

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 24, 2019

**ALIGN TECHNOLOGY, INC.**

(Exact Name of Registrant as Specified in Its Charter)

**Delaware**

(State or Other Jurisdiction of Incorporation)

**0-32259**

(Commission File Number)

**94-3267295**

(IRS Employer Identification No.)

**2820 Orchard Parkway, San Jose, California**

(Address of Principal Executive Offices)

**95134**

(Zip Code)

**(408) 470-1000**

(Registrant's Telephone Number, Including Area Code)

Not applicable

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common Stock, \$0.0001 par value	ALGN	The NASDAQ Stock Market LLC (NASDAQ Global Market)

**ITEM 2.02 RESULTS OF OPERATIONS AND FINANCIAL CONDITIONS**

On July 24, 2019, 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, 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

<b>Exhibit No.</b>	<b>Description</b>
<a href="#"><u>99.1</u></a>	<a href="#"><u>Press Release of Align Technology, Inc. announcing its second quarter ended June 30, 2019 financial results</u></a>



**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 24, 2019

**ALIGN TECHNOLOGY, INC.**

By: /s/ John F. Morici  
John F. Morici  
Sr. Vice President, Finance and Chief Financial Officer

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## INDEX TO EXHIBITS

Exhibit No.	Description
<a href="#">99.1</a>	<a href="#">Press Release of Align Technology, Inc. announcing second quarter ended June 30, 2019 financial results</a>



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## **ALIGN TECHNOLOGY ANNOUNCES SECOND QUARTER 2019 FINANCIAL RESULTS** **Achieves 7 Millionth Invisalign Patient Milestone**

- Q2 revenues up 22.5% year-over-year to a record \$600.7 million
- Q2 Invisalign volume up 24.6% year-over-year to 377.1 thousand cases
- Q2 scanner and services revenues up 82.4% year-over-year to \$104.0 million
- Q2 Invisalign cases for teenage patients up 32.2% year-over-year to 103.7 thousand
- Q2 operating income of \$176.5 million includes \$51.0 million benefit from Straumann settlement
- Q2 net profit of \$147.1 million and \$1.83 diluted EPS

SAN JOSE, Calif., July 24, 2019 (GLOBE NEWSWIRE) -- Align Technology, Inc. (Nasdaq: ALGN) today reported financial results for the second quarter ended June 30, 2019. Q2'19 Invisalign volume was 377.1 thousand cases, up 24.6% year-over-year. For the Americas and International regions, Q2'19 Invisalign volume was up 16.5% and 36.7% year-over-year, respectively. Q2'19 Invisalign volume for teenage patients was 103.7 thousand cases, up 32.2% year-over-year. Q2'19 total revenues were \$600.7 million, up 22.5% year-over-year, and Q2'19 scanner and services revenues were \$104.0 million, up 82.4% year-over-year.

Q2'19 operating income of \$176.5 million was up 43.8% year-over-year resulting in an operating margin of 29.4%. Q2'19 net profit was \$147.1 million, or \$1.83 per diluted EPS. Q2'19 operating expense included a \$51.0 million benefit from the ClearCorrect settlement with Straumann, which increased Q2 operating margin by approximately 8 points and benefited EPS by \$0.57, respectively.

Commenting on Align's second quarter results and outlook for the third quarter, Align Technology President and CEO Joe Hogan said, "Our second quarter revenues were at the high-end of our guidance, reflecting Invisalign volume growth primarily from international doctors, as well as very strong sales from iTero scanner and services. Q2 Invisalign volumes were up 24.6% year-over-year reflecting continued adoption from teenage and younger patients, as well as increased utilization among orthodontists and expansion of our customer base which totaled 60,000 active doctors worldwide. In Q2, total Invisalign case shipments were lower than expected, primarily due to a softness in China related to a tougher consumer environment and slower growth in young adult case in North America. Given the uncertainty in China, our outlook for the third quarter reflects a more cautious view for growth in the Asia Pacific region."

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

	Q2'19	Q1'19	Q2'18	Q/Q Change	Y/Y Change
Invisalign Case Shipments <sup>1</sup>	377,145	349,195	302,685	+8.0%	+24.6%
Net Revenues	\$ 600.7M	\$ 549.0M	\$ 490.3M	+9.4%	+22.5%
Clear Aligner <sup>2</sup>	\$ 496.7M	\$ 469.2M	\$ 433.3M	+5.9%	+14.6%
Scanner & Services	\$ 104.0M	\$ 79.8M	\$ 57.0M	+30.4%	+82.4%
Net Profit <sup>3, 4</sup>	\$ 147.1M	\$ 71.8M	\$ 106.1M	+104.8%	+38.7%
Diluted EPS <sup>3, 4</sup>	\$ 1.83	\$ 0.89	\$ 1.30	+\$0.94	+\$0.53

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 of \$29.8 million related to closing Invisalign Stores as a result of the arbitrator's decision regarding SmileDirectClub announced March 5, 2019.

<sup>4</sup> Q2'19 results include a \$51.0 million gain from Straumann litigation settlement.

As of June 30, 2019, Align had \$765.9 million in cash, cash equivalents and marketable securities compared to \$732.5 million as of March 31, 2019. In May 2019, we purchased on the open market approximately 0.2 million shares of our common stock at an average price of \$307.48 per share, including commission, for an aggregate purchase price of \$49.5 million. We have \$400.5 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:

**Corporate**

- During the quarter, Align shipped its 7 millionth Invisalign patient who is a young child in the U.S. being treated with Invisalign First.
- Announced that Align and Straumann Group terminated discussions concerning a possible development and distribution agreement that was disclosed as part of the patent settlement agreement announced by the two companies in March of this year.
- Announced that Simon Beard was appointed as senior vice president of the Americas region and Markus Sebastian was promoted to senior vice president of the EMEA region.
- Align awarded ten research grants totaling \$250,000 as part of its ongoing annual research awards program to universities worldwide.
- Announced that Roger E. George, Align senior vice president, chief legal and regulatory officer has retired and that Julie Coletti was appointed to senior vice president and Chief Legal and Regulatory Officer.
- Announced that on April 26, 2019, an Administrative Law Judge with the United States International Trade Commission issued an Initial Determination regarding her investigation of 3Shape's infringement on Align's patents.

- Align completed the purchase of the Raleigh office building located in Morrisville, NC. This office serves as the Americas headquarters.

**Invisalign and iTero Intraoral Scanner**

- Launched the new iTero Element Foundation intraoral scanner with restorative software. The iTero Element Foundation extends Align's portfolio of intraoral scanners with powerful 3D visualization to better meet the needs of doctors, labs and patients.

**Q3 2019 Business Outlook**

For the third quarter of 2019 (Q3'19), Align provides the following guidance:

- Net revenues in the range of \$585 million to \$600 million, up approximately 16% to 19% over the same period a year ago
- Invisalign case shipments in the range of 370 thousand to 380 thousand, up approximately 16% to 19% over the same period a year ago
- Operating margin in the range of 19.8% to 20.5%
- Diluted EPS in the range of \$1.09 to \$1.16
- In addition, we expect to repurchase at least \$100 million of our stock in the open market in Q3
- As we continue our operational expansion efforts, we expect CapEx for Q3 to be approximately \$50 million to \$55 million, and we expect depreciation and amortization to be \$24 million to 26 million

**Align Web Cast and Conference Call**

Align will host a conference call today, July 24, 2019 at 4:30 p.m. ET, 1:30 p.m. PT, to review its second 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 13691835 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 7, 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 third quarter of 2019, including, but not limited to, anticipated net revenues, gross margin, operating expenses, operating profit, capital expenditures, depreciation and amortization, diluted earnings per share, tax rate, case shipments, and our expectations regarding stock repurchases during the quarter. 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, including Align's predictions related to a tougher consumer demand environment in China, especially for U.S. based products and services, Align's expectations regarding the continued growth of our international markets, Align's ability to protect its intellectual property rights, continued compliance with regulatory requirements, competition from existing and new competitors, Align's expectations regarding the sales growth of its intra-oral scanner sales in international markets, its belief that technology features and functionality of the iTero scanners will increase adoption of Invisalign and increase sales of Align's intra-oral scanners, Align's expectations regarding the financial and strategic benefits of establishing regional order acquisition, treatment planning and manufacturing facilities, 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, Align's expectation to incur additional costs related to the planned corporate structure reorganization, the risks relating to Align's ability to sustain or increase profitability or revenue growth in future periods while controlling expenses, the expected impact additional sales representatives will have on our sales in 2019, 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, system integration and implementation issues, 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 and its latest Quarterly Report on Form 10-Q for the quarter ended March 31, 2019, which was filed with the SEC on May 2, 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)

	Three Months Ended June 30,		Six Month Ended June 30,	
	2019	2018	2019	2018
Net revenues	\$ 600,697	\$ 490,259	\$ 1,149,668	\$ 927,183
Cost of net revenues	168,408	124,677	315,283	234,193
Gross profit	432,289	365,582	834,385	692,990
Operating expenses:				
Selling, general and administrative	267,948	212,087	515,058	411,712
Research and development	38,851	30,804	76,354	60,395
Impairments and other charges	-	-	29,782	-
Litigation settlement gain	(51,000)	-	(51,000)	-
Total operating expenses	255,799	242,891	570,194	472,107
Income from operations	176,490	122,691	264,191	220,883
Interest income	3,465	1,917	6,098	4,093
Other income (expense), net	13,892	(7,099)	8,146	(6,922)
Net income before provision for income taxes and equity in losses of investee	193,847	117,509	278,435	218,054
Provision for income taxes	43,121	7,703	51,917	10,605
Equity in losses of investee, net of tax	3,584	3,701	7,528	5,478
Net income	<u>\$ 147,142</u>	<u>\$ 106,105</u>	<u>\$ 218,990</u>	<u>\$ 201,971</u>
Net income per share:				
Basic	<u>\$ 1.84</u>	<u>\$ 1.32</u>	<u>\$ 2.74</u>	<u>\$ 2.52</u>
Diluted	<u>\$ 1.83</u>	<u>\$ 1.30</u>	<u>\$ 2.71</u>	<u>\$ 2.48</u>
Shares used in computing net income per share:				
Basic	<u>79,943</u>	<u>80,216</u>	<u>79,901</u>	<u>80,127</u>
Diluted	<u>80,590</u>	<u>81,471</u>	<u>80,665</u>	<u>81,575</u>

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

	June 30, 2019	December 31, 2018
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 423,500	\$ 636,899
Marketable securities, short-term	297,422	98,460
Accounts receivable, net	520,094	439,009
Inventories	81,124	55,641
Prepaid expenses and other current assets	135,234	72,470
Total current assets	1,457,374	1,302,479
Marketable securities, long-term	44,969	9,112
Property, plant and equipment, net	599,611	521,329
Operating lease right-of-use assets	57,269	-
Equity method investments	-	45,913
Goodwill and intangible assets, net	78,852	81,949
Deferred tax assets	59,050	64,689
Other assets	48,892	26,987
Total assets	<u>\$ 2,346,017</u>	<u>\$ 2,052,458</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 61,950	\$ 64,256
Accrued liabilities	245,634	234,679
Deferred revenues	481,462	393,138
Total current liabilities	789,046	692,073
Income tax payable	98,182	78,008
Operating lease liabilities	59,140	-
Other long-term liabilities	25,967	29,486
Total liabilities	972,335	799,567
Total stockholders' equity	1,373,682	1,252,891
Total liabilities and stockholders' equity	<u>\$ 2,346,017</u>	<u>\$ 2,052,458</u>

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

	<b>Six Months Ended</b>	
	<b>June 30,</b>	
	<b>2019</b>	<b>2018</b>
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>		
Net cash provided by operating activities	\$ 294,561	\$ 217,121
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>		
Net cash (used in) provided by investing activities	(321,020)	54,003
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>		
Net cash used in financing activities	(188,381)	(170,745)
Effect of foreign exchange rate changes on cash, cash equivalents, and restricted cash	1,467	(1,923)
Net (decrease) increase in cash, cash equivalents, and restricted cash	(213,373)	98,456
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>\$ 424,193</u>	<u>\$ 548,581</u>

ALIGN TECHNOLOGY, INC.  
INVISALIGN BUSINESS METRICS\*

	Q1 2018	Q2 2018	Q3 2018	Q4 2018	Fiscal 2018	Q1 2019	Q2 2019
<b>Invisalign Average Selling Price (ASP):</b>							
Worldwide ASP	\$ 1,310	\$ 1,315	\$ 1,230	\$ 1,235	\$ 1,270	\$ 1,245	\$ 1,230
International ASP	\$ 1,435	\$ 1,425	\$ 1,340	\$ 1,295	\$ 1,370	\$ 1,330	\$ 1,305
<b>Invisalign Cases Shipped by Geography:</b>							
Americas	166,665	181,425	190,615	189,410	728,115	202,935	211,360
International	105,570	121,260	128,730	144,390	499,950	146,260	165,785
Total Cases Shipped	272,235	302,685	319,345	333,800	1,228,065	349,195	377,145
YoY % growth	30.8%	30.5%	35.3%	30.9%	31.9%	28.3%	24.6%
QoQ % growth	6.7%	11.2%	5.5%	4.5%		4.6%	8.0%
<b>Number of Invisalign Doctors Cases Were Shipped To:</b>							
Americas	27,105	28,280	28,890	29,215	42,000	30,200	31,445
International	19,700	21,805	23,270	25,475	36,040	26,510	28,970
Total Doctors Cases Shipped To	46,805	50,085	52,160	54,690	78,040	56,710	60,415
<b>Invisalign Doctor Utilization Rates**:</b>							
North America	6.3	6.6	6.9	6.7	18.2	7.0	7.0
North American Orthodontists	15.3	16.4	17.4	16.5	56.7	18.3	18.9
North American GP Dentists	3.4	3.6	3.5	3.6	9.1	3.6	3.6
International	5.4	5.6	5.5	5.7	13.9	5.5	5.7
Total Utilization Rates	5.8	6.0	6.1	6.1	15.7	6.2	6.2
<b>Number of Invisalign Doctors Trained***:</b>							
Americas	1,630	1,880	2,085	2,290	7,885	1,725	2,890
International	2,645	3,300	2,845	2,980	11,770	2,410	3,520
Total Doctors Trained Worldwide	4,275	5,180	4,930	5,270	19,655	4,135	6,410
Total to Date Worldwide	136,575	141,755	146,685	151,955	151,955	156,090	162,500

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	Q2 2019
<b>Stock-based Compensation (SBC)</b>							
SBC included in Gross Profit	\$ 881	\$ 900	\$ 966	\$ 948	\$ 3,695	\$ 1,112	\$ 1,278
SBC included in Operating Expenses	14,949	15,990	18,232	17,897	67,068	19,932	21,189
Total SBC Expense	\$ 15,830	\$ 16,890	\$ 19,198	\$ 18,845	\$ 70,763	\$ 21,044	\$ 22,467

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>Q3'19 Guidance</u>
	<u>GAAP</u>
<b>Net Revenues</b>	\$585M - \$600M
<b>Gross Margin</b>	71.9% - 72.5%
<b>Operating Expenses</b>	\$305M - \$312M
<b>Operating Margin</b>	19.8% - 20.5%
<b>Net Income per Diluted Share</b>	\$1.09 - \$1.16

**Business Metrics:**

	<u>Q3'19</u>
Case Shipments	370K - 380K
Capital Expenditure	\$50M-\$55M
Depreciation & Amortization	\$24M-\$26M
Diluted Shares Outstanding	80.6M (1)
Stock Based Compensation Expense	\$25.0M
Effective Tax Rate	~24% (2)

(1) Excludes any stock repurchases during the quarter

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