

ALIGN TECHNOLOGY INC

FORM 8-K (Current report filing)

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Address	2560 ORCHARD PARKWAY SAN JOSE, CA, 95131
Telephone	4087381500
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Industry	Medical Equipment, Supplies & Distribution
Sector	Healthcare
Fiscal Year	12/31

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: October 26, 2017
(Date of earliest event reported)

Align Technology, Inc.
(Exact name of registrant as specified in its charter)

DE
(State or other jurisdiction of incorporation)

0-32259
(Commission File Number)

94-3267295
(IRS Employer Identification Number)

2820 Orchard Parkway, San Jose, CA
(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:

- 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 Condition

On October 26, 2017, 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, 2017. 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

[Press Release of Align Technology, Inc. dated October 26, 2017](#)

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.

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

Dated: October 26, 2017

Exhibit Index

Exhibit No.
99.1

Description
Press Release of Align Technology, Inc. dated October 26, 2017

Align Technology Announces Record Third Quarter 2017 Results

SAN JOSE, CA -- (Marketwired - October 26, 2017) -

-- Q3 revenues up 38.3% year-over-year, up 8.1% sequentially to a record \$385.3 million

-- Q3 total Invisalign case shipments up 32.8% year-over-year to 236.1 thousand

-- Q3 Invisalign case shipments to teenage patients up 46.3% year-over-year, up 26.5% sequentially

-- Q3 scanner and services revenues up 25.0% year-over-year, up 23.2% sequentially to \$43.7 million

-- Q3 diluted EPS \$1.01, up 60.3% year-over-year

Align Technology, Inc. (NASDAQ: ALGN) today reported financial results for the third quarter ended September 30, 2017. Invisalign case shipments in the third quarter of 2017 (Q3'17) were 236.1 thousand, a 32.8% increase year-over-year. North America and International case shipments were up year-over-year 25.0% and 47.4%, respectively. Q3'17 Invisalign case shipments to teenage patients were 69.8 thousand, a 46.3% increase year-over-year. For Q3'17, revenues were \$385.3 million, a 38.3% increase year-over-year, and net profit was \$82.6 million, or \$1.01 per diluted share, up 60.3% per diluted share compared to the same period in the prior year.

Commenting on Align's Q3 2017 results, Align Technology President and CEO Joe Hogan said, "I'm pleased to report another strong quarter and results that exceeded our expectations across our key financial metrics including revenue, volume, margins, and EPS. Third quarter revenues increased 38.3% year-over-year driven by increased Invisalign volumes across all our geographies, as well as strong growth from iTero scanners. Our strong third quarter results also reflect accelerated growth from teenager patients in both North America and the Asia Pacific region, with total Invisalign shipments up 46.3% year-over-year and up 26.5% from the second quarter. On a sequential basis, revenues increased 8.1% driven by continued strength across Asia Pacific, which offset expected seasonality in Europe, as well as higher than expected revenues from shipments to SmileDirectClub."

GAAP Summary Financial Comparisons
Third Quarter Fiscal 2017

Q3'17 Q2'17 Q3'16 Q/Q Change Y/Y Change

Invisalign Case

Shipments* 236,065 231,890 177,755 +1.8% +32.8%

Net Revenues \$385.3M \$356.5M \$278.6M +8.1% +38.3%

Clear Aligner** \$341.6M \$321.0M \$243.7M +6.4% +40.2%

Scanner & Services \$43.7M \$35.4M \$34.9M +23.2% +25.0%

Net Profit \$82.6M \$69.2M \$51.4M +19.3% +60.7%

Diluted EPS \$1.01 \$0.85 \$0.63 +\$0.16 +\$0.38

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

* Invisalign Shipment figures do not include SmileDirectClub aligners

** Clear aligner revenue includes revenues from Invisalign clear aligners and SmileDirectClub aligners

As of September 30, 2017, Align had \$737.9 million in cash, cash equivalents and marketable securities compared to \$676.6 million as of June 30, 2017. During Q3'17, Align concluded its previously announced \$50.0 million accelerated stock repurchase program (ASR) receiving a total of 0.4 million shares at a weighted average share price of \$146.48 under the ASR. We have \$250.0 million remaining available for repurchases under the existing stock repurchase authorization.

Q3 2017 Business Highlights

-- Align Technology Introduces a New Brand Identity for iTero® Scanning

System and Tools: Align announced a new global brand identity for the company's leading iTero® scanning system and innovative tools at the recent bi-annual Invisalign GP Summit customer event. The introduction of a new, vibrant brand identity for the iTero scanner reflects its critical and central role in digital treatment and the practice of the future.

-- Patterson Dental and Align Technology Announce Distribution Agreement

for iTero® Element Intraoral Scanning System: Align announced a distribution agreement for Align's iTero Element intraoral scanning system. This agreement provides access to Patterson's sales force and general dentist customers who are looking to grow their business through practice digitization. The iTero scanner enables dentists to scan in as little as 60 seconds, visualize changes in dentition, and perform restorative and orthodontic workflows that enhance their patient care and help them grow their practice.

-- Align Technology Moves Corporate Headquarters to New Buildings in San

Jose, California: In August, Align relocated its corporate headquarters to a new location at 2820 Orchard Parkway, San Jose, CA. The Company had purchased the new buildings in January 2017 in anticipation of the lease expiration for its prior location.

-- Align Technology Expands Its Presence in Raleigh, North Carolina with

Larger Office to Support Continued Headcount Growth: Align has opened a larger office in Raleigh, North Carolina to accommodate headcount growth and leverage the area's diverse and broad-based talent resources. Align intends to hire more than 200 employees over the next several years in Raleigh in various areas illustrating its commitment to driving continued innovation and supporting its expanding customer base globally.

-- Align Technology Opens First Office in Canada to Support Continued

Growth: In August, Align opened its' first office in Canada to support continued growth across the region. Canada is Align's second largest country market and has a large opportunity for expansion and accelerated growth. Sian Roberts, who joined Align earlier this year as VP and General Manager, will lead the strategy and execution for Canada.

Q4 2017 Business Outlook
For the fourth quarter of 2017 (Q4'17), Align provides the following guidance:

-- Invisalign case shipments in the range of 245 thousand to 250 thousand, up approximately 29% to 32% over the same period a year ago.
-- Net revenues in the range of \$391 million to \$398 million, up approximately 33% to 36% over the same period a year ago.
-- Diluted EPS in the range of \$0.92 to \$0.95.

Align Web Cast and Conference Call

Align will host a conference call today, October 26, 2017 at 4:30 p.m. ET, 1:30 p.m. PT, to review its third quarter 2017 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 13671493 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 9, 2017.

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 fourth quarter of 2017, 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, 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, 2016, which was filed with the Securities and Exchange Commission (SEC) on February 28, 2017, and its latest Quarterly Report on Form 10-Q for the quarter ended June 30, 2017, which was filed with the SEC on August 3, 2017. 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 Nine Months Ended

September 30, September 30, September 30, September 30,

2017 2016 2017 2016

Net revenues \$ 385,267 \$ 278,589 \$ 1,052,090 \$ 786,671

Cost of net revenues 92,779 69,387 253,060 191,626

Gross profit 292,488 209,202 799,030 595,045

Operating expenses:

Selling, general

and administrative 169,524 126,708 483,636 360,385

Research and

development 24,201 20,415 71,389 54,111

Total operating

expenses 193,725 147,123 555,025 414,496

Income from

operations 98,763 62,079 244,005 180,549

Interest and other

income (expense),

net 3,750 1,463 8,607 1,161

Net income before

provision for

income taxes and

equity in losses of

investee 102,513 63,542 252,612 181,710

Provision for income

taxes 18,344 11,698 26,508 39,172

Equity in losses of

investee, net of

tax 1,614 477 4,950 477

Net income \$ 82,555 \$ 51,367 \$ 221,154 \$ 142,061

Net income per
share:
Basic \$ 1.03 \$ 0.64 \$ 2.76 \$ 1.78

Diluted \$ 1.01 \$ 0.63 \$ 2.71 \$ 1.74

Shares used in
computing net
income per share:
Basic 80,163 79,977 80,086 79,920

Diluted 81,789 81,466 81,757 81,523

ALIGN TECHNOLOGY, INC.

UNAUDITED CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands)

September 30, December 31,

2017 2016

ASSETS

Current assets:

Cash and cash equivalents \$ 362,613 \$ 389,275

Marketable securities, short-term 316,454 250,981

Accounts receivable, net 321,328 247,415

Inventories 36,941 27,131

Prepaid expenses and other current assets 63,667 38,176

Total current assets 1,101,003 952,978

Marketable securities, long-term 58,842 59,783

Property, plant and equipment, net 295,901 175,167

Equity method investments 52,875 45,061

Goodwill and intangible assets, net 90,070 81,998

Deferred tax assets 73,532 67,844

Other assets 25,400 13,320

Total assets \$ 1,697,623 \$ 1,396,151

LIABILITIES AND STOCKHOLDERS' EQUITY

Current liabilities:

Accounts payable \$ 45,942 \$ 28,596

Accrued liabilities 173,851 134,332

Deferred revenues 241,576 191,407

Total current liabilities 461,369 354,335

Income tax payable 45,375 45,133

Other long-term liabilities 8,921 1,294

Total liabilities 515,665 400,762

Total stockholders' equity 1,181,958 995,389

Total liabilities and stockholders' equity \$ 1,697,623 \$ 1,396,151

ALIGN TECHNOLOGY, INC.

INVISALIGN BUSINESS METRICS*

Q1 Q2 Q3 Q4

2016 2016 2016 2016

Invisalign Average Selling Price (ASP):

Worldwide ASP \$ 1,255 \$ 1,285 \$ 1,285 \$ 1,230

International ASP \$ 1,315 \$ 1,345 \$ 1,365 \$ 1,315

Invisalign Cases Shipped by Geography:

North America 110,500 114,855 115,900 122,555

International 53,195 62,140 61,855 67,500

Total Cases Shipped 163,695 176,995 177,755 190,055

YoY % growth 25.2% 22.4% 20.5% 18.5%

QoQ % growth 2.1% 8.1% 0.4% 6.9%

Number of Invisalign Doctors Cases Were

Shipped To:

North America 22,355 22,575 22,570 23,265

International 11,280 12,485 12,720 13,635

Total Doctors Cases Shipped To 33,635 35,060 35,290 36,900
=====

Invisalign Doctor Utilization Rates*:

North America 4.9 5.1 5.1 5.3

North American Orthodontists 10.4 10.7 11.1 11.3

North American GP Dentists 3.0 3.1 3.0 3.2

International 4.7 5.0 4.9 5.0

Total Utilization Rates 4.9 5.1 5.0 5.2

* # of cases shipped/# of doctors to

whom cases were shipped

Number of Invisalign Doctors Trained:

North America 875 1,125 1,300 1,420

International 1,605 1,760 1,315 2,280

Total Doctors Trained Worldwide 2,480 2,885 2,615 3,700
=====

Total to Date Worldwide 106,270 109,155 111,770 115,470
=====

Fiscal Q1 Q2 Q3

2016 2017 2017 2017

Invisalign Average Selling Price (ASP):

Worldwide ASP \$ 1,265 \$ 1,270 \$ 1,285 \$ 1,310

International ASP \$ 1,335 \$ 1,325 \$ 1,335 \$ 1,390

Invisalign Cases Shipped by Geography:

North America 463,810 132,885 146,510 144,870

International 244,690 75,175 85,380 91,195

Total Cases Shipped 708,500 208,060 231,890 236,065
=====

YoY % growth 21.5% 27.1% 31.0% 32.8%

QoQ % growth 9.5% 11.5% 1.8%

Number of Invisalign Doctors Cases Were

Shipped To:

North America 34,065 23,910 24,695 24,845

International 20,415 14,955 16,570 17,760

Total Doctors Cases Shipped To 54,480 38,865 41,265 42,605
=====

Invisalign Doctor Utilization Rates*:

North America 13.6 5.6 5.9 5.8

North American Orthodontists 36.6 12.6 13.6 13.8

North American GP Dentists 7.6 3.1 3.3 3.1

International 12.0 5.0 5.2 5.1

Total Utilization Rates 13.0 5.4 5.6 5.5

* # of cases shipped/# of doctors to

whom cases were shipped

Number of Invisalign Doctors Trained:

North America 4,720 980 1,620 1,460

International 6,960 2,280 3,255 2,820

Total Doctors Trained Worldwide 11,680 3,260 4,875 4,280
=====

Total to Date Worldwide 115,470 118,730 123,605 127,885
=====

Note: Historical public data may differ due to rounding. Additionally,
rounding may affect totals.

*Invisalign business metrics exclude SmileDirectClub aligners.

ALIGN TECHNOLOGY, INC.

STOCK-BASED COMPENSATION

(in thousands)

Q1 Q2 Q3 Q4

2016 2016 2016 2016

Stock-based Compensation (SBC)

SBC included in Gross Profit \$ 961 \$ 932 \$ 995 \$ 1,078

SBC included in Operating Expenses 11,563 12,767 12,716 13,136

Total SBC Expense \$ 12,524 \$ 13,699 \$ 13,711 \$ 14,214
=====

Fiscal Q1 Q2 Q3

2016 2017 2017 2017

Stock-based Compensation (SBC)

SBC included in Gross Profit \$ 3,966 \$ 925 \$ 768 \$ 833

SBC included in Operating Expenses 50,182 13,887 13,477 14,134

Total SBC Expense \$ 54,148 \$ 14,812 \$ 14,245 \$ 14,967
=====

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)

Q4'17 Guidance

GAAP

Net Revenues \$391 - \$398

Gross Margin 75.0% - 75.5%

Operating Expenses \$198 - \$202

Operating Margin 24.3% - 24.8%

Net Income per Diluted Share \$0.92 - \$0.95 (1)

Business Metrics: Q4'17

Case Shipments 245K - 250K

Capital Expenditure \$55M - \$60M

Depreciation & Amortization \$10.5M - \$11M

Diluted Shares Outstanding 81.9M (2)

Stock Based Compensation Expense \$15.3M

Effective Tax Rate 22% (1)

(1) Includes the benefit from the adoption of the new accounting standard update for share-based compensation

(2) Excludes any stock repurchases during the quarter

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