

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) October 24, 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)

(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 October 24, 2018, Align Technology, Inc. ("Align") is issuing a press release and holding a conference call regarding its financial results for its third quarter ended September 30, 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 third quarter ended September 30, 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: October 24, 2018

ALIGN TECHNOLOGY, INC.

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

INDEX TO EXHIBITS

Exhibit No.

Description

[99.1](#) [Press Release of Align Technology, Inc. announcing third quarter ended September 30, 2018 financial results](#)



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ALIGN TECHNOLOGY ANNOUNCES THIRD QUARTER 2018 FINANCIAL RESULTS

- Q3 revenues up 31.2% year-over-year to a record \$505.3 million, and diluted EPS of \$1.24
- Q3 operating income up 26.8% year-over-year to \$125.2 million, operating margin of 24.8%
- Q3 total Invisalign case shipments up 35.3% year-over-year to 319.3 thousand
- Q3 Invisalign cases for teenage patients up 41.1% year-over-year to 98.5 thousand
- Q3 iTero scanner and services revenues up 79.1% year-over-year to \$78.2 million

SAN JOSE, Calif., October 24, 2018 -- Align Technology, Inc. (Nasdaq: ALGN) today reported financial results for the third quarter ended September 30, 2018. Invisalign case shipments in the third quarter of 2018 (Q3'18) were 319.3 thousand, up 35.3% year-over-year. Americas and International region case shipments were up year-over-year 29.1% and 45.6%, respectively. Q3'18 Invisalign cases for teenage patients were 98.5 thousand, up 41.1% year-over-year. Q3'18 revenues were \$505.3 million, up 31.2% year-over-year and Q3'18 operating income was \$125.2 million, up 26.8% year-over-year resulting in an operating margin of 24.8%. Net profit was \$100.9 million, or \$1.24 per diluted share, up \$0.23 year-over-year.

Commenting on Align's Q3 2018 results, Align Technology President and CEO Joe Hogan said, "I'm pleased to report third quarter results with revenue and earnings above our outlook driven by higher than expected Invisalign volume -- offset somewhat by lower ASPs and foreign exchange. We also had another record quarter for the iTero scanner business with revenues up 79.1% year-over-year. Q3 Invisalign volume increased 5.5% sequentially and up 35.3% year-over-year reflecting strength across regions and customer channels, as well as strong growth from both teen and adult patients. From a product perspective, we saw strength across the Invisalign portfolio with growth from both comprehensive and non-comprehensive products, reflecting an acceleration in the non-comprehensive category related to expansion of our product portfolio, as well as new sales programs and promotions intended to increase adoption and utilization. We also saw continued strength from international regions, especially Asia Pacific, which was our 2nd largest region after the Americas in Q3."

GAAP Summary Financial Comparisons Third Quarter Fiscal 2018

	Q3'18	Q2'18	Q3'17	Q/Q Change	Y/Y Change
Invisalign Case Shipments ¹	319,345	302,685	236,065	+5.5%	+35.3%
Net Revenues	\$505.3M	\$490.3M	\$385.3M	+3.1%	+31.2%
Clear Aligner ²	\$427.1M	\$433.2M	\$341.6M	(1.4)%	+25.0%
Scanner & Services	\$78.2M	\$57.0M	\$43.7M	+37.2%	+79.1%
Net Profit	\$100.9M	\$106.1M	\$82.6M	(4.9)%	+22.2%
Diluted EPS	\$1.24	\$1.30	\$1.01	\$(0.06)	+\$0.23

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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*

As of September 30, 2018, Align had \$613.2 million in cash, cash equivalents and marketable securities compared to \$720.7 million as of June 30, 2018. During Q3'18, we repurchased \$150.0 million of our stock against our stock buy-back authorizations and have \$550.0 million still available for repurchase under the May 2018 Repurchase Program.

Announcements and Highlights

During the third quarter Align announced the following:

- Expanded the interactive brand experience program that was piloted in late 2017, and will add eight new locations in major U.S. cities in the fourth quarter of 2018. The program expansion is designed to address the rapidly-evolving consumer market for clear aligners and connects consumers interested in Invisalign treatment with Invisalign doctors in their communities.
- The first four Invisalign Experience locations in California, Pennsylvania and Maryland have shown great progress since opening and have contributed to a significant influx of consumer interest in the orthodontic marketplace surrounding each location. Key performance metrics to date suggest that the addition of an Invisalign Experience location can have a significant positive impact or “halo effect” on overall Invisalign patient growth in the surrounding area, even among doctors that are not directly participating in the Invisalign Experience pilot program.
- Announced the Invisalign Experience Branded Practice Pilot (doctor owned pilot). In Q4, Align will also partner with a few Invisalign doctors in select U.S. cities who will pilot Invisalign Experience branded practices to test new ways to reach consumers and connect them directly with doctors to start Invisalign treatment. This pilot is intended to help doctors integrate consumer-friendly design and consultation workflow into their practices and test new Invisalign Experience branding and a consumer-focused approach to consultations and Invisalign treatment starts. It includes an initial digital scan and smile visualization with a scanner, and immediate appointments for walk-ins.
- Launched the new digital treatment planning facility and education center in Madrid, Spain. The new launch reflects the dynamic growth of Spain and Portugal (jointly known as Iberia) in the Europe, Middle East and Africa (EMEA) region and beyond. The second of its kind in Europe and the fourth worldwide, the treatment planning facility in Madrid aims to increase our commitment to Invisalign trained doctors in Spain and Portugal, and will play a key role in Align trained doctors in Spain and Portugal, and will play a key role in Align Technology’s strategy to be closer to its customers and support them in digital treatment planning. The new facility, which also acts as an education center for doctors, brings together current commercial teams representing Iberia and the new treatment planning team to provide Spanish and Portuguese doctors with first-hand support from the local staff.

- Announced that on August 22, 2018, the United States Court of Appeals for the Federal Circuit (“Federal Circuit”) vacated the Patent Trial and Appeal Board’s (“PTAB”) decision invalidating certain claims of Align’s patent no. 6,699,037, entitled “Method and System for Incrementally Moving Teeth” (the ‘037 Patent). Although Align is not currently asserting this patent in any litigation against ClearCorrect, ClearCorrect challenged the validity of the patent in an *inter partes* review procedure and the resulting PTAB decision had invalidated four of the patent’s claims as obvious. The Federal Circuit disagreed and set aside the obviousness determination because “[n]either the Board’s decision nor ClearCorrect’s brief on appeal reveals substantial evidence in support of those findings.” The Federal Circuit remanded the matter to the PTAB for further proceedings consistent with its opinion.
- Shared the results of a new study by *RealSelf*, recognizing Invisalign clear aligners as the most popular non-surgical cosmetic treatment brides and grooms are choosing and reviewing on its website before their big day. The study analyzed reviews on the *RealSelf* website over the past year that mention wedding-related keywords and rank the treatments based on percentage of total reviews.
- Launched its Orthodontic Aligner Fellowship Certificate Program, in collaboration with DentalXP, a global dental education provider on August 6, 2018. The training program will provide general practitioner dentists with professional education to help integrate Invisalign clear aligner therapy and iTero intraoral scanning more seamlessly into their comprehensive patient care.
- Expanded operations in Costa Rica with new facilities to support continued long-term growth. The grand opening of our newest facilities in Costa Rica on July 20 was attended by Carlos Alvarado Quesada, President of Costa Rica, as well as local government officials. Align invested approximately \$50.0 million in two new multi-story office buildings, located at San Antonio Business Center (Belén, Heredia), with plans to open another multimillion dollar facility located in La Lima (Cartago) later this year. The new facilities will eventually house all of Align’s Costa Rica employees and provide space to accommodate our long-term growth.

Q4 2018 Business Outlook

For the fourth quarter of 2018 (Q4'18), Align provides the following guidance:

- Net revenues in the range of \$505 million to \$515 million, up approximately 20% to 22% over the same period a year ago
- Invisalign case shipments in the range of 330 thousand to 335 thousand, up approximately 29% to 31% over the same period a year ago
- Operating margin in the range of 23.2% to 23.9%
- Diluted EPS in the range of \$1.10 to \$1.15

Align Web Cast and Conference Call

Align will host a conference call today, October 24, 2018 at 4:30 p.m. ET, 1:30 p.m. PT, to review its third quarter 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 13683414 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 November 7, 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 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 fourth quarter of 2018, including, but not limited to, anticipated net revenues, gross margin, operating expenses, operating profit, diluted earnings per share, tax rate including the financial impact of recent U.S. Tax Cuts and Jobs Act 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, risks relating to international sales, which are increasingly a larger portion of our total revenues, 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, changes to our interpretation of the U.S. Tax Cuts and Jobs Act which may change as we receive additional clarification and implementation guidance, possibly materially, foreign operational, political and other risks relating to Align's international manufacturing operations, litigation risks, uncertainties involved in any contract dispute resolution and the possibility of Align choosing to settle the litigation for business or other reasons. 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. 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 September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Net revenues	\$ 505,289	\$ 385,267	\$ 1,432,472	\$ 1,052,090
Cost of net revenues	133,508	92,779	367,701	253,060
Gross profit	371,781	292,488	1,064,771	799,030
Operating expenses:				
Selling, general and administrative	213,873	169,524	625,585	483,636
Research and development	32,700	24,201	93,095	71,389
Total operating expenses	246,573	193,725	718,680	555,025
Income from operations	125,208	98,763	346,091	244,005
Interest income	2,234	1,826	6,327	4,462
Other income (expense), net	(837)	1,924	(7,759)	4,145
Net income before provision for income taxes and equity in losses of investee	126,605	102,513	344,659	252,612
Provision for income taxes	24,601	18,344	35,206	26,508
Equity in losses of investee, net of tax	1,132	1,614	6,610	4,950
Net income	\$ 100,872	\$ 82,555	\$ 302,843	\$ 221,154
Net income per share:				
Basic	\$ 1.26	\$ 1.03	\$ 3.78	\$ 2.76
Diluted	\$ 1.24	\$ 1.01	\$ 3.71	\$ 2.71
Shares used in computing net income per share:				
Basic	80,111	80,163	80,122	80,086
Diluted	81,359	81,789	81,538	81,757

* 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.

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

	September 30, 2018	December 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 420,860	\$ 449,511
Marketable securities, short-term	184,297	272,031
Accounts receivable, net	420,276	324,189
Inventories	48,858	31,688
Prepaid expenses and other current assets	149,891	80,948
Total current assets	<u>1,224,182</u>	<u>1,158,367</u>
Marketable securities, long-term	8,091	39,948
Property, plant and equipment, net	491,630	348,793
Equity method investments	47,996	54,606
Goodwill and intangible assets, net	83,607	89,068
Deferred tax assets	47,435	49,334
Other assets	25,464	43,893
Total assets	<u>\$ 1,928,405</u>	<u>\$ 1,784,009</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 43,065	\$ 36,776
Accrued liabilities	219,035	195,562
Deferred revenues	356,109	267,713
Total current liabilities	<u>618,209</u>	<u>500,051</u>
Income tax payable	95,655	114,091
Other long-term liabilities	21,558	15,579
Total liabilities	<u>735,422</u>	<u>629,721</u>
Total stockholders' equity	<u>1,192,983</u>	<u>1,154,288</u>
Total liabilities and stockholders' equity	<u>\$ 1,928,405</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)

	Nine Months Ended	
	September 30,	
	2018	2017
CASH FLOWS FROM OPERATING ACTIVITIES		
Net income	\$ 302,843	\$ 221,154
Net cash provided by operating activities	<u>313,386</u>	<u>276,213</u>
CASH FLOWS FROM INVESTING ACTIVITIES		
Net cash used in investing activities	<u>(24,021)</u>	<u>(231,784)</u>
CASH FLOWS FROM FINANCING ACTIVITIES		
Net cash used in financing activities	<u>(315,151)</u>	<u>(79,036)</u>
Effect of foreign exchange rate changes on cash, cash equivalents, and restricted cash	(2,890)	4,806
Net decrease in cash, cash equivalents, and restricted cash	<u>(28,676)</u>	<u>(29,801)</u>
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>\$ 421,449</u>	<u>\$ 363,218</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 nine months ended September 30, 2017 has been recasted to comply with the adoption.

ALIGN TECHNOLOGY, INC.
INVISALIGN BUSINESS METRICS*

	Q1 2017	Q2 2017	Q3 2017	Q4 2017	Fiscal 2017	Q1 2018	Q2 2018	Q3 2018
Invisalign Average Selling Price (ASP):								
Worldwide ASP	\$ 1,270	\$ 1,285	\$ 1,310	\$ 1,305	\$ 1,295	\$ 1,310	\$ 1,315	\$ 1,230
International ASP	\$ 1,345	\$ 1,340	\$ 1,395	\$ 1,400	\$ 1,375	\$ 1,435	\$ 1,425	\$ 1,340
Invisalign Cases Shipped by Geography:								
Americas	134,450	148,470	147,660	155,625	586,205	166,665	181,425	190,615
International	73,610	83,420	88,405	99,405	344,840	105,570	121,260	128,730
Total Cases Shipped	208,060	231,890	236,065	255,030	931,045	272,235	302,685	319,345
YoY% growth	27.1%	31.0%	32.8%	34.2%	31.4%	30.8%	30.5%	35.3%
QoQ% growth	9.5%	11.5%	1.8%	8.0%		6.7%	11.2%	5.5%
Number of Invisalign Doctors Cases Were Shipped To:								
Americas	24,595	25,570	25,865	26,480	38,230	27,105	28,280	28,890
International	14,270	15,695	16,740	18,505	26,175	19,700	21,805	23,270
Total Doctors Cases Shipped To	38,865	41,265	42,605	44,985	64,405	46,805	50,085	52,160
Invisalign Doctor Utilization Rates**:								
North America	5.6	5.9	5.8	6.0	15.8	6.3	6.6	6.9
North American Orthodontists	12.6	13.6	13.8	14.0	46.6	15.3	16.4	17.4
North American GP Dentists	3.1	3.3	3.1	3.3	8.2	3.4	3.6	3.5
International	5.2	5.3	5.3	5.4	13.2	5.4	5.6	5.5
Total Utilization Rates	5.4	5.6	5.5	5.7	14.5	5.8	6.0	6.1
Number of Invisalign Doctors Trained***:								
Americas	1,050	1,825	1,980	1,760	6,615	1,630	1,880	2,085
International	2,220	3,055	2,540	2,400	10,215	2,645	3,300	2,845
Total Doctors Trained Worldwide	3,270	4,880	4,520	4,160	16,830	4,275	5,180	4,930
Total to Date Worldwide	118,740	123,620	128,140	132,300	132,300	136,575	141,755	146,685

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)

	Q1 2017	Q2 2017	Q3 2017	Q4 2017	Fiscal 2017	Q1 2018	Q2 2018	Q3 2018
Stock-based Compensation (SBC)								
SBC included in Gross Profit	\$ 925	\$ 768	\$ 833	\$ 804	\$ 3,330	\$ 881	\$ 900	\$ 966
SBC included in Operating Expenses	13,887	13,477	14,134	14,026	55,524	14,949	15,990	18,232
Total SBC Expense	\$ 14,812	\$ 14,245	\$ 14,967	\$ 14,830	\$ 58,854	\$ 15,830	\$ 16,890	\$ 19,198

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)

	Q4'18 Guidance	
	GAAP	
Net Revenues	\$505.0 - \$515.0	
Gross Margin	72.3% - 73.0%	
Operating Expenses	\$248.0 - \$253.0	
Operating Margin	23.2% - 23.9%	
Net Income per Diluted Share	\$1.10 - \$1.15	(1,2)
Business Metrics:		
	Q4'18	
Case Shipments	330.0K - 335.0K	
Capital Expenditure	\$50M - \$55M	
Depreciation & Amortization	\$15M - \$16M	
Diluted Shares Outstanding	81.3M	(2)
Stock Based Compensation Expense	\$19.1M	
Effective Tax Rate	~22.5%	(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