# 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: April 23, 2015** (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:

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

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

On April 23, 2015, 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, 2015. 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

99.1 Press Release of Align Technology, Inc. dated April 23, 2015

# **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: April 23, 2015 ALIGN TECHNOLOGY, INC.

By: <u>/s/ Roger E. George</u> Roger E. George

Vice President, Legal and Corporate Affairs and General

Counsel

# **Exhibit Index**

Exhibit No.

**Description** 

99.1

Press Release of Align Technology, Inc. dated April 23, 2015

## **Align Technology Announces First Quarter 2015 Results**

SAN JOSE, CA -- (Marketwired - April 23, 2015) - Align Technology (NASDAQ: ALGN)

- Q1 revenues of \$198 million, up 10% year-over-year, and diluted EPS of \$0.44
- Q1 worldwide Clear Aligner shipments of 131 thousand cases, up 17% year-over-year, with North America up 12% and International up 29%

Align Technology, Inc. (NASDAQ: ALGN) today reported financial results for the first quarter ended March 31, 2015. Revenues for the first quarter of 2015 (Q1'15) were \$198.1 million, a 9.7% increase year-over-year from \$180.6 million in the first quarter of 2014 (Q1'14). Clear Aligner case shipments in Q1'15 were 130.8 thousand, a 16.6% increase year-over-year from 112.2 thousand in Q1'14. Net profit for Q1'15 was \$36.2 million, or \$0.44 per diluted share, compared to \$32.4 million, or \$0.39 per diluted share in Q1'14. Q1'15 operating income included a one-time benefit of \$6.8 million from a refund of Medical Device Excise Taxes paid in 2013, contributing \$0.06 per diluted share, net of tax.

"Our first quarter was a bit stronger than we expected, getting us off to a good start to the year. This progress was driven by continued strong year-over-year growth from our International team and solid improvement in our North American business as well," said Thomas M. Prescott, Align president and CEO. "We are pleased to have delivered better than expected results with strong revenues, margins, and EPS, driven primarily by higher Invisalign volume from our North American orthodontists."

## **Summary Financial Comparisons**

(In millions except for shipments and per share amounts)

		Q1'15	 Q4'14	 Q1'14	 Q/Q	Υ,	/Y
GAAP				 			
Clear Aligner shipments	1	30,780	.26,905	.12,180	 3.1%	16	. 6%
Net revenues	\$	198.1	\$ 198.6	\$ 180.6	(0.3)%	9.	. 7%
Clear Aligner	\$	187.0	\$ 186.4	\$ 168.2	0.3%	11.	. 2%
Scanner & Services	\$	11.1	\$ 12.2	\$ 12.4	(9.1)%	(10.	.9)%
Net profit	\$	36.2	\$ 39.5	\$ 32.4	(8.5)%	11.	. 5%
Diluted EPS	\$	0.44	\$ 0.48	\$ 0.39	\$ (0.04) \$	0.0	95

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

As of March 31, 2015, Align had \$613.0 million in cash, cash equivalents and short-term and long-term marketable securities compared to \$602.6 million as of December 31, 2014. We repurchased approximately 0.03 million shares of stock for \$1.8 million in Q1'15. These repurchases were part of a three-year, \$300 million stock repurchase program announced on April 23, 2014 of which the first \$100 million of the program was completed in Q1'15.

# **Q2 2015 Business Outlook**

For the second quarter of 2015 (Q2'15), Align provides the following guidance:

- Clear Aligner case shipments in a range of 139.5 thousand to 142.0 thousand, up approximately 18% over the same period a year-ago at the mid-point of the range and above our three-year average.
- Net revenues in a range of \$206.6 million to \$210.4 million.
- Diluted EPS in a range of \$0.35 to \$0.38.

# **Align Web Cast and Conference Call**

Align will host a conference call today, April 23, 2015 at 4:30 p.m. ET, 1:30 p.m. PT, to review its first quarter 2015 results, discuss future operating trends and the business outlook. The conference call will also be web cast live via the Internet. To access the web cast, 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 approximately fifteen minutes prior to the start of the call. 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 13605393 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 April 30, 2015.

#### About Align Technology, Inc.

Align Technology is the leader in modern clear aligner orthodontics that designs, manufactures and markets the Invisalign® system, which provides dental professionals with a range of treatment options for adults and teenagers. Align also offers the iTero 3D digital scanning system and services for orthodontic and restorative dentistry. Align was founded in March 1997 and received FDA clearance to market the Invisalign system in 1998. 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 the iTero 3D 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 second quarter of 2015, including, but not limited to, anticipated net revenues, gross margin, operating expenses, operating profit, diluted earnings per share, case shipments, and additional common stock repurchases. 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, 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, 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, our ability to successfully achieve the anticipated benefits from the scanner and services business, 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 protect its intellectual property rights, continued compliance with regulatory requirements, competition from existing and new competitors, 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, 2014, which was filed with the Securities and Exchange Commission on February 26, 2015. Align undertakes no obligation to revise or update publicly any forward-looking statements for any reason.

Three Months Ended

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

	inree Months Ended		
	March 31, March 31, 2015 2014		
Net revenues	\$ 198,086 \$ 180,646		
Cost of revenues	46,996 43,395		
Gross profit	151,090 137,251		
Operating expenses: Selling, general and adminstrative Research and development	88,281 82,067 13,885 13,380		
Total operating expenses	102,166 95,447		
Operating profit	48,924 41,804		
Interest and other income (expense), net	(1,452) 601		
Profit before income taxes	47,472 42,405		
Provision for income taxes	11,295 9,961		
Net profit	\$ 36,177 \$ 32,444 ==================================		
Net profit per share - basic - diluted	\$ 0.45 \$ 0.40 ===================================		
Shares used in computing net profit per share - basic	80,459 81,120 ====================================		
- diluted	81,824 82,817 ====================================		

				March 31, 2015		2014
ASSETS			-			
Current assets: Cash and cash equivalents Marketable securities, short-te Accounts receivable, net Inventories Prepaid expenses and other curr		assets	\$	189,978 254,823 138,159 14,572 59,780		199,871 254,787 129,751 15,928 56,823
Total current assets			-			657,160
Marketable securities, long-term Property, plant and equipment, no Goodwill and intangible assets, n Deferred tax assets Other assets			-	99,764 81,274 14,630 7,254		147,892 90,125 82,056 3,099 7,665
Total assets				1,028,405 ======		987,997 ======
LIABILITIES AND STOCKHOLDER	RS' E	QUITY				
Current liabilities: Accounts payable Accrued liabilities Deferred revenues			\$	24,996 81,711 93,868	\$	23,247 87,880 90,684
Total current liabilities						201,811
Other long term liabilities			-	34,296		33,415
Total liabilities				234,871		235, 226
Total stockholders' equity			_	793,534		752,771
Total liabilities and stockholo	lers'	equity		1,028,405 ======		
ALIGN TECHNOLOGY, INC. Q1 2015 FINANCIAL AND BUSINESS ME (in thousands except average sell			liz	ation and do	cto	rs trained)
		Q1 2014		Q2 2014		Q3 2014
Invisalign Clear Aligner Net Revenues by Geography: North America International Non-case*	\$	107,910 49,848 10,481		111,648 55,988 12,099	\$	113,349 53,439 11,350
Total Clear Aligner Net Revenues	\$	168,239	\$	179,735		
YoY % growth QoQ % growth *includes Invisalign training, ancillary products, and retainers	===	18.8% 1.2%		17.2% 6.8%		 16.0% -0.9%
Average Invisalign Selling Price (ASP):						
Worldwide ASP	\$	1 405	\$	1.405	\$	1.395

Worldwide ASP International ASP

International

Invisalign Clear Aligner Cases Shipped by Geography: North America \$ 1,405 \$ 1,405 \$ 1,395 \$ 1,620 \$ 1,625 \$ 1,560

> 84,850 34,450

85,405 34,210

81,420 30,760

Total Cases Shipped	==:			119,300		119,615
Number of Invisalign Doctors Cases Shipped To: North America International		19,015 7,185		19,505 7,685		19,550 7,950
Total Doctors Cases Shipped To	)	26,200		27,190		7,950  27,500
Invisalign Doctor Utilization Rates*: North America						
North American Orthodontists North American GP Dentists International		4.3		2.9 4.5		
Total Utilization Rates		4.3		4.4		4.4
<pre>* # of cases shipped/# of doctors to whom cases were shipped</pre>	==:	======	= ==	=======	==	=======
Number of Invisalign Doctors Trained: North America		700		1,150		1,125
International		1,255		1,380		1,125 1,400
Total Doctors Trained Worldwid	le ==:	1,955 =======	= ==	2,530 ======	==	2,525 =======
Total to Date Worldwide	==:			89,045 ======		91,570
Total Net Revenues: Clear Aligner Net Revenues Scanner & Services Net Revenues	\$	168,239 12,407	\$	179,735 12,796	\$	178,138 11,738
Total Worldwide Net Revenues				192,531		
YoY % growth QoQ % growth	==:	17.69	%	17.5%	,	15.4% -1.4%
Stock-based Compensation (SBC) SBC included in Gross Profit SBC included in Operating	\$	800	\$	940	\$	865
Expenses		8,300		9,370		9,045
Total SBC Expense	\$ ==:			10,310 ======		
		Q4 2014		Fiscal 2014		Q1 2015
Invisalign Clear Aligner Net Revenues by Geography: North America International	\$	60,467		446,577 219,742		55,920
Non-case*		12,300		46,230		12,265
Total Clear Aligner Net Revenues	\$ ====			712,549 ======		
YoY % growth QoQ % growth *includes Invisalign training, ancillary products, and retainers		12.2% 4.7%		15.9%		11.2% 0.3%
Average Invisalign Selling Price (ASP): Worldwide ASP International ASP	\$ \$	1,370 1,510				
International ASP	Ψ	1,510	Ψ	1,575	Ψ	1,410
Invisalign Clear Aligner Cases Shipped by Geography: North America International		86,855 40,050		338,530 139,470		91,110 39,670

Total Cases Shipped	====		478,000 ======	130,780
Number of Invisalign Doctors				
Cases Shipped To: North America International		8,945	29,890 13,450	9,050
Total Doctors Cases Shipped To		28,690	43,340	29,215
Invisalign Doctor Utilization Rates*:				
North America North American Orthodontists North American GP Dentists International		4.4 8.6 2.9 4.5	11.3 27.7 6.9 10.4	4.5 9.0 2.9 4.4
Total Utilization Rates		4.4	11.0	4.5
<pre>* # of cases shipped/# of doctors to whom cases were shipped</pre>		======	 	 
Number of Invisalign Doctors Trained:				
North America International		1,170 1,255	4,145 5,290	870 1,540
Total Doctors Trained Worldwide	Э	2,425	9,435	2,410
Total to Date Worldwide		93,995	93,995 =======	96,405
Total Net Revenues:				
Clear Aligner Net Revenues Scanner & Services Net Revenues		186,437 12,163	712,549 49,104	11,057
Total Worldwide Net Revenues	\$	198,600	\$ 761,653	\$ 198,086
YoY % growth QoQ % growth		11.4% 4.6%	15.4%	
Stock-based Compensation (SBC) SBC included in Gross Profit SBC included in Operating	\$	965	\$ 3,570	\$ 980
Expenses		9,510	 36,225	 10,670
Total SBC Expense	\$ ====	10,475 ======	39,795 =======	11,650

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

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)

Q2'15 Guidance
----GAAP
----\$206.6 - \$210.4

Net Revenues

75.0% - 75.7%

Gross Margin

Operating Expenses	\$117.3 - \$118.3
Operating Margin	18.3% - 19.5%
Net Income per Diluted Share	\$0.35 - \$0.38
Business Metrics:	Q2'15
Case Shipments Capital Expenditure Depreciation & Amortization Diluted Shares Outstanding Stock Based Compensation Expense Tax Rate	139.5K - 142.0K \$20M - \$25M \$4.5M - \$5.0M 82.0M* \$13.7M 24.0%

\* Excludes any stock repurchases during the quarter

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