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

FORM 8-K

CURRENT REPORT

**Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934**

Date of report (Date of earliest event reported) October 23, 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 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 (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 October 23, 2019, Align Technology, Inc. ("Align") is issuing a press release and holding a conference call regarding its financial results for its third quarter ended September 30, 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
<u>99.1</u>	<u>Press Release of Align Technology, Inc. announcing its third quarter ended September 30, 2019 financial results</u>

SIGNATURES

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

Dated: October 23, 2019

Align Technology, INC.

By: /s/John F. Morici

John F. Morici

Chief Financial Officer and Senior Vice President, Global Finance

INDEX TO EXHIBITS

Exhibit No. **Description**

[99.1](#) [Press Release of Align Technology, Inc. announcing third quarter ended September 30, 2019 financial results](#)

Align Technology Announces Third Quarter 2019 Financial Results

- Q3 revenues up 20.2% year-over-year to a record \$607.3 million
- Q3 Invisalign volume up 20.7% year-over-year to 385.4 thousand cases
- Q3 scanner and services revenues up 16.5% year-over-year to \$91.1 million
- Q3 Invisalign cases for teens and kids were up 31.5% year-over-year to 129.6 thousand cases
- Q3 net profit of \$102.5 million and \$1.28 diluted EPS

SAN JOSE, Calif., Oct. 23, 2019 (GLOBE NEWSWIRE) -- Align Technology, Inc. (Nasdaq: ALGN) today reported financial results for the third quarter ended September 30, 2019. Q3'19 Invisalign volume was 385.4 thousand cases, up 20.7% year-over-year. For the Americas and International regions, Q3'19 Invisalign volume was up 13.0% and 32.1% year-over-year, respectively. Q3'19 Invisalign volume for teenage patients was 129.6 thousand cases, up 31.5% year-over-year. Q3'19 total revenues were \$607.3 million, up 20.2% year-over-year, and Q3'19 scanner and services revenues were \$91.1 million, up 16.5% year-over-year.

Q3'19 operating income was \$127.2 million or operating margin of 20.9%. Q3'19 net profit was \$102.5 million, or \$1.28 per diluted EPS. Q3'19 operating expenses included a \$6.8 million benefit from the settlement of our Invisalign Store leases, which increased Q3'19 operating margin by approximately 1.1 points and benefited diluted EPS by \$0.06. This compares to Q2'19 operating income of \$176.5 million or operating margin of 29.4% and Q2'19 net profit of \$147.1 million, or \$1.83 per diluted EPS. Q2'19 operating expenses included a \$51.0 million benefit from the ClearCorrect settlement with Straumann, which increased Q2'19 operating margin by approximately 8 points and benefited diluted EPS by \$0.57.

Commenting on Align's third quarter results, Align Technology President and CEO Joe Hogan said, "I'm pleased to report revenues, volume, and earnings above our third quarter outlook driven by better than expected volume across the Invisalign portfolio in Asia Pacific and Latin America, reflecting record highs for both regions and improving trends in the North American orthodontic channel. Notwithstanding EMEA summer seasonality, we saw continued adoption from teens and especially younger patients using Invisalign First across the board. Q3 Invisalign volumes were up 20.7% year-over-year driven by growth across the product portfolio, as well as expansion of our customer base, which increased by 6,000 new Invisalign doctors for a total of 63,000 active doctors worldwide. The iTero scanner and services business was up 16.5% year over year reflecting continue growth across each region, and down sequentially as expected coming off a record second quarter."

GAAP Summary Financial Comparisons Third Quarter Fiscal 2019

	Q3'19	Q2'19	Q3'18	Q/Q Change	Y/Y Change
Invisalign Case Shipments ¹	385,360	377,145	319,345	+2.2%	+20.7%
Net Revenues	\$607.3M	\$600.7M	\$505.3M	+1.1%	+20.2%
Clear Aligner ²	\$516.3M	\$496.7M	\$427.1M	+3.9%	+20.9%
Scanner & Services	\$91.1M	\$104.0M	\$78.2M	(12.4)%	+16.5%
Net Profit ³	\$102.5M	\$147.1M	\$100.9M	(30.3)%	+1.6%
Diluted EPS ³	\$1.28	\$1.83	\$1.24	\$(0.55)	+\$0.04

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

³ Q2'19 results include a \$51.0 million gain from Straumann litigation settlement

As of September 30, 2019, Align had \$782.4 million in cash, cash equivalents and marketable securities compared to \$765.9 million as of June 30, 2019. In July 2019, we entered into an accelerated stock repurchase agreement ("ASR") to repurchase \$200.0 million of our common stock which was completed in September 2019. We received a total of approximately 1.1 million shares for an average price of \$176.61 per share. We have \$200.5 million remaining available for repurchase under the May 2018 Repurchase Program.

Align Announcement Highlights

The following highlights recap Align's recent announcements:

Corporate

- Align recently announced exciting co-marketing relationships with the San Francisco 49ers, Carolina Hurricanes, Super Bowl winning New England Patriots, and the 2019 NBA Champions the Toronto Raptors, making the Invisalign brand the official smile partner for each of these winning teams and creating new channels for Invisalign brand marketing. Working with great sports brands is a natural fit for Align. Partnering with teams who have adopted an omnichannel approach to brand marketing and engagement gives Align direct access to large, loyal fan bases and helps us reach individual consumers and whole families through a variety of existing fan platforms: in-stadium and through televised games, online, via social media, and in each team's local community outreach programs. Align's goal is the same for each: build awareness and demand for Invisalign treatment and connect interested and engaged consumers with Invisalign practices in their markets. It's one more way that we can support doctors in this market of increased consumer choice.
- Align and Covestro AG announced that the Invisalign clear aligner system for straightening teeth, made with patented SmartTrack material, will be showcased at the K 2019 Plastics Trade Fair in Düsseldorf. The SmartTrack material solution was jointly developed by Align and Covestro.

- Align entered into and completed an ASR with Morgan Stanley & Co. LLC, to repurchase \$200 million of Align's common stock as part of Align's \$600 million stock repurchase program announced on May 23, 2018.
- Align appointed Ms. Anne Myong to the board of directors. Ms. Myong was previously Senior Vice President and Chief Financial Officer at Walmart Global eCommerce, where she accelerated the growth and digital transformation of their retail and e-commerce operations in the United States, China and Brazil.
- As part of Align's \$120 million annual commitment to raise consumer awareness of doctor directed Invisalign clear aligner treatment for better smiles, Align announced that it is a national sponsor for the premier healthy lifestyle brand Life Time.

Product

- Announced a global distribution agreement for the award-winning iTero Element family of intraoral scanners with Zimmer Biomet Dental, a global dental industry leader and provider of implant and restorative solutions and continuing education for dental professionals.
- Announced commercial availability of the iTero Element 2 scanner in China at the 2019 International Orthodontic Conference and the 18th Annual Meeting of the Chinese Orthodontic Society in Nanjing, China. The launch exemplifies Align's continued innovation and investment to advance digital dentistry in China.

Q4 2019 Business Outlook

For the fourth quarter of 2019 (Q4'19), Align provides the following guidance:

- Net revenues in the range of \$640 million to \$650 million, up approximately 20% to 22% over the same period a year ago
- Invisalign case shipments in the range of 400 thousand to 407 thousand, up approximately 20% to 22% over the same period a year ago
- Operating margin in the range of 22.0% to 22.7%
- Diluted EPS in the range of \$1.35 to \$1.42
- In addition, we expect to repurchase at least \$100 million of our stock in the open market in Q4'19

Align Web Cast and Conference Call

Align will host a conference call today, October 23, 2019 at 4:30 p.m. ET, 1:30 p.m. PT, to review its third 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 13694915 followed by #. For international callers, please dial 201-612-7415 and use the same conference number referenced above. The telephonic replay will be available through 5:30 p.m. ET on November 6, 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 for more information.

For additional information about the Invisalign system or to find an Invisalign doctor in your area, please visit www.invisalign.com. For additional information about iTero digital scanning system, please visit www.itero.com.

Forward-Looking Statement

This news release, including the tables below, contains forward-looking statements, including statements regarding certain business metrics for the fourth quarter of 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, 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 June 30, 2019, which was filed with the SEC on August 1, 2019. Align undertakes no obligation to revise or update publicly any forward-looking statements for any reason.

Align Technology

Madelyn Homick

Zeno Group:

Sarah Johnson

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

	Three Months Ended September 30,		Nine Month Ended September 30,	
	2019	2018	2019	2018
Net revenues	\$607,341	\$505,289	\$1,757,009	\$1,432,472
Cost of net revenues	169,787	133,508	485,070	367,701
Gross profit	437,554	371,781	1,271,939	1,064,771
Operating expenses:				
Selling, general and administrative	277,514	213,873	792,572	625,585
Research and development	39,680	32,700	116,034	93,095
Impairments and other (gains) charges	(6,792)	-	22,990	-
Litigation settlement gain	-	-	(51,000)	-
Total operating expenses	310,402	246,573	880,596	718,680
Income from operations	127,152	125,208	391,343	346,091
Interest income	3,478	2,234	9,576	6,327
Other income (expense), net	(2,211)	(837)	5,935	(7,759)
Net income before provision for income taxes and equity in losses of investee	128,419	126,605	406,854	344,659
Provision for income taxes	25,895	24,601	77,812	35,206
Equity in losses of investee, net of tax	-	1,132	7,528	6,610
Net income	\$102,524	\$100,872	\$ 321,514	\$ 302,843
Net income per share:				
Basic	\$ 1.29	\$ 1.26	\$ 4.03	\$ 3.78
Diluted	\$ 1.28	\$ 1.24	\$ 4.00	\$ 3.71
Shares used in computing net income per share:				
Basic	79,332	80,111	79,709	80,122
Diluted	79,825	81,359	80,397	81,538

(in thousands)

	September 30, 2019	December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 490,362	\$ 636,899
Marketable securities, short-term	292,011	98,460
Accounts receivable, net	531,816	439,009
Inventories	94,795	55,641
Prepaid expenses and other current assets	96,595	72,470
Total current assets	<u>1,505,579</u>	<u>1,302,479</u>
Marketable securities, long-term	-	9,112
Property, plant and equipment, net	606,581	521,329
Operating lease right-of-use assets, net	53,923	-
Equity method investments	-	45,913
Goodwill and intangible assets, net	77,012	81,949
Deferred tax assets	63,150	64,689
Other assets	44,135	26,987
Total assets	<u>\$ 2,350,380</u>	<u>\$ 2,052,458</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 63,300	\$ 64,256
Accrued liabilities	286,132	234,679
Deferred revenues	520,712	393,138
Total current liabilities	<u>870,144</u>	<u>692,073</u>
Income tax payable	101,914	78,008
Operating lease liabilities	43,365	-
Other long-term liabilities	29,408	29,486
Total liabilities	<u>1,044,831</u>	<u>799,567</u>
Total stockholders' equity	<u>1,305,549</u>	<u>1,252,891</u>
Total liabilities and stockholders' equity	<u>\$ 2,350,380</u>	<u>\$ 2,052,458</u>

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

Nine Months Ended September 30,	
2019	2018

CASH FLOWS FROM OPERATING ACTIVITIES

Net cash provided by operating activities	\$	529,093	\$	313,386
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CASH FLOWS FROM INVESTING ACTIVITIES

Net cash used in investing activities		(290,333)		(24,021)
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CASH FLOWS FROM FINANCING ACTIVITIES

Net cash used in financing activities		(383,163)		(315,151)
Effect of foreign exchange rate changes on cash, cash equivalents, and restricted cash		(2,098)		(2,890)
Net decrease in cash, cash equivalents, and restricted cash		(146,501)		(28,676)
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	\$	491,065	\$	421,449

ALIGN
TECHNOLOGY,
INC.
INVISALIGN
BUSINESS
METRICS*

	Q1 2018	Q2 2018	Q3 2018	Q4 2018	Fiscal 2018	Q1 2019	Q2 2019	Q3 2019
Invisalign Average Selling Price (ASP):								
Worldwide ASP	\$ 1,310	\$ 1,315	\$ 1,230	\$ 1,235	\$ 1,270	\$ 1,245	\$ 1,230	\$ 1,260
International ASP	\$ 1,435	\$ 1,425	\$ 1,340	\$ 1,295	\$ 1,370	\$ 1,330	\$ 1,305	\$ 1,330
Invisalign Cases Shipped by Geography:								
Americas	166,665	181,425	190,615	189,410	728,115	202,935	211,360	215,355
International	105,570	121,260	128,730	144,390	499,950	146,260	165,785	170,005
Total Cases Shipped	272,235	302,685	319,345	333,800	1,228,065	349,195	377,145	385,360
YoY % growth	30.8%	30.5%	35.3%	30.9%	31.9%	28.3%	24.6%	20.7%
QoQ % growth	6.7%	11.2%	5.5%	4.5%		4.6%	8.0%	2.2%
Number of Invisalign Doctors Cases Were Shipped To:								
Americas	27,105	28,280	28,890	29,215	42,000	30,200	31,445	31,975
International	19,700	21,805	23,270	25,475	36,040	26,510	28,970	30,980

Total Doctors Cases Shipped To	46,805	50,085	52,160	54,690	78,040	56,710	60,415	62,955
Invisalign Doctor Utilization Rates**:								
North America	6.3	6.6	6.9	6.7	18.2	7.0	7.0	7.0
North American Orthodontists	15.3	16.4	17.4	16.5	56.7	18.3	18.9	19.1
North American GP Dentists	3.4	3.6	3.5	3.6	9.1	3.6	3.6	3.5
International	5.4	5.6	5.5	5.7	13.9	5.5	5.7	5.5
Total Utilization Rates	5.8	6.0	6.1	6.1	15.7	6.2	6.2	6.1
Number of Invisalign Doctors Trained:								
Americas	1,630	1,880	2,085	2,290	7,885	1,840	3,070	2,760
International	2,645	3,300	2,845	2,980	11,770	2,410	3,520	3,135
Total Doctors Trained Worldwide	4,275	5,180	4,930	5,270	19,655	4,250	6,590	5,895
Total to Date Worldwide	136,575	141,755	146,685	151,955	151,955	156,205	162,795	168,690

* 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 2018	Q2 2018	Q3 2018	Q4 2018	Fiscal 2018	Q1 2019	Q2 2019	Q3 2019
Stock-based Compensation (SBC)								
SBC included in Gross Profit	\$ 881	\$ 900	\$ 966	\$ 948	\$ 3,695	\$ 1,112	\$ 1,278	\$ 1,354
SBC included in Operating Expenses	14,949	15,990	18,232	17,897	67,068	19,932	21,189	22,822
Total SBC	<u>\$ 15,830</u>	<u>\$ 16,890</u>	<u>\$ 19,198</u>	<u>\$ 18,845</u>	<u>\$ 70,763</u>	<u>\$ 21,044</u>	<u>\$ 22,467</u>	<u>\$ 24,176</u>

ALIGN TECHNOLOGY, INC.
BUSINESS OUTLOOK SUMMARY
(unaudited)

The outlook figures provided below and elsewhere in this press release are approximate in nature since Align's business outlook is difficult to predict. Align's future performance involves numerous risks and uncertainties and the company's results could differ materially from the outlook provided. Some of the factors that could affect Align's future financial performance and business outlook are set forth under "Forward Looking Information" above in this press release.

Financial Outlook

(in millions, except per share amounts and percentages)

	Q4'19 Guidance
	GAAP
Net Revenues	\$640 - \$650
Gross Margin	71.7% - 72.4%
Operating Expenses	\$318 - \$323
Operating Margin	22.0% - 22.7%
Net Income per Diluted Share	\$1.35 - \$1.42

Business Metrics:

	Q4'19
Case Shipments	400K - 407K
Capital Expenditure	\$30M-\$35M
Depreciation & Amortization	\$22M-\$24M
Diluted Shares Outstanding	79.4M (1)
Stock Based Compensation Expense	\$24.0M
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

