Ended December 31,</b>		<b>Year Ended December 31,</b>	
	<b>2017</b>	<b>2016</b>	<b>2017</b>	<b>2016</b>
Net revenues	\$ 421,323	\$ 293,203	\$ 1,473,413	\$ 1,079,874
Cost of net revenues	103,406	72,954	356,466	264,580
Gross profit	317,917	220,249	1,116,947	815,294
Operating expenses:				
Selling, general and administrative	182,141	130,268	665,777	490,653
Research and development	26,170	21,609	97,559	75,720
Total operating expenses	208,311	151,877	763,336	566,373
Income from operations	109,606	68,372	353,611	248,921
Interest and other income (expense), net	2,581	(7,516)	11,188	(6,355)
Net income before provision for income taxes and equity in losses (gains) of investee	112,187	60,856	364,799	242,566
Provision for income taxes	103,654	12,028	130,162	51,200
Equity in losses (gains) of investee, net of tax	(1,731)	1,207	3,219	1,684
Net income	\$ 10,264	\$ 47,621	\$ 231,418	\$ 189,682
Net income per share:				
Basic	\$ 0.13	\$ 0.60	\$ 2.89	\$ 2.38
Diluted	\$ 0.13	\$ 0.59	\$ 2.83	\$ 2.33
Shares used in computing net income per share:				
Basic	80,080	79,667	80,085	79,856
Diluted	81,863	81,248	81,832	81,484

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

<b>ASSETS</b>	<b>December 31, 2017</b>	<b>December 31, 2016</b>
Current assets:		
Cash and cash equivalents	\$ 449,511	\$ 389,275
Marketable securities, short-term	272,031	250,981
Accounts receivable, net	322,825	247,415
Inventories	31,688	27,131
Prepaid expenses and other current assets	80,948	38,176
Total current assets	1,157,003	952,978
Marketable securities, long-term	39,948	59,783
Property, plant and equipment, net	348,793	175,167
Equity method investments	54,606	45,061
Goodwill and intangible assets, net	89,068	81,998
Deferred tax assets	50,059	67,844
Other assets	38,379	13,320
Total assets	\$ 1,777,856	\$ 1,396,151
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 36,776	\$ 28,596
Accrued liabilities	194,198	134,332
Deferred revenues	266,842	191,407
Total current liabilities	497,816	354,335
Income tax payable	114,091	45,133
Other long-term liabilities	15,579	1,294
Total liabilities	627,486	400,762
Total stockholders' equity	1,150,370	995,389
Total liabilities and stockholders' equity	\$ 1,777,856	\$ 1,396,151

ALIGN TECHNOLOGY, INC.  
INVISALIGN BUSINESS METRICS\*

	Q4 2016	Fiscal 2016	Q1 2017	Q2 2017	Q3 2017	Q4 2017	Fiscal 2017
<b>Invisalign Average Selling Price (ASP):</b>							
Worldwide ASP	\$ 1,230	\$ 1,265	\$ 1,270	\$ 1,285	\$ 1,310	\$ 1,305	\$ 1,295
International ASP	\$ 1,315	\$ 1,335	\$ 1,325	\$ 1,335	\$ 1,390	\$ 1,390	\$ 1,360
<b>Invisalign Cases Shipped by Geography:</b>							
North America	122,555	463,810	132,885	146,510	144,870	152,245	576,510
International	67,500	244,690	75,175	85,380	91,195	102,785	354,535
Total Cases Shipped	190,055	708,500	208,060	231,890	236,065	255,030	931,045
YoY % growth	18.5%	21.5%	27.1%	31.0%	32.8%	34.2%	31.4%
QoQ % growth	6.9%		9.5%	11.5%	1.8%	8.0%	
<b>Number of Invisalign Doctors Cases Were Shipped To:</b>							
North America	23,265	34,065	23,910	24,695	24,845	25,365	36,415
International	13,635	20,415	14,955	16,570	17,760	19,620	27,990
Total Doctors Cases Shipped To	36,900	54,480	38,865	41,265	42,605	44,985	64,405
<b>Invisalign Doctor Utilization Rates*:</b>							
North America	5.3	13.6	5.6	5.9	5.8	6.0	15.8
North American Orthodontists	11.3	36.6	12.6	13.6	13.8	14.0	46.6
North American GP Dentists	3.2	7.6	3.1	3.3	3.1	3.3	8.2
International	5.0	12.0	5.0	5.2	5.1	5.2	12.7
Total Utilization Rates	5.2	13.0	5.4	5.6	5.5	5.7	14.5
*# of cases shipped/# of doctors to whom cases were shipped							
<b>Number of Invisalign Doctors Trained:</b>							
North America	1,420	4,720	980	1,620	1,460	1,340	5,400
International	2,280	6,960	2,280	3,255	2,820	2,745	11,100
Total Doctors Trained Worldwide	3,700	11,680	3,260	4,875	4,280	4,085	16,500
Total to Date Worldwide	115,470	115,470	118,730	123,605	127,885	131,970	131,970

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

\*Invisalign business metrics exclude SmileDirectClub aligners.

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

	Q4 2016	Fiscal 2016	Q1 2017	Q2 2017	Q3 2017	Q4 2017	Fiscal 2017
<b>Stock-based Compensation (SBC)</b>							
SBC included in Gross Profit	\$ 1,078	\$ 3,966	\$ 925	\$ 768	\$ 833	\$ 804	\$ 3,330
SBC included in Operating Expenses	13,136	50,182	13,887	13,477	14,134	14,026	55,524
Total SBC Expense	\$ 14,214	\$ 54,148	\$ 14,812	\$ 14,245	\$ 14,967	\$ 14,830	\$ 58,854

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)

	Q1'18 Guidance	
	GAAP	
<b>Net Revenues</b>	\$400.0 - \$410.0	
<b>Gross Margin</b>	74.3% - 75.0%	
<b>Operating Expenses</b>	\$223.5 - \$227.5	
<b>Operating Margin</b>	18.5% - 19.5%	
<b>Net Income per Diluted Share</b>	\$0.94 - \$0.98	(1)

**Business Metrics:**

	Q1'18	
Case Shipments	264.0K - 269.0K	
Capital Expenditure	\$65M - \$70M	
Depreciation & Amortization	\$10.5M - \$11M	
Diluted Shares Outstanding	82.0M	(2)
Stock Based Compensation Expense	\$16.2M	
Effective Tax Rate	2.0%	(1)

(1) Includes the benefit from the adoption of the accounting standard update 2016-09 related to share-based compensation expense

(2) Excludes any stock repurchases during the quarter