

ALIGN TECHNOLOGY INC

FORM 8-K (Current report filing)

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Address	2560 ORCHARD PARKWAY SAN JOSE, CA 95131
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Sector	Healthcare
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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: July 27, 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)

2560 Orchard Parkway, San Jose, CA
(Address of principal executive offices)

95131
(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 July 27, 2017, 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, 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 July 27, 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.

Dated: July 27, 2017

Align Technology, Inc.

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

Exhibit Index

Exhibit No.
99.1

Description
Press Release of Align Technology, Inc. dated July 27, 2017

Align Technology Announces Record Second Quarter 2017 Results

SAN JOSE, CA -- (Marketwired - July 27, 2017) -

-- Q2 revenues up 32.3% year-over-year, up 14.9% sequentially to a record

\$356.5 million

-- Q2 Invisalign case shipments for North America and International were up

year-over-year 27.6% and 37.4%, respectively

-- Q2 Invisalign case shipments to teenage patients up 37.6% year-over-

year, up 12.6% sequentially reaching a milestone of 1 million teen

patients who have started Invisalign treatment

-- Q2 diluted EPS \$0.85, up 37.1% year-over-year

Align Technology, Inc. (NASDAQ: ALGN) today reported financial results for the second quarter ended June 30, 2017. Invisalign case shipments in the second quarter of 2017 (Q2'17) were 231.9 thousand, a 31.0% increase year-over-year. For Q2'17, revenues were \$356.5 million, a 32.3% increase year-over-year, and net profit was \$69.2 million, or \$0.85 per diluted share, up 37.1% per diluted share compared to the same period in the prior year.

Commenting on Align's Q2 2017 results, Align Technology President and CEO Joe Hogan said, "Our second quarter results were better than expected across key financial metrics including revenue, volume, margins, and EPS. Q2 revenues increased 32.3% year-over-year driven by strong Invisalign case shipments across all channels and especially in the teen segment. Solid execution of our strategy and key investments continue to deliver strong growth across the board, with record Invisalign volume in almost every geography. The second quarter also had an all-time high of nearly 5,000 newly trained Invisalign doctors in a quarter. Our iTero scanner business also performed well this quarter with revenues up 36.7% year-over-year."

GAAP Summary Financial Comparisons

Second Quarter Fiscal 2017

Q2'17 Q1'17 Q2'16 Q/Q Change Y/Y Change

Invisalign Case Shipments* 231,890 208,060 176,995 +11.5% +31.0%

Net Revenues \$356.5M \$310.3M \$269.4M +14.9% +32.3%

Clear Aligner** \$321.0M \$282.4M \$243.4M +13.7% +31.9%

Scanner & Services \$35.4M \$27.9M \$25.9M +26.9% +36.7%

Net Profit \$69.2M \$69.4M \$50.1M (0.3)% +37.9%

Diluted EPS \$0.85 \$0.85 \$0.62 \$0.00 +\$0.23

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

* Invisalign Shipment figures does not include SmileDirectClub aligners

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

As of June 30, 2017, Align had \$676.6 million in cash, cash equivalents and marketable securities compared to \$644.2 million as of March 31, 2017. During Q2'17, we paid \$50 million under an accelerated stock repurchase plan ("ASR") in which we received an initial delivery of approximately 0.3 million shares of common stock. The final number of shares repurchased will be determined at completion of the ASR based on Align's volume-weighted average stock price during the term of the ASR, less an agreed upon discount. There remains approximately \$250 million available for repurchases under the existing stock repurchase authorization.

On July 24, 2017, Align increased the revolving line of credit with SmileDirectClub, LLC to \$30.0 million and purchased an additional 2% equity interest in SmileDirectClub for \$12.8 million. As a result of this purchase, the Company now holds a 19% equity interest, on a fully diluted basis. Additionally, on July 24, 2017, Align entered into an agreement to purchase a new facility in Costa Rica for \$26.1 million.

Q2 2017 Business Highlights

The following list highlights Align's key announcements for the second quarter:

-- Opens New Invisalign Treatment Planning Facility in Chengdu, China:

Align announced its first manufacturing operations in China and represents the Company's commitment to geographic expansion and investment in the Asia Pacific region. The Chengdu Treatment Planning and Training Centre of Excellence will provide treatment planning services for Invisalign providers in China.

-- Launched TimeLapse Technology for Scan Comparisons and 1 Minute Scan:

Align announced a software upgrade for its iTero Element® intraoral scanners that includes the ability to compare patient scans over time with the new TimeLapse technology, providing general practitioner dentists and orthodontists with enhanced visualization, assessment and communication tools. In addition, with the 1.5 software upgrade, patient scans can be completed in as little as 1 minute.

-- Receives U.S. Patents for SmartTrack Material: Align announced that two

U.S. Patents, Nos. 9,655,691 and 9,655,693, have been issued by the United States Patent and Trademark Office (USPTO) for SmartTrack aligner material, used exclusively for Invisalign aligner treatment. Launched commercially in 2013, Align's proprietary SmartTrack material is an innovative multi-layer polymer that delivers more gentle, constant force to improve control of tooth movements with Invisalign clear aligners.

-- Reaches 1 Million Invisalign Teen-aged Patients: Align announced that 1

million teenage patients have started treatment with Invisalign, the most advanced clear aligner system in the world. This is a significant accomplishment for the company and its more than 100,000 Invisalign-trained doctors, reflecting increasing preference for Invisalign clear aligners for teenage orthodontic treatment.

-- Global Funding Awarded Toward Advancing Orthodontic and Dental Research:

Align announced twelve recipients of research grants under the company's

Annual Research Award Program. Now in its eighth year of funding, nearly

\$300,000 is being awarded for 2017 to researchers at universities in

North America, Europe and Asia Pacific.

-- Launched Invisalign Brand Marketing Campaign: Align announced that it

has launched a comprehensive, multi-million dollar marketing campaign

for its Invisalign brand designed to challenge metal braces as the

status quo method for straightening teen teeth.

Q3 2017 Business Outlook

For the third quarter of 2017 (Q3'17), Align provides the following guidance:

-- Invisalign case shipments in the range of 231 thousand to 234 thousand,

up approximately 30% to 32% over the same period a year ago.

-- Net revenues in the range of \$355 million to \$360 million, up

approximately 27% to 29% over the same period a year ago.

-- Diluted EPS in the range of \$0.78 to \$0.81, which includes \$0.01 of

excess tax benefit.

Align Web Cast and Conference Call

Align will host a conference call today, July 27, 2017 at 4:30 p.m. ET, 1:30 p.m. PT, to review its second 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 13665263 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 10, 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 third 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 Quarterly Report on Form 10-Q for the quarter ended March 31, 2017, which was filed with the SEC on May 4, 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 Six Months Ended

June 30, June 30, June 30, June 30,

2017 2016 2017 2016

Net revenues \$ 356,482 \$ 269,362 \$ 666,823 \$ 508,082

Cost of net revenues 85,565 64,146 160,281 122,239

Gross profit 270,917 205,216 506,542 385,843

Operating expenses:

Selling, general and

administrative 162,964 121,467 314,112 233,677

Research and development 24,384 18,613 47,188 33,696

Total operating expenses 187,348 140,080 361,300 267,373

Income from operations 83,569 65,136 145,242 118,470

Interest and other income

(expense), net 3,212 125 4,857 (302)

Net income before provision

for income taxes and equity

in losses of investee 86,781 65,261 150,099 118,168

Provision for income taxes 15,387 15,113 8,164 27,474

Equity in losses of

investee, net of tax 2,215 - 3,336 -

Net income \$ 69,179 \$ 50,148 \$ 138,599 \$ 90,694

Net income per share:

Basic \$ 0.86 \$ 0.63 \$ 1.73 \$ 1.14

Diluted \$ 0.85 \$ 0.62 \$ 1.70 \$ 1.11

Shares used in computing net

income per share:

Basic 80,188 79,951 80,047 79,891

Diluted 81,631 81,281 81,668 81,440

ALIGN TECHNOLOGY, INC.

UNAUDITED CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands)

June 30, December 31,

2017 2016

ASSETS

Current assets:

Cash and cash equivalents \$ 358,182 \$ 389,275

Marketable securities, short-term 243,786 250,981

Accounts receivable, net 291,694 247,415

Inventories 35,133 27,131

Prepaid expenses and other current

assets 74,427 38,176

Total current assets 1,003,222 952,978

Marketable securities, long-term 74,619 59,783

Property, plant and equipment, net 255,539 175,167

Equity method investments 41,724 45,061

Goodwill and intangible assets, net 91,308 81,998

Deferred tax assets 61,783 67,844

Other assets 22,992 13,320

Total assets \$ 1,551,187 \$ 1,396,151

LIABILITIES AND STOCKHOLDERS' EQUITY

Current liabilities:

Accounts payable \$ 45,953 \$ 28,596

Accrued liabilities 158,838 134,332

Deferred revenues 220,005 191,407

Total current liabilities 424,796 354,335

Income tax payable 44,581 45,133

Other long term liabilities 3,522 1,294

Total liabilities 472,899 400,762

Total stockholders' equity 1,078,288 995,389

Total liabilities and

stockholders' equity \$ 1,551,187 \$ 1,396,151

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

ALIGN TECHNOLOGY, INC.

STOCK-BASED COMPENSATION

(in thousands)

Fiscal Q1 Q2	2016 2017 2017
Stock-based Compensation (SBC)	
SBC included in Gross Profit	\$ 3,966 \$ 925 \$ 768
SBC included in Operating Expenses	50,182 13,887 13,477
Total SBC Expense	
	\$ 54,148 \$ 14,812 \$ 14,245

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	International
	22,355 22,575 22,570 23,265	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	North American Orthodontists	North American GP Dentists	International
	4.9 5.1 5.1 5.3	10.4 10.7 11.1 11.3	3.0 3.1 3.0 3.2	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	International
	875 1,125 1,300 1,420	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

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

*Invisalign business metrics exclude SmileDirectClub aligners.

Fiscal Q1 Q2	2016 2017 2017
\$ 1,265 \$ 1,270 \$ 1,285	
\$ 1,335 \$ 1,325 \$ 1,335	
463,810 132,885 146,510	
244,690 75,175 85,380	

708,500 208,060 231,890

21.5% 27.1% 31.0%

9.5%	11.5%
34,065	23,910 24,695
20,415	14,955 16,570

54,480	38,865 41,265
=====	
13.6	5.6 5.9
36.6	12.6 13.6
7.6	3.1 3.3
12.0	5.0 5.2
13.0	5.4 5.6
* # of cases shipped/# of doctors to whom	
cases were shipped	
4,720	980 1,620
6,960	2,280 3,255

11,680	3,260 4,875
=====	
115,470	118,730 123,605
=====	

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

*Invisalign business metrics exclude SmileDirectClub aligners.

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)

Q3'17 Guidance

GAAP

Net Revenues \$355.0 - \$360.0
Gross Margin 74.7% - 75.7%
Operating Expenses \$184.5 - \$187.5
Operating Margin 22.7% - 23.6%
Net Income per Diluted Share \$0.78 - \$0.81 (1)
Business Metrics: Q3'17

Case Shipments 231.0K - 234.0K
Capital Expenditure \$70M - \$75M
Depreciation & Amortization \$9.5M - \$10.0M
Diluted Shares Outstanding 81.8M* (2)
Stock Based Compensation Expense \$14.9M
Effective Tax Rate 21.0% (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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