

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) July 25, 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 July 25, 2018, Align Technology, Inc. ("Align") is issuing a press release and holding a conference call regarding its financial results for its second quarter ended June 30, 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 second quarter ended June 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: July 25, 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
<u>99.1</u>	<u>Press Release of Align Technology, Inc. announcing second quarter ended June 30, 2018 financial results</u>



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ALIGN TECHNOLOGY ANNOUNCES SECOND QUARTER 2018 FINANCIAL RESULTS

- Q2 revenues up 37.5% year-over-year to a record \$490.3 million, and diluted EPS of \$1.30
- Q2 operating income up 46.8% year-over-year to \$122.7 million, operating margin of 25.0%
- Q2 total Invisalign case shipments up 30.5% year-over-year to 302.7 thousand
- Q2 Invisalign cases for teenage patients up 42.1% year-over-year to 78.4 thousand
- Q2 iTero scanner and services revenues up 60.9% year-over-year to \$57.0 million

SAN JOSE, Calif., July 25, 2018 -- Align Technology, Inc. (Nasdaq: ALGN) today reported financial results for the second quarter ended June 30, 2018. Invisalign case shipments in the second quarter of 2018 (Q2'18) were 302.7 thousand, up 30.5% year-over-year. Americas and International region case shipments were up year-over-year 22.2% and 45.4%, respectively. Q2'18 Invisalign cases for teenage patients were 78.4 thousand, up 42.1% year-over-year. Q2'18 revenues were \$490.3 million, up 37.5% year-over-year and Q2'18 operating income was \$122.7 million, up 46.8% year-over-year resulting in an operating margin of 25.0%. Net profit was \$106.1 million, or \$1.30 per diluted share, up \$0.45 year-over-year.

Commenting on Align's Q2 2018 results, Align Technology President and CEO Joe Hogan said, "I'm pleased to report another better than expected quarter for Align. Our second quarter results reflect strong growth across our customer channels with record volume in all regions and in almost every country market. Year-over-year revenue growth of 37.5% was driven by continued momentum from Invisalign doctors and increased adoption of Invisalign treatment for teenage patients which grew 42.1%. Q2 Invisalign volume growth of 30.5% year-over-year reflects increased utilization and expansion of our customer base, which was over 50,000 for the first time and included more than 5,000 new Invisalign-trained doctors. We also saw momentum from the iTero scanner and services business which includes the continued rollout of iTero scanners across Heartland Dental's installed base, as well as the first iTero scanner shipments to China."

GAAP Summary Financial Comparisons Second Quarter Fiscal 2018

	Q2'18	Q1'18	Q2'17	Q/Q Change	Y/Y Change
Invisalign Case Shipments ¹	302,685	272,235	231,890	+11.2%	+30.5%
Net Revenues	\$490.3M	\$436.9M	\$356.5M	+12.2%	+37.5%
Clear Aligner ²	\$433.3M	\$385.5M	\$321.0M	+12.4%	+35.0%
Scanner & Services	\$57.0M	\$51.4M	\$35.4M	+10.9%	+60.9%
Net Profit	\$106.1M	\$95.9M	\$69.2M	+10.7%	+53.4%
Diluted EPS	\$1.30	\$1.17	\$0.85	+\$0.13	+\$0.45

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 June 30, 2018, Align had \$720.7 million in cash, cash equivalents and marketable securities compared to \$673.0 million as of March 31, 2018. In May 2018, we announced an additional \$600 million stock buy-back authorization. We also have \$100 million remaining under the April 2016 repurchase program, which we expect to utilize during the remainder of 2018.

Announcements and Highlights

- Today, Align issued a separate press releases announcing that the Company has opened new facilities in Costa Rica to support continued long term growth. The Company hosted a grand opening celebration on Friday, July 20 attended by Costa Rican President Carlos Alvarado Quesada and local government officials. Today, the Company also announced that it has received Certificate of Medical Device Registration and Certificate of Production from the China Food and Drug Administration (CFDA) to manufacture the iTero Element intraoral scanner in China. Align had previously announced in April that it had received approval from the CFDA to market the iTero Element intraoral scanner in China.

Q2 2018 Company Highlights. During the second quarter Align announced the following:

- The One Millionth Invisalign case for the Europe, Middle East and Africa (“EMEA”) region. This is a significant milestone for the Company with more than 34 thousand Invisalign-trained orthodontists and general dentists in the region and reflects accelerating adoption of Invisalign clear aligner therapy in EMEA.
- Eleven recipients of research grants under the Company’s Annual Research Award Program. Now in its ninth year of funding, nearly \$300,000 has been awarded for 2018 to researchers at universities in the Americas, Europe, and Asia Pacific regions.
- The grand opening of the first Invisalign treatment planning facility in Europe, located in Cologne, Germany. The Cologne facility is one of only three Invisalign treatment planning facilities in the world and reflects the rapid growth and expansion of Align globally. It serves as a training facility for Invisalign doctors within the German-speaking market, providing clinical education and support in local language for doctors in Germany, Austria, Switzerland and Lichtenstein.
- The extension of the Invisalign product family with Invisalign First clear aligners, designed with features specifically for younger patients with early mixed dentition (mixture of primary/baby and permanent teeth). Phase 1 treatment is early interceptive orthodontic treatment for young patients, traditionally done through arch expanders, or partial metal braces, before all permanent teeth have erupted - typically at ages 6 through 10 years. Invisalign First clear aligners are designed specifically to address a broad range of younger patients' malocclusions, including shorter clinical crowns, management of erupting dentition, and predictable dental arch expansion.

- A new expanded Invisalign product portfolio that includes new options and greater flexibility to treat a broader range of patients. The new Invisalign product portfolio offers doctors more choices by extending desirable features across the entire portfolio and creating new Invisalign Treatment Packages, as well as new options to treat young patients with early mixed dentition. The new end-to-end Invisalign portfolio now includes clear aligner product offerings for almost every patient age group and case complexity to make it easier for doctors to tailor treatment planning to the needs of each unique patient.
- The new Invisalign Go product with a more user-friendly iTero digital chairside experience and greater flexibility to treat a wider range of mild to moderate cases such as crowded or gap teeth that require teeth straightening prior to restorative treatments. Invisalign Go also incorporates new data-driven clinical protocols for predictable tooth movement and automated case assessments that leverage over 5.5 million Invisalign patients treated to date. These improvements make it easier for dentists to tailor their treatment plans to the individual needs of each patient.
- 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. First introduced in 2014 with Invisalign G5 Innovations, Precision Bite Ramps are designed to disocclude the posterior teeth or "open the bite" for improved efficiency in deep bite Invisalign treatments.
- The expansion of the iTero Element portfolio with the launch of the iTero Element 2 and the iTero Element Flex scanners. These additions build on the existing high precision, full-color imaging and fast scan times of the iTero Element portfolio. The next-generation iTero Element 2 is designed for greater performance with 2X faster start-up and 25% faster scan processing time compared to the iTero Element.
- Regulatory approval from the China Food and Drug Administration (CFDA) to market the iTero Element intraoral scanner in China.

Q3 2018 Business Outlook

For the third quarter of 2018 (Q3'18), Align provides the following guidance:

- Net revenues in the range of \$493 million to \$503 million, up approximately 28% to 31% over the same period a year ago
- Invisalign case shipments in the range of 302 thousand to 307 thousand, up approximately 28% to 30% over the same period a year ago
- Operating margin in the range of 24.2% to 24.9%
- Diluted EPS in the range of \$1.13 to \$1.18

Align Web Cast and Conference Call

Align will host a conference call today, July 25, 2018 at 4:30 p.m. ET, 1:30 p.m. PT, to review its second 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 13681104 followed by #. For international callers, please dial 201-612-7415 and use the same conference number referenced above. The telephonic replay will be available through 5:30 p.m. ET on August 8, 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 third 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 June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Net revenues	\$ 490,259	\$ 356,482	\$ 927,183	\$ 666,823
Cost of net revenues	124,677	85,565	234,193	160,281
Gross profit	365,582	270,917	692,990	506,542
Operating expenses:				
Selling, general and administrative	212,087	162,964	411,712	314,112
Research and development	30,804	24,384	60,395	47,188
Total operating expenses	242,891	187,348	472,107	361,300
Income from operations	122,691	83,569	220,883	145,242
Interest income	1,917	1,441	4,093	2,636
Other income (expense), net	(7,099)	1,771	(6,922)	2,221
Net income before provision for income taxes and equity in losses of investee	117,509	86,781	218,054	150,099
Provision for income taxes	7,703	15,387	10,605	8,164
Equity in losses of investee, net of tax	3,701	2,215	5,478	3,336
Net income	\$ 106,105	\$ 69,179	\$ 201,971	\$ 138,599
Net income per share:				
Basic	\$ 1.32	\$ 0.86	\$ 2.52	\$ 1.73
Diluted	\$ 1.30	\$ 0.85	\$ 2.48	\$ 1.70
Shares used in computing net income per share:				
Basic	80,216	80,188	80,127	80,047
Diluted	81,471	81,631	81,575	81,668

* 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)

	June 30, 2018	December 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 547,993	\$ 449,511
Marketable securities, short-term	164,629	272,031
Accounts receivable, net	374,371	324,189
Inventories	47,252	31,688
Prepaid expenses and other current assets	126,754	80,948
Total current assets	<u>1,260,999</u>	<u>1,158,367</u>
Marketable securities, long-term	8,061	39,948
Property, plant and equipment, net	447,933	348,793
Equity method investments	49,128	54,606
Goodwill and intangible assets, net	85,307	89,068
Deferred tax assets	45,859	49,334
Other assets	19,302	43,893
Total assets	<u>\$ 1,916,589</u>	<u>\$ 1,784,009</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 48,744	\$ 36,776
Accrued liabilities	196,754	195,562
Deferred revenues	321,148	267,713
Total current liabilities	<u>566,646</u>	<u>500,051</u>
Income tax payable	115,701	114,091
Other long-term liabilities	15,283	15,579
Total liabilities	<u>697,630</u>	<u>629,721</u>
Total stockholders' equity	<u>1,218,959</u>	<u>1,154,288</u>
Total liabilities and stockholders' equity	<u>\$ 1,916,589</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)

	Six Months Ended June 30,	
	2018	2017
CASH FLOWS FROM OPERATING ACTIVITIES		
Net income	\$ 201,971	\$ 138,599
Net cash provided by operating activities	<u>217,121</u>	<u>158,088</u>
CASH FLOWS FROM INVESTING ACTIVITIES		
Net cash provided by (used in) investing activities	<u>54,003</u>	<u>(111,718)</u>
CASH FLOWS FROM FINANCING ACTIVITIES		
Net cash used in financing activities	<u>(170,745)</u>	<u>(84,240)</u>
Effect of foreign exchange rate changes on cash, cash equivalents, and restricted cash	<u>(1,923)</u>	<u>3,640</u>
Net increase (decrease) in cash, cash equivalents, and restricted cash	98,456	(34,230)
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>\$ 548,581</u>	<u>\$ 358,789</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 six months ended June 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
Invisalign Average Selling Price (ASP):							
Worldwide ASP	\$ 1,270	\$ 1,285	\$ 1,310	\$ 1,305	\$ 1,295	\$ 1,310	\$ 1,315
International ASP	\$ 1,345	\$ 1,340	\$ 1,395	\$ 1,400	\$ 1,375	\$ 1,435	\$ 1,425
Invisalign Cases Shipped by Geography:							
Americas	134,450	148,470	147,660	155,625	586,205	166,665	181,425
International	73,610	83,420	88,405	99,405	344,840	105,570	121,260
Total Cases Shipped	208,060	231,890	236,065	255,030	931,045	272,235	302,685
YoY % growth	27.1%	31.0%	32.8%	34.2%	31.4%	30.8%	30.5%
QoQ % growth	9.5%	11.5%	1.8%	8.0%		6.7%	11.2%
Number of Invisalign Doctors Cases Were Shipped To:							
Americas	24,595	25,570	25,865	26,480	38,230	27,105	28,280
International	14,270	15,695	16,740	18,505	26,175	19,700	21,805
Total Doctors Cases Shipped To	38,865	41,265	42,605	44,985	64,405	46,805	50,085
Invisalign Doctor Utilization Rates**:							
North America	5.6	5.9	5.8	6.0	15.8	6.3	6.6
North American Orthodontists	12.6	13.6	13.8	14.0	46.6	15.3	16.4
North American GP Dentists	3.1	3.3	3.1	3.3	8.2	3.4	3.6
International	5.2	5.3	5.3	5.4	13.2	5.4	5.6
Total Utilization Rates	5.4	5.6	5.5	5.7	14.5	5.8	6.0
Number of Invisalign Doctors Trained:							
Americas	1,040	1,820	1,740	1,685	6,285	1,605	1,795
International	2,220	3,055	2,540	2,400	10,215	2,645	3,300
Total Doctors Trained Worldwide	3,260	4,875	4,280	4,085	16,500	4,250	5,095
Total to Date Worldwide	118,730	123,605	127,885	131,970	131,970	136,220	141,315

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.

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

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

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>Q3'18 Guidance</u>	
	<u>GAAP</u>	
Net Revenues	\$493 - \$503	
Gross Margin	74.0% - 74.4%	
Operating Expenses	\$245 - \$249	
Operating Margin	24.2% - 24.9%	
Net Income per Diluted Share	\$1.13 - \$1.18	(1, 2)

Business Metrics:

	<u>Q3'18</u>	
Case Shipments	302K - 307K	
Capital Expenditure	\$60M - \$65M	
Depreciation & Amortization	\$10M - \$11M	
Diluted Shares Outstanding	81.6M	(2)
Stock Based Compensation Expense	\$18.8M	
Effective Tax Rate	~21%	(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