

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) April 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 April 25, 2018, Align Technology, Inc. ("Align") issued a press release and is holding a conference call regarding its financial results for its first quarter ended March 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 8.01. OTHER EVENTS

On April 25, 2018, Align issued a press release titled "Align Technology Provides Update Regarding SmileDirectClub (SDC) Dispute". A copy of the press release is attached hereto as Exhibit 99.2.

ITEM 9.01. Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	Description
<u>99.1</u>	<u>Press Release of Align Technology, Inc. announcing first quarter ended March 31, 2018 financial results</u>
<u>99.2</u>	<u>Press Release of Align Technology, Inc. updating SDC Dispute</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: April 25, 2018

ALIGN TECHNOLOGY, INC.

By: /s/ Roger E. George
Roger E. George
Sr. Vice President, Corporate and Legal Affairs

INDEX TO EXHIBITS

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ALIGN TECHNOLOGY ANNOUNCES FIRST QUARTER 2018 FINANCIAL RESULTS

- Q1 revenues up 40.8% year-over-year to a record \$436.9 million, and diluted EPS of \$1.17
- Q1 operating income up 59.2% year-over-year to \$98.2 million or operating margin of 22.5%
- Q1 total Invisalign case shipments up 30.8% year-over-year to 272.2 thousand
- Q1 Invisalign cases for teenage patients up 40.9% year-over-year to 69.1 thousand
- Q1 scanner and services revenues up 84.0% year-over-year to \$51.4 million

SAN JOSE, Calif., April 25, 2018 -- Align Technology, Inc. (Nasdaq: ALGN) today reported financial results for the first quarter ended March 31, 2018. Invisalign case shipments in the first quarter of 2018 (Q1'18) were 272.2 thousand, up 30.8% year-over-year. Americas and International region case shipments were up year-over-year 24.0% and 43.4%, respectively. Beginning Q1'18, Americas region includes North America and LATAM and the International region includes EMEA and APAC. Q1'18 Invisalign cases for teenage patients were 69.1 thousand, up 40.9% year-over-year. Q1'18 revenues were \$436.9 million, up 40.8% year-over-year with Q1'18 operating income \$98.2 million, up 59.2% year-over-year resulting in an operating margin of 22.5%. Net profit was \$95.9 million, or \$1.17 per diluted share, up \$0.32 over the prior year.

Commenting on Align's Q1 2018 results, Align Technology President and CEO Joe Hogan said, "I'm pleased to report better than expected first quarter results and a strong start to the year for Align, with revenues, volumes and EPS above our guidance. Record Q1 revenues were up 41% year-over-year reflecting continued strong Invisalign volume across all geographies and customer channels, as well as iTero scanner sales which were up 84% year-over-year. Q1 Invisalign volume growth of 31% year-over-year was driven by increased utilization including strong teen case growth globally, and expansion of our customer base, which included over 4,200 new Invisalign-trained doctors worldwide."

GAAP Summary Financial Comparisons First Quarter Fiscal 2018

	Q1'18	Q4'17	Q1'17	Q/Q Change	Y/Y Change
Invisalign Case Shipments ¹	272,235	255,030	208,060	+6.7%	+30.8%
Net Revenues	\$436.9M	\$421.3M	\$310.3M	+3.7%	+40.8%
Clear Aligner ²	\$385.5M	\$364.2M	\$282.4M	+5.8%	+36.5%
Scanner & Services	\$51.4M	\$57.1M	\$27.9M	(10.0)%	+84.0%
Net Profit ³	\$95.9M	\$10.3M	\$69.4M	834.0%	38.1%
Diluted EPS ³	\$1.17	\$0.13	\$0.85	\$1.04	\$0.32

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

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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 net profit and diluted EPS includes \$86.6 million tax expense, or \$1.06 per diluted share negative impact due to the U.S. Tax Cut and Jobs Act

As of March 31, 2018, Align had \$673.0 million in cash, cash equivalents and marketable securities compared to \$761.5 million as of December 31, 2017. We repurchased approximately 0.4 million shares of stock for \$100.0 million in Q1'18 under the April 2016 Repurchase Program. We have \$100.0 million remaining available for repurchases under the existing stock repurchase authorization.

Announcements and Highlights

Today, Align issued the following press releases entitled:

- Align Introduces New Invisalign Go Clear Aligner System Integrated with iTero Scanner for Mild to Moderate Cases
- Align Technology To Introduce Two New iTero Scanners Featuring Greater Power and Portability
- Align Announces China Food and Drug Administration Approval for the iTero Element Scanner

Additional highlights in 2018 include:

- Announced 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.
- Announced it is extending the Invisalign product family with Invisalign First clear aligners, designed with features specifically for younger patients with early mixed dentition (with a mixture of primary/baby and permanent teeth).
- 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.

Q2 2018 Business Outlook

For the second quarter of 2018 (Q2'18), Align provides the following guidance:

- Net revenues in the range of \$460 million to \$470 million, up approximately 29% to 32% over the same period a year ago.
- Invisalign case shipments in the range of 296 thousand to 301 thousand, up approximately 28% to 30% over the same period a year ago.
- Operating margin in the range of 21.0% to 21.8%
- Diluted EPS in the range of \$1.02 to \$1.06

Align Web Cast and Conference Call

Align will host a conference call today, April 25, 2018 at 4:30 p.m. ET, 1:30 p.m. PT, to review its first 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 13678038 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 May 9, 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 provider 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 second quarter of 2018, 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, 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, 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 March 31,	
	2018	2017
Net revenues	\$ 436,924	\$ 310,341
Cost of net revenues	109,516	74,716
Gross profit	327,408	235,625
Operating expenses:		
Selling, general and administrative	199,625	151,148
Research and development	29,591	22,804
Total operating expenses	229,216	173,952
Income from operations	98,192	61,673
Interest income	2,176	1,195
Other income (expense), net	177	450
Net income before provision for (benefit from) income taxes and equity in losses of investee	100,545	63,318
Provision for (benefit from) income taxes	2,902	(7,223)
Equity in losses of investee, net of tax	1,777	1,121
Net income	\$ 95,866	\$ 69,420
Net income per share:		
Basic	\$ 1.20	\$ 0.87
Diluted	\$ 1.17	\$ 0.85
Shares used in computing net income per share:		
Basic	80,036	79,904
Diluted	81,628	81,534

* 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)

	March 31, 2018	December 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 498,003	\$ 449,511
Marketable securities, short-term	164,740	272,031
Accounts receivable, net	361,459	324,189
Inventories	35,866	31,688
Prepaid expenses and other current assets	108,708	80,948
Total current assets	<u>1,168,776</u>	<u>1,158,367</u>
Marketable securities, long-term	10,212	39,948
Property, plant and equipment, net	400,528	348,793
Equity method investments	52,829	54,606
Goodwill and intangible assets, net	87,629	89,068
Deferred tax assets	45,524	49,334
Other assets	17,233	43,893
Total assets	<u>\$ 1,782,731</u>	<u>\$ 1,784,009</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 41,881	\$ 36,776
Accrued liabilities	180,093	195,562
Deferred revenues	296,011	267,713
Total current liabilities	<u>517,985</u>	<u>500,051</u>
Income tax payable	119,349	114,091
Other long-term liabilities	17,937	15,579
Total liabilities	<u>655,271</u>	<u>629,721</u>
Total stockholders' equity	<u>1,127,460</u>	<u>1,154,288</u>
Total liabilities and stockholders' equity	<u>\$ 1,782,731</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)

	Three Months Ended	
	March 31,	
	2018	2017
CASH FLOWS FROM OPERATING ACTIVITIES		
Net income	\$ 95,866	\$ 69,420
Net cash provided by operating activities	77,332	47,621
CASH FLOWS FROM INVESTING ACTIVITIES		
Net cash provided by (used in) investing activities	109,269	(148,462)
CASH FLOWS FROM FINANCING ACTIVITIES		
Net cash used in financing activities	(139,822)	(33,001)
Effect of foreign exchange rate changes on cash, cash equivalents, and restricted cash	1,715	2,430
Net increase (decrease) in cash, cash equivalents, and restricted cash	48,494	(131,412)
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	\$ 498,619	\$ 261,607

**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 three months ended March 31, 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
Invisalign Average Selling Price (ASP):						
Worldwide ASP	\$ 1,270	\$ 1,285	\$ 1,310	\$ 1,305	\$ 1,295	\$ 1,310
International ASP	\$ 1,345	\$ 1,340	\$ 1,395	\$ 1,400	\$ 1,375	\$ 1,435
Invisalign Cases Shipped by Geography:						
Americas	134,450	148,470	147,660	155,625	586,205	166,665
International	73,610	83,420	88,405	99,405	344,840	105,570
Total Cases Shipped	208,060	231,890	236,065	255,030	931,045	272,235
YoY % growth	27.1%	31.0%	32.8%	34.2%	31.4%	30.8%
QoQ % growth	9.5%	11.5%	1.8%	8.0%		6.7%
Number of Invisalign Doctors Cases Were Shipped To:						
Americas	24,595	25,570	25,865	26,480	38,230	27,105
International	14,270	15,695	16,740	18,505	26,175	19,700
Total Doctors Cases Shipped To	38,865	41,265	42,605	44,985	64,405	46,805
Invisalign Doctor Utilization Rates**:						
North America	5.6	5.9	5.8	6.0	15.8	6.3
North American Orthodontists	12.6	13.6	13.8	14.0	46.6	15.3
North American GP Dentists	3.1	3.3	3.1	3.3	8.2	3.4
International	5.2	5.3	5.3	5.4	13.2	5.4
Total Utilization Rates	5.4	5.6	5.5	5.7	14.5	5.8
Number of Invisalign Doctors Trained:						
Americas	1,040	1,820	1,740	1,685	6,285	1,605
International	2,220	3,055	2,540	2,400	10,215	2,645
Total Doctors Trained Worldwide	3,260	4,875	4,280	4,085	16,500	4,250
Total to Date Worldwide	118,730	123,605	127,885	131,970	131,970	136,220

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
Stock-based Compensation (SBC)						
SBC included in Gross Profit	\$ 925	\$ 768	\$ 833	\$ 804	\$ 3,330	\$ 881
SBC included in Operating Expenses	13,887	13,477	14,134	14,026	55,524	14,949
Total SBC Expense	\$ 14,812	\$ 14,245	\$ 14,967	\$ 14,830	\$ 58,854	\$ 15,830

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>Q2'18 Guidance</u>
	<u>GAAP</u>
Net Revenues	\$460.0 - \$470.0
Gross Margin	74.2% - 75.0%
Operating Expenses	\$245.0 - \$250.0
Operating Margin	21.0% - 21.8%
Net Income per Diluted Share	\$1.02 - \$1.06 (1)

Business Metrics:

	<u>Q2'18</u>
Case Shipments	296K - 301K
Capital Expenditure	\$65M - \$70M
Depreciation & Amortization	\$10M - \$11M
Diluted Shares Outstanding	81.6M (2)
Stock Based Compensation Expense	\$18.3M
Effective Tax Rate	13.0% (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

Align Technology Provides Update Regarding SmileDirectClub (SDC) Dispute

SAN JOSE, Calif., April 25, 2018 (GLOBE NEWSWIRE) -- Align Technology, Inc. (NASDAQ:ALGN) today provided an update to its February 28, 2018 disclosure regarding SDC Financial LLC and SmileDirectClub LLC's (collectively, the "SDC Entities") allegation that the launch and operation of Align's Invisalign store pilot program constitutes a breach of non-compete provisions applicable to the members of SDC Financial LLC, including Align. In April 2018, the SDC Entities initiated proceedings that seek, among other forms of relief, to preliminarily and permanently enjoin all activities related to the Invisalign store pilot project, require Align to close the existing Invisalign stores, prohibit Align from opening any additional stores, and allow the SDC Entities to exercise a right to repurchase all of Align's SDC Financial LLC membership interests for a purchase price equal to Align's current capital account balance.

Align disputes the allegations that it has breached its obligations to the SDC Entities or under applicable law and will oppose and vigorously defend itself in the proceedings. This dispute does not impact Align's existing supply agreement with SDC which remains in place through 2019 and includes a minimum volume commitment.

Forward Looking Statement:

This release may contain forward-looking statements based on Align Technology's current expectations. These forward-looking statements involve risks and uncertainties. A number of important factors could cause actual results to differ materially from those in the forward-looking statements. These factors include, uncertainties involved in any contract dispute resolution and the possibility of Align choosing to settle the litigation for business or other reasons. These factors, as well as other factors that could cause actual results to differ materially, are discussed in more detail in Align Technology's Annual Report on Form 10-K for the year ended December 31, 2017, filed with the Securities and Exchange Commission on February 28, 2018, as well as in other reports and documents filed from time to time with the Securities and Exchange Commission.

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 provider in your area, please visit www.invisalign.com. For additional information about iTero digital scanning system, please visit www.itero.com.

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