

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 29, 2019

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)

(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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter)

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.

ITEM 2.02 RESULTS OF OPERATIONS AND FINANCIAL CONDITIONS

On January 29, 2019, 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, 2018. 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

Exhibit No.	Description
<u>99.1</u>	<u>Press Release of Align Technology, Inc. announcing its fourth quarter and year ended December 31, 2018 financial results</u>

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 29, 2019

ALIGN TECHNOLOGY, INC.

By: /s/Roger E. George
Roger E. George
Sr. Vice President, Chief Legal and Regulatory Officer

INDEX TO EXHIBITS

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<u>99.1</u>	<u>Press Release of Align Technology, Inc. announcing fourth quarter and year ended December 31, 2018 financial results</u>



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ALIGN TECHNOLOGY ANNOUNCES RECORD 2018 FINANCIAL RESULTS

- 2018 revenues up 33.5% to a record \$2.0 billion
- 2018 Invisalign volume of 1.2 million cases up 31.9% and iTero scanner volume up 77.2%
- 2018 operating margin of 23.7% and diluted EPS of \$4.92
- 2018 Invisalign volume in Americas and International regions up 24.2% and 45.0%, respectively
- Q4 total revenues up 26.7% year-over-year to a record \$534.0 million, and diluted EPS of \$1.20
- Q4 Invisalign volume up 30.9% year-over-year to 333.8 thousand cases
- Q4 scanner and services revenues up 54.8% year-over-year to \$88.4 million
- Q4 operating income up 9.9% year-over-year to \$120.5 million or operating margin of 22.6%

SAN JOSE, Calif., January 29, 2019 -- Align Technology, Inc. (Nasdaq: ALGN) today reported financial results for the fourth quarter (Q4'18) and year ended December 31, 2018 (FY 2018). Q4'18 Invisalign volume was 333.8 thousand cases, up 30.9% year-over-year. For the Americas and International regions, Q4'18 Invisalign volume was up 21.7% and 45.3% year-over-year, respectively. Q4'18 Invisalign volume for teenage patients was 87.1 thousand cases, up 37.3% year-over-year. Q4'18 total revenues were \$534.0 million, up 26.7% year-over-year, and Q4'18 scanner and services revenues were \$88.4 million, up 54.8% year-over-year. Q4'18 operating income of \$120.5 million was up 9.9% year-over-year resulting in an operating margin of 22.6%. Q4'18 net profit was \$97.4 million, or \$1.20 per diluted share.

For 2018, record Invisalign revenues were \$1.7 billion, up 29.4% year-over-year with Invisalign case shipments of 1.2 million, up 31.9% year-over-year. 2018 iTero revenues were \$275.0 million, up 67.5% year-over-year with record volume, up 77.2% year-over-year. 2018 Invisalign cases for teenage patients were 333.1 thousand, up 40.3% year-over-year. For 2018, total revenues were \$2.0 billion, up 33.5% year-over-year, and net profit was \$400.2 million, or \$4.92 per diluted share.

Commenting on Align's Q4 and 2018 results, Align Technology President and CEO Joe Hogan said, "Our fourth quarter was a strong finish to a great year. Q4 revenues were better than expected reflecting higher Invisalign ASPs and volume growth of 31% year-over-year, as well as another record quarter for our iTero scanners with revenue up 55% year-over-year. Q4 sequential growth was driven by a strong quarter for EMEA with record growth from teens, as well as continued traction with Invisalign Lite and Invisalign Go. Q4 operating margin of 22.6% reflects higher doctor training and manufacturing costs, as well as higher legal fees than anticipated, partially offset by a sequential improvement in Invisalign ASPs."

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Hogan continued, “We achieved record revenues of nearly \$2.0 billion for the year and had over 1.2 million people start treatment with Invisalign clear aligners the first time, resulting in our 6th millionth Invisalign patient – a teenager from China. These results reflect record revenues and volumes for both Invisalign and iTero across customer channels and country markets, and continued strength from teens, which grew 40.3%. The total number of teenagers treated with Invisalign this year was over 333 thousand representing 27.1% of our volume. Finally, in 2018, we trained a record number of new Invisalign doctors – nearly 20 thousand worldwide – and more than half of them were international doctors.”

GAAP Summary Financial Comparisons

Fourth Quarter Fiscal 2018

	Q4'18	Q3'18	Q4'17	Q/Q Change	Y/Y Change
Invisalign Case Shipments ¹	333,800	319,345	255,030	+4.5%	+30.9%
Net Revenues	\$534.0M	\$505.3M	\$421.3M	+5.7%	+26.7%
Clear Aligner ²	\$445.6M	\$427.1M	\$364.2M	+4.3%	+22.4%
Scanner & Services	\$88.4M	\$78.2M	\$57.1M	+13.0%	+54.8%
Net Profit	\$97.4M	\$100.9M	\$10.3M	(3.4)%	+848.9%
Diluted EPS ³	\$1.20	\$1.24	\$0.13	\$(0.04)	\$1.07

Fiscal 2018

	2018	2017	Y/Y Change
Invisalign Case Shipments ¹	1,228,065	931,045	+31.9%
Net Revenues	\$1,966.5M	\$1,473.4M	+33.5%
Clear Aligner ²	\$1,691.5M	\$1,309.3M	+29.2%
Scanner & Services	\$275.0M	\$164.2M	+67.5%
Net Profit	\$400.2M	\$231.4M	+72.9%
Diluted EPS ³	\$4.92	\$2.83	+\$2.09

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

¹ Invisalign shipment figures do not include SmileDirectClub aligners

² Clear aligner revenue includes revenues from Invisalign clear aligners and SmileDirectClub aligners

³ Q4'17 includes deemed repatriation tax impact of \$1.06

As of December 31, 2018, Align had \$744.5 million in cash, cash equivalents and marketable securities compared to \$761.5 million as of December 31, 2017. During Q4'18, we repurchased \$50.0 million of our stock against our stock buy-back authorizations and have \$500.0 million still available for repurchase under the May 2018 Repurchase Program.

2018 Business Highlights

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

Invisalign and iTero Intraoral Scanner

- Launched Invisalign treatment with mandibular advancement in the U.S. for teen Class II treatment following FDA approval.
- Introduced Invisalign First clear aligners worldwide for treatment of growing children.

- Expanded the Invisalign product portfolio with new options and greater flexibility for a broader range of patients.
- Launched the new Invisalign Go product with a more user-friendly iTero chair side experience.
- Announced multiple industry awards for iTero Element 2 and iTero Element Flex scanners, including *2018 DrBicuspid.com Dental Excellence Award* and *2018 GOOD DESIGN® Award*.
- Entered into multi-year agreements with both Aspen Dental and Heartland Dental for iTero Element scanners in their U.S. locations.
- Expanded the iTero Element portfolio with the launch of the iTero Element 2 and the iTero Element Flex scanners, along with new functionality connectivity to exocad and Dextrix.
- Began marketing the iTero Element intraoral scanner in China.
- Announced the commercial availability of Vivera Retainers with Precision Bite Ramps, the first retainers in the market that can be customized to provide additional support after deep bite correction.

Invisalign Experience Program

- Expanded the interactive brand experience program that was piloted in late 2017, and added eight new stores in major U.S. cities in the fourth quarter of 2018 to end the year with twelve stores in the U.S.
- Announced the Invisalign Experience Branded Practice Pilot (doctor owned pilot). In late 2018, Align partnered with a few Invisalign doctors in select U.S. cities to pilot Invisalign Experience branded practices to test new ways to reach consumers and connect them directly with doctors to start Invisalign treatment.

Patient Milestones

- Reached 6th millionth Invisalign patient milestone with a teenage patient from China.
- Announced the one millionth Invisalign case for the Europe, Middle East and Africa (EMEA) region.

International Expansion

- Opened the first Invisalign treatment planning facility in Europe, located in Cologne, Germany.
- Launched a new digital treatment planning facility and education center in Madrid, Spain.

Research and Awards

- Announced eleven recipients of research grants under Align's 2018 Research Award Program, and opened the 2019 Research Award Program to support clinical and scientific dental research in universities across the globe.
- Launched the Orthodontic Aligner Fellowship Certificate Program, in collaboration with DentalXP, a global dental education provider on August 6, 2018.

Corporate

- Announced entering into an accelerated stock repurchase agreement to repurchase \$50.0 million of Align's common stock as part of Align's \$600.0 million stock repurchase program announced on May 23, 2018.
- Announced that on August 22, 2018, the United States Court of Appeals for the Federal Circuit vacated the Patent Trial and Appeal Board's decision invalidating certain claims of Align's patent no. 6,699,037, entitled "Method and System for Incrementally Moving Teeth."

Q1 2019 Business Outlook

For the first quarter of 2019 (Q1'19), Align provides the following guidance:

- Net revenues in the range of \$525.0 million to \$535.0 million, up approximately 20% to 22% over the same period a year ago.
- Invisalign case shipments in the range of 340 thousand to 345 thousand, up approximately 25% to 27% over the same period a year ago.
- Operating margin in the range of 15.1% to 16.1%.
- Diluted EPS in the range of \$0.78 to \$0.84.

Align Web Cast and Conference Call

Align will host a conference call today, January 29, 2019 at 4:30 p.m. ET, 1:30 p.m. PT, to review its fourth quarter and year ended 2018 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 13685779 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 12, 2019.

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 for more information.

For additional information about the Invisalign system or to find an Invisalign doctor in your area, please visit www.invisalign.com. For additional information about iTero 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 2019, 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 excess or constrained capacity at our manufacturing and treat operations facilities 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 as well as an increased manufacturing costs per case, 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, 2017, which was filed with the Securities and Exchange Commission (SEC) on February 28, 2018, and its latest Quarterly Report on Form 10-Q for the quarter ended September 30, 2018, which was filed with the SEC on November 1, 2018. 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 December 31,		Year Ended December 31,	
	2018	2017	2018	2017
Net revenues	\$ 534,020	\$ 421,323	\$ 1,966,492	\$ 1,473,413
Cost of net revenues	150,924	103,406	518,625	356,466
Gross profit	383,096	317,917	1,447,867	1,116,947
Operating expenses:				
Selling, general and administrative	226,819	182,141	852,404	665,777
Research and development	35,804	26,170	128,899	97,559
Total operating expenses	262,623	208,311	981,303	763,336
Income from operations	120,473	109,606	466,564	353,611
Interest income	2,249	2,486	8,576	6,948
Other income (expense), net	(730)	95	(8,489)	4,240
Net income before provision for income taxes and equity in losses of investee	121,992	112,187	466,651	364,799
Provision for income taxes**	22,517	103,654	57,723	130,162
Equity in losses (gains) of investee, net of tax	2,083	(1,731)	8,693	3,219
Net income	\$ 97,392	\$ 10,264	\$ 400,235	\$ 231,418
Net income per share:				
Basic	\$ 1.22	\$ 0.13	\$ 5.00	\$ 2.89
Diluted	\$ 1.20	\$ 0.13	\$ 4.92	\$ 2.83
Shares used in computing net income per share:				
Basic	79,891	80,080	80,064	80,085
Diluted	80,943	81,863	81,357	81,832

* During Q1'18, we adopted the ASC 606, "Revenues from Contracts with Customers" using the full retrospective method. The adoption of ASC 606 did not have a material impact on our Condensed Consolidated Statements of Operations presented herein.

** During Q4'17, the U.S. Tax Cuts and Jobs Act was enacted into law and we recorded the tax impacts in our provision for income taxes.

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

	December 31, 2018	December 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 636,899	\$ 449,511
Marketable securities, short-term	98,460	272,031
Accounts receivable, net	439,009	324,189
Inventories	55,641	31,688
Prepaid expenses and other current assets	72,470	80,948
Total current assets	<u>1,302,479</u>	<u>1,158,367</u>
Marketable securities, long-term	9,112	39,948
Property, plant and equipment, net	521,329	348,793
Equity method investments	45,913	54,606
Goodwill and intangible assets, net	81,949	89,068
Deferred tax assets	64,689	49,334
Other assets	26,987	43,893
Total assets	<u>\$ 2,052,458</u>	<u>\$ 1,784,009</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 64,256	\$ 36,776
Accrued liabilities	234,679	195,562
Deferred revenues	393,138	267,713
Total current liabilities	<u>692,073</u>	<u>500,051</u>
Income tax payable	78,008	114,091
Other long-term liabilities	29,486	15,579
Total liabilities	<u>799,567</u>	<u>629,721</u>
Total stockholders' equity	<u>1,252,891</u>	<u>1,154,288</u>
Total liabilities and stockholders' equity	<u>\$ 2,052,458</u>	<u>\$ 1,784,009</u>

* During Q1'18, we adopted the ASC 606, "Revenues from Contracts with Customers" using the full retrospective method. Condensed Consolidated Balance Sheet as of December 31, 2017 has been recasted to comply with the adoption.

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

	Year Ended December 31,	
	2018	2017
CASH FLOWS FROM OPERATING ACTIVITIES		
Net cash provided by operating activities	\$ 554,681	\$ 438,539
CASH FLOWS FROM INVESTING ACTIVITIES		
Net cash provided by (used in) investing activities	6,927	(251,477)
CASH FLOWS FROM FINANCING ACTIVITIES		
Net cash used in financing activities	(369,434)	(135,500)
Effect of foreign exchange rate changes on cash, cash equivalents, and restricted cash	(4,733)	5,544
Net decrease in cash, cash equivalents, and restricted cash	187,441	57,106
Cash, cash equivalents, and restricted cash at beginning of the period	450,125	393,019
Cash, cash equivalents, and restricted cash at end of the period	<u>\$ 637,566</u>	<u>\$ 450,125</u>

*During Q1'18, we adopted ASU 2016-18, "Statement of Cash Flows - Restricted Cash" on a retrospective basis. Condensed Consolidated Statement of Cash Flows for the year ended December 31, 2017 has been recasted to comply with the adoption.

ALIGN TECHNOLOGY, INC.
INVISALIGN BUSINESS METRICS*

	Q4 2017	Fiscal 2017	Q1 2018	Q2 2018	Q3 2018	Q4 2018	Fiscal 2018
Invisalign Average Selling Price (ASP):							
Worldwide ASP	\$ 1,305	\$ 1,295	\$ 1,310	\$ 1,315	\$ 1,230	\$ 1,235	\$ 1,270
International ASP	\$ 1,400	\$ 1,375	\$ 1,435	\$ 1,425	\$ 1,340	\$ 1,295	\$ 1,370
Invisalign Cases Shipped by Geography:							
Americas	155,625	586,205	166,665	181,425	190,615	189,410	728,115
International	99,405	344,840	105,570	121,260	128,730	144,390	499,950
Total Cases Shipped	255,030	931,045	272,235	302,685	319,345	333,800	1,228,065
YoY % growth	34.2%	31.4%	30.8%	30.5%	35.3%	30.9%	31.9%
QoQ % growth	8.0%		6.7%	11.2%	5.5%	4.5%	
Number of Invisalign Doctors Cases Were Shipped To:							
Americas	26,480	38,230	27,105	28,280	28,890	29,215	38,640
International	18,505	26,175	19,700	21,805	23,270	25,475	31,300
Total Doctors Cases Shipped To	44,985	64,405	46,805	50,085	52,160	54,690	69,940
Invisalign Doctor Utilization Rates**:							
North America	6.0	15.8	6.3	6.6	6.9	6.7	19.6
North American Orthodontists	14.0	46.6	15.3	16.4	17.4	16.5	58.4
North American GP Dentists	3.3	8.2	3.4	3.6	3.5	3.6	9.9
International	5.4	13.2	5.4	5.6	5.5	5.7	16.0
Total Utilization Rates	5.7	14.5	5.8	6.0	6.1	6.1	17.6
Number of Invisalign Doctors Trained***:							
Americas	1,760	6,615	1,630	1,880	2,085	2,290	7,885
International	2,400	10,215	2,645	3,300	2,845	2,980	11,770
Total Doctors Trained Worldwide	4,160	16,830	4,275	5,180	4,930	5,270	19,655
Total to Date Worldwide	132,300	132,300	136,575	141,755	146,685	151,955	151,955

Note: Historical public data may differ due to rounding. Additionally, rounding may effect totals. Effective Q1'18, Americas region includes North America and LATAM. International region includes EMEA and APAC. We have recasted historical data to reflect the change.

* Invisalign business metrics exclude SmileDirectClub aligners.

** # of cases shipped / # of doctors to whom cases were shipped. LATAM utilization rate is not separately disclosed, but included in the total utilization rates.

***2018 and 2017 adjusted to reflect Americas doctors trained for Invisalign iGo

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

	Q4 2017	Fiscal 2017	Q1 2018	Q2 2018	Q3 2018	Q4 2018	Fiscal 2018
Stock-based Compensation (SBC)							
SBC included in Gross Profit	\$ 804	\$ 3,330	\$ 881	\$ 900	\$ 966	\$ 948	\$ 3,695
SBC included in Operating Expenses	14,026	55,524	14,949	15,990	18,232	17,897	67,068
Total SBC Expense	\$ 14,830	\$ 58,854	\$ 15,830	\$ 16,890	\$ 19,198	\$ 18,845	\$ 70,763

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)

	<u>Q1'19 Guidance</u>
	<u>GAAP</u>
Net Revenues	\$525.0 - \$535.0
Gross Margin	70.3% - 71.0%
Operating Expenses	\$289.8 - \$293.8
Operating Margin	15.1% - 16.1%
Net Income per Diluted Share	\$0.78 - \$0.84

Business Metrics:

	<u>Q1'19</u>
Case Shipments	340.0K - 345.0K
Capital Expenditure	\$19M - \$20M
Depreciation & Amortization	\$60M - \$65M
Diluted Shares Outstanding	80.9M (2)
Stock Based Compensation Expense	\$19.9M
Effective Tax Rate	~16% (1)

(1) Includes excess tax benefits related to share-based compensation expense pursuant to ASU 2016-09

(2) Excludes any stock repurchases during the quarter