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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549**

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**FORM 8-K**

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**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 24, 2019

**ALIGN TECHNOLOGY, INC.**

(Exact Name of Registrant as Specified in Charter)

**Delaware**  
(State or Other Jurisdiction of Incorporation)

**0-32259**  
(Commission File Number)

**94-3267295**  
(I.R.S. Employer Identification Number)

**2820 Orchard Parkway, San Jose, California 95134**  
(Address of Principal Executive Offices) (Zip Code)

**(408) 470-1000**  
(Registrant's telephone number, including area code)

**Not applicable**  
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- 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 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2). 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.

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**Item 2.02. Results of Operations and Financial Condition.**

On April 24, 2019, Align Technology, Inc. ("Align") is issuing a press release and holding a conference call regarding its financial results for its first quarter ended March 31, 2019. 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**

[99.1](#) [Press Release of Align Technology, Inc. announcing its first quarter ended March 31, 2019 financial results](#)

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**SIGNATURE**

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

**ALIGN TECHNOLOGY, INC.**

Date: April 24, 2019

By: /s/ Roger E. George  
Roger E. George  
Senior Vice President, Chief Legal and Regulatory Affairs

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## INDEX TO EXHIBITS

Exhibit No.	Description
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<a href="#"><u>99.1</u></a>	<a href="#"><u>Press Release of Align Technology, Inc. announcing first quarter ended March 31, 2019 financial results</u></a>
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#### ALIGN TECHNOLOGY ANNOUNCES FIRST QUARTER 2019 FINANCIAL RESULTS

- Q1 revenues up 25.6% year-over-year to a record \$549.0 million
- Q1 Invisalign volume up 28.3% year-over-year to 349.2 thousand cases
- Q1 scanner and services revenues up 55.1% year-over-year to \$79.8 million
- Q1 Invisalign cases for teenage patients up 41.1% year-over-year to 97.4 thousand
- Q1 operating income of \$87.7 million included impairments and other charges of \$29.8 million related to the U.S. Invisalign Store closures
- Q1 net profit of \$71.8 million and \$0.89 diluted EPS

SAN JOSE, Calif., April 24, 2019 (GLOBE NEWSWIRE) -- Align Technology, Inc. (Nasdaq: ALGN) today reported financial results for the first quarter ended March 31, 2019. Q1'19 Invisalign volume was 349.2 thousand cases, up 28.3% year-over-year. For the Americas and International regions, Q1'19 Invisalign volume was up 21.8% and 38.5% year-over-year, respectively. Q1'19 Invisalign volume for teenage patients was 97.4 thousand cases, up 41.1% year-over-year. Q1'19 total revenues were \$549.0 million, up 25.6% year-over-year, and Q1'19 scanner and services revenues were \$79.8 million, up 55.1% year-over-year.

Q1'19 operating income of \$87.7 million was down 10.7% year-over-year resulting in an operating margin of 16.0%. As a result of the arbitrator's decision regarding SmileDirectClub (SDC) announced on March 5, 2019, Q1'19 operating income included impairments and other charges related to the U.S. Invisalign Store closures of \$29.8 million which reduced operating margin by 5.4%. Q1'19 net profit was \$71.8 million, or \$0.89 per diluted EPS which reflected the Invisalign Store closure charges of \$22.2 million, net of tax effects of \$7.5 million, or \$0.28 per diluted EPS.

Commenting on Align's Q1 2019 results, Align Technology President and CEO Joe Hogan said, "Our first quarter was a very good start to the year with revenues, volumes, gross margin, and EPS above our guidance. Record Q1 revenues and Invisalign volumes were up 25.6% and 28.3% year-over-year, respectively, reflecting continued strong growth across all geographies and customer channels, as well as strong iTero scanner and services revenues, which were up 55.1% year-over-year. Q1 sequential growth was driven primarily by North America and the EMEA region, reflecting strength across the Invisalign product portfolio. We also saw a nice uptick in adoption of Invisalign treatment with record utilization overall, as well as expansion of our customer base which totaled 57,000 active doctors worldwide in Q1."

Align Technology, Inc. 2820 Orchard Pkwy, San Jose, CA 95134  
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WWW.ALIGNTECH.COM

**GAAP Summary Financial Comparisons  
First Quarter Fiscal 2019**

	Q1'19	Q4'18	Q1'18	Q/Q Change	Y/Y Change
Invisalign Case Shipments <sup>1</sup>	349,195	333,800	272,235	+4.6%	+28.3%
Net Revenues	\$549.0M	\$534.0M	\$436.9M	+2.8%	+25.6%
Clear Aligner <sup>2</sup>	\$469.2M	\$445.6M	\$385.5M	+5.3%	+21.7%
Scanner & Services	\$79.8M	\$88.4M	\$51.4M	(9.8)%	+55.1%
Net Profit <sup>3</sup>	\$71.8M	\$97.4M	\$95.9M	(26.2)%	(25.1)%
Diluted EPS <sup>3</sup>	\$0.89	\$1.20	\$1.17	\$(0.31)	\$(0.28)

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

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

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

<sup>3</sup> Q1'19 results include impairments and other charges related to closing Invisalign Stores in the U.S. as a result of the arbitrator's decision regarding SmileDirectClub (SDC) announced March 5, 2019.

As of March 31, 2019, Align had \$732.5 million in cash, cash equivalents and marketable securities compared to \$744.5 million as of December 31, 2018. In February 2019, we purchased on the open market approximately 0.2 million shares of our common stock at an average price of \$243.42 per share, including commission for an aggregate purchase price of approximately of \$50.0 million. We have \$450.0 million remaining available for repurchase under the May 2018 Repurchase Program.

**Announcements and Highlights**

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

**Invisalign and iTero Intraoral Scanner**

- Launched the new iTero Element 5D Imaging System for comprehensive, preventative and restorative oral care. The iTero Element 5D Imaging System provides a new comprehensive approach to clinical applications, workflows and user experience that expands the suite of existing high-precision, full-color imaging and fast scan times of the iTero Element portfolio.
- Launched SmileView, an online tool designed to help prospective Invisalign patients visualize a new, straighter smile before they opt for Invisalign treatment.

**Corporate**

- Announced that Raj Pudipeddi joined Align Technology as senior vice president and CMO, responsible for Align's global marketing organization including product portfolio, product management, commercialization, and global branding for the Invisalign and iTero product brands.
- Announced that on February 27, 2019, the United States International Trade Commission voted to institute a third investigation based on Align's claims of scanner related 3Shape patent infringement.
- Announced the outcome of the arbitration decision with SDC Entities requiring Align to close its U.S. Invisalign Stores by April 3, 2019.

- Announced that on March 1, 2019, an Administrative Law Judge with the United States International Trade Commission determined that 3Shape infringes four claims from three Align patents, but declined to find a violation of Section 337.
- Entered into a distribution agreement with Benco Dental, the largest privately-owned dental distributor in the United States, for Align's family of iTero Element intraoral scanners.
- Entered into a partnership with Digital Smile Design (DSD), a leader in holistic, digital and emotional dentistry solutions, to bring dedicated tools that incorporate DSD into Align's end-to-end digital workflow, including iTero scanning technology.
- Opened Align University Training Institute in Shanghai, China, Align's second training facility in China.
- Announced that Align Technology and Straumann Group settled global ClearCorrect patent disputes and signed a non-binding letter of intent for Straumann to distribute iTero scanners.

#### **Q2 2019 Business Outlook**

For the second quarter of 2019 (Q2'19), Align provides the following guidance:

- Net revenues in the range of \$590 million to \$600 million, up approximately 20% to 22% over the same period a year ago
- Invisalign case shipments in the range of 380 thousand to 385 thousand, up approximately 26% to 27% over the same period a year ago
- Operating margin in the range of 24.5% to 25.4%
- Diluted EPS in the range of \$1.47 to \$1.54

#### **Align Web Cast and Conference Call**

Align will host a conference call today, April 24, 2019 at 4:30 p.m. ET, 1:30 p.m. PT, to review its first quarter 2019 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 13689188 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 8, 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](http://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](http://www.invisalign.com). For additional information about iTero digital scanning system, please visit [www.itero.com](http://www.itero.com).

**Forward-Looking Statement**

This news release, including the tables below, contains forward-looking statements, including statements regarding certain business metrics for the second 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, 2018, which was filed with the Securities and Exchange Commission (SEC) on February 28, 2019. Align undertakes no obligation to revise or update publicly any forward-looking statements for any reason.



ALIGN TECHNOLOGY, INC.  
 UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS  
 (in thousands, except per share data)

	<b>Three Months Ended March 31,</b>	
	<b>2019</b>	<b>2018</b>
Net revenues	\$ 548,971	\$ 436,924
Cost of net revenues	146,875	109,516
Gross profit	402,096	327,408
Operating expenses:		
Selling, general and administrative	247,110	199,625
Research and development	37,503	29,591
Impairments and other charges	29,782	-
Total operating expenses	314,395	229,216
Income from operations	87,701	98,192
Interest income	2,633	2,176
Other income (expense), net	(5,746)	177
Net income before provision for income taxes and equity in losses of investee	84,588	100,545
Provision for income taxes	8,796	2,902
Equity in losses of investee, net of tax	3,944	1,777
Net income	<u>\$ 71,848</u>	<u>\$ 95,866</u>
Net income per share:		
Basic	<u>\$ 0.90</u>	<u>\$ 1.20</u>
Diluted	<u>\$ 0.89</u>	<u>\$ 1.17</u>
Shares used in computing net income per share:		
Basic	<u>79,860</u>	<u>80,036</u>
Diluted	<u>80,687</u>	<u>81,628</u>

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

	March 31, 2019	December 31, 2018
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 588,001	\$ 636,899
Marketable securities, short-term	144,540	98,460
Equity method investments	41,969	-
Accounts receivable, net	479,281	439,009
Inventories	68,489	55,641
Prepaid expenses and other current assets	116,833	72,470
Total current assets	1,439,113	1,302,479
Marketable securities, long-term	-	9,112
Property, plant and equipment, net	575,267	521,329
Operating lease right-of-use assets	56,384	-
Equity method investments	-	45,913
Goodwill and intangible assets, net	80,329	81,949
Deferred tax assets	57,151	64,689
Other assets	26,186	26,987
Total assets	<u>\$ 2,234,430</u>	<u>\$ 2,052,458</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 62,512	\$ 64,256
Accrued liabilities	252,754	234,679
Finance lease liabilities	56,100	-
Deferred revenues	433,518	393,138
Total current liabilities	804,884	692,073
Income tax payable	93,463	78,008
Operating lease liabilities	59,307	-
Other long-term liabilities	21,072	29,486
Total liabilities	978,726	799,567
Total stockholders' equity	1,255,704	1,252,891
Total liabilities and stockholders' equity	<u>\$ 2,234,430</u>	<u>\$ 2,052,458</u>

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

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2019</b>	<b>2018</b>
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>		
Net cash provided by operating activities	\$ 117,207	\$ 77,332
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>		
Net cash (used in) provided by investing activities	(74,418)	109,269
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>		
Net cash used in financing activities	(92,762)	(139,822)
Effect of foreign exchange rate changes on cash, cash equivalents, and restricted cash	1,089	1,715
Net (decrease) increase in cash, cash equivalents, and restricted cash	(48,884)	48,494
Cash, cash equivalents, and restricted cash at beginning of the period	637,566	450,125
Cash, cash equivalents, and restricted cash at end of the period	<u>\$ 588,682</u>	<u>\$ 498,619</u>

ALIGN TECHNOLOGY, INC.  
INVISALIGN BUSINESS METRICS\*

	Q1 2018	Q2 2018	Q3 2018	Q4 2018	Fiscal 2018	Q1 2019
<b>Invisalign Average Selling Price (ASP):</b>						
Worldwide ASP	\$ 1,310	\$ 1,315	\$ 1,230	\$ 1,235	\$ 1,270	\$ 1,245
International ASP	\$ 1,435	\$ 1,425	\$ 1,340	\$ 1,295	\$ 1,370	\$ 1,330
<b>Invisalign Cases Shipped by Geography:</b>						
Americas	166,665	181,425	190,615	189,410	728,115	202,935
International	105,570	121,260	128,730	144,390	499,950	146,260
Total Cases Shipped	272,235	302,685	319,345	333,800	1,228,065	349,195
YoY % growth	30.8%	30.5%	35.3%	30.9%	31.9%	28.3%
QoQ % growth	6.7%	11.2%	5.5%	4.5%		4.6%
<b>Number of Invisalign Doctors Cases Were Shipped To:</b>						
Americas	27,105	28,280	28,890	29,215	42,000	30,200
International	19,700	21,805	23,270	25,475	36,040	26,510
Total Doctors Cases Shipped To	46,805	50,085	52,160	54,690	78,040	56,710
<b>Invisalign Doctor Utilization Rates**:</b>						
North America	6.3	6.6	6.9	6.7	18.2	7.0
North American Orthodontists	15.3	16.4	17.4	16.5	56.7	18.3
North American GP Dentists	3.4	3.6	3.5	3.6	9.1	3.6
International	5.4	5.6	5.5	5.7	13.9	5.5
Total Utilization Rates	5.8	6.0	6.1	6.1	15.7	6.2
<b>Number of Invisalign Doctors Trained***:</b>						
Americas	1,630	1,880	2,085	2,290	7,885	1,725
International	2,645	3,300	2,845	2,980	11,770	2,410
Total Doctors Trained Worldwide	4,275	5,180	4,930	5,270	19,655	4,135
Total to Date Worldwide	136,575	141,755	146,685	151,955	151,955	156,090

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 adjusted to reflect Americas doctors trained for Invisalign iGo

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

	Q1 2018	Q2 2018	Q3 2018	Q4 2018	Fiscal 2018	Q1 2019
<b>Stock-based Compensation (SBC)</b>						
SBC included in Gross Profit	\$ 881	\$ 900	\$ 966	\$ 948	\$ 3,695	\$ 1,112
SBC included in Operating Expenses	14,949	15,990	18,232	17,897	67,068	19,932
Total SBC Expense	\$ 15,830	\$ 16,890	\$ 19,198	\$ 18,845	\$ 70,763	\$ 21,044

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>Q2'19 Guidance</u>
	<u>GAAP</u>
<b>Net Revenues</b>	\$590.0 - \$600.0
<b>Gross Margin</b>	71.5% - 72.5%
<b>Operating Expenses</b>	\$277.0 - \$282.0
<b>Operating Margin</b>	24.5% - 25.4%
<b>Net Income per Diluted Share</b>	\$1.47 - \$1.54

**Business Metrics:**

	<u>Q2'19</u>
Case Shipments	380.0K - 385.0K
Capital Expenditure	\$85M-\$90M
Depreciation & Amortization	\$20M-22M
Diluted Shares Outstanding	80.6 (2)
Stock Based Compensation Expense	\$23M
Effective Tax Rate	~24% (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