# 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) April 22, 2010

## **Align Technology**

(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.)

**881 Martin Avenue Santa Clara, California** (Address of principal executive offices)

**95050** (Zip Code)

,

Registrant's telephone number, including area code: (408) 470-1000

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))

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

On April 22, 2010, 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, 2010. 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.

Align is making reference to non-GAAP financial information in both the press release and the conference call. A reconciliation of non-GAAP financial measures contained in the attached press release to the comparable GAAP financial measures is contained in the attached press release and a reconciliation of these and certain other non-GAAP financial information provided on the conference call (to the extent not reconciled on such call) is contained on the Investor Relations section of our website at investor.aligntech.com.

## Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No. Description

99.1 Press Release of Align Technology, Inc. dated April 22, 2010

Align Technology

(Registrant)

April 22, 2010

(Date)

Kenneth B. Arola
Vice President, Finance and Chief Financial Officer

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

## **INDEX TO EXHIBITS**

Exhibit No. Description

99.1 Press Release of Align Technology, Inc. dated April 22, 2010

## **Align Technology Announces First Quarter Fiscal 2010 Results**

- Q1 revenues of \$90.1 million increase 4.0% sequentially and 28.5% year-over-year
- Q1 Invisalign case shipments of 63.6 thousand increase 4.2% sequentially and 27.1% year-over-year

SANTA CLARA, Calif., April 22, 2010 (GLOBE NEWSWIRE) -- Align Technology, Inc. (Nasdaq:ALGN) today reported financial results for the first quarter of fiscal 2010, ended March 31, 2010.

Total net revenues for the first quarter of fiscal 2010 (Q1 10) were \$90.1 million compared to \$86.6 million reported in the fourth quarter of 2009 (Q4 09) and compared to \$70.1 million reported in the first quarter of 2009 (Q1 09). Invisalign case shipments for Q1 10 were a record 63.6 thousand, compared to 61.1 thousand in Q4 09 and compared to 50.1 thousand in Q1 09.

Gross margin for Q1 10 was a record 77.4%, compared to 73.7% in Q4 09 and 75.2% in Q1 09. The increase in Q1 gross margin primarily reflects the manufacturing efficiencies associated with higher case volumes. These efficiencies were somewhat offset by \$630 thousand of continuing education (CE) training costs that have been re-classified from sales and marketing expense. Historically, with the exception of initial training classes (CE1), continuing education fees and costs for educational programs were charged to sales and marketing expense. As a result of the Proficiency Program annual CE requirement, all training and education fees and costs, in which CE credit is provided, will now be charged to revenue and costs of sales, respectively.

Net profit for Q1 10 was \$14.9 million, or \$0.19 per diluted share. This is compared to net profit of \$11.5 million, or \$0.15 per diluted share in Q4 09 and net profit of \$2.6 million, or \$0.04 per diluted share in Q1 09. Stock-based compensation expense included in Q1 10 was \$3.5 million compared to \$3.1 million in Q4 09 and \$3.7 million in Q1 09.

"I'm pleased to report strong results for our first quarter," said Thomas M. Prescott, president and CEO. "Record revenues and case shipments combined with lower spending resulted in better than anticipated earnings."

To supplement our consolidated financial statements, we use the following non-GAAP financial measures: non-GAAP gross profit, non-GAAP operating expense, non-GAAP operating margin, non-GAAP net profit and non-GAAP earnings per share. Detailed reconciliations between GAAP and non-GAAP information are contained in the tables following the financial tables of this release.

Non-GAAP net profit for Q1 10 was \$15.5 million, or \$0.20 per diluted share. This is compared to non-GAAP net profit of \$12.1 million, or \$0.16 per diluted share in Q4 09 and non-GAAP net profit of \$3.2 million, or \$0.05 per diluted share in Q1 09.

## **Q1 10 Operating Results**

Key GAAP Operating Results	Q1 10	Q4 09	Q1 09
Gross Margin	77.4%	73.7%	75.2%
Operating Expense	\$49.0M	\$49.2M	\$47.4M
Operating Margin	23.0%	16.9%	7.5%
Net Profit	\$14.9M	\$11.5M	\$2.6M
Earnings Per Diluted Share (EPS)	\$0.19	\$0.15	\$0.04
Key Non-GAAP Operating Results	Q1 10	Q4 09	Q1 09
Non-GAAP Gross Margin	78.3%	78.6%	75.2%
Non-GAAP Operating Expense	\$49.0M	\$49.2M	\$46.5M
Non-GAAP Operating Margin	23.9%	21.8%	8.8%
Non-GAAP Net Profit	\$15.5M	\$12.1M	\$3.2M
Non-GAAP Earnings Per Diluted Share (EPS)	\$0.20	\$0.16	\$0.05

## **Liquidity and Capital Resources**

As of March 31, 2010, Align had \$205.4 million in cash, cash equivalents, and short-term marketable securities compared to \$186.5 million as of December 31, 2009.

#### **Kev Business Metrics**

The following table highlights business metrics for Align's first quarter of 2010. Additional historical information is available on the Company's website at http://investor.aligntech.com.

Revenue by Channel (\$M):	Q1 10	% of Total Revenue	Q1 10/Q4 09 % Change
North American Orthodontists	\$28.2	31.3%	12.6%

North Associace OR Restitute	407.0	44.007	2.00/
North American GP Dentists	\$37.2	41.3%	2.8%
International	\$20.0 \$4.7	22.2% 5.2%	(5.8%) 12.5%
Non-case Revenue*	\$90.1	100%	4.0%
Total Revenue	<del></del>	100%	4.0%
Revenue by Product (\$M):	Q1 10	% of Total Revenue	Q1 10/Q4 09 % Change
Invisalign Full	\$65.7	72.9%	3.9%
Invisalign Express	\$8.6	9.6%	13.7%
Invisalign Teen	\$8.2	9.1%	(12.6%)
Invisalign Assist	\$2.9	3.2%	30.2%
Non-case Revenue*	\$4.7	5.2%	11.7%
Total Revenue	\$90.1	100%	4.0%
*includes training, ancillary products, and retainers			
Cases Shipped by Channel:	Q1 10	% of Total Cases	Q1 10/Q4 09 % Change
North American Orthodontists	22,150	34.8%	12.0%
North American GP Dentists	28,490	44.8%	2.8%
International	12,970	20.4%	(4.3%)
Total Cases Shipped	63,610	100%	4.2%
Cases Shipped by Product:	Q1 10	% of Total Cases	Q1 10/Q4 09 % Change
Invisalign Full	43,715	68.7%	5.2%
Invisalign Express	9,225	14.5%	8.1%
Invisalign Teen	7,370	11.6%	(9.9%)
Invisalign Assist	3,300	5.2%	19.0%
Total Cases Shipped	63,610	100%	4.2%
Average Selling Price (ASP), as billed:	Q1 10		
Total Worldwide Blended ASP	\$1,395		
Total Worldwide Blended ASP International ASP	\$1,395 \$1,590		
International ASP	\$1,590		
International ASP  Number of Doctors Cases were Shipped to:	\$1,590 <b>Q1 10</b>		
Number of Doctors Cases were Shipped to: North American Orthodontists	\$1,590 <b>Q1 10</b> 4,015		
Number of Doctors Cases were Shipped to: North American Orthodontists North American GP Dentists	\$1,590 <b>Q1 10</b> 4,015 10,850		
Number of Doctors Cases were Shipped to: North American Orthodontists North American GP Dentists International	\$1,590  Q1 10  4,015  10,850  3,535		
Number of Doctors Cases were Shipped to: North American Orthodontists North American GP Dentists International	\$1,590  Q1 10  4,015 10,850 3,535 18,400	Cumulative	Active**
Number of Doctors Cases were Shipped to: North American Orthodontists North American GP Dentists International Total Doctors Cases were Shipped to Worldwide  Number of Doctors Trained Worldwide: North American Orthodontists	\$1,590  Q1 10  4,015 10,850 3,535 18,400  Q1 10  75	9,010	5,615
International ASP  Number of Doctors Cases were Shipped to: North American Orthodontists North American GP Dentists International Total Doctors Cases were Shipped to Worldwide  Number of Doctors Trained Worldwide: North American Orthodontists North American GP Dentists	\$1,590  Q1 10  4,015 10,850 3,535 18,400  Q1 10  75 315	9,010 35,530	5,615 17,895
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For the second quarter of fiscal 2010 (Q2 10), Align Technology expects net revenues to be in a range of \$88.0 million to \$91.0 million. GAAP earnings per diluted share for Q2 10 is expected to be in a range of \$0.12 to \$0.14. Stock-based compensation expense for Q2 10 is expected to be approximately \$4.4 million. A more comprehensive business outlook is available following the financial tables of this release.

Commenting on Align's business outlook for the second quarter of 2010, Kenneth Arola, vice president and CFO made the following statement:

There are several factors that contribute to our outlook:

- With the change we have made to the Proficiency Program, it is uncertain how doctors, particularly lower volume doctors, will respond. It is likely that some practices that have been working hard to accelerate adoption will want to take a breather, while others who started to get that acceleration and enjoying the progress they made may want to continue at their new pace.
- In Q2, we will introduce a consumer rebate program that will run through the end of the quarter, as well as an additional volume rebate for the Elite and Premier providers. This is expected to have some negative impact on ASPs and gross margin during the quarter.
- For our International business, Q2 is historically a seasonally stronger sequential quarter and we expect it to be the same again this year. We do business in Euros and therefore major changes quarter-to-quarter in foreign exchange rates can impact top-line revenues and gross margin.
- June marks the beginning of the summer and we are looking forward to participating in another full season of teen orthodontic case starts and continue gaining share of chair both at the tail end of Q2 and into Q3.

#### **Other Announcements**

In a separate announcement today Align also announced a significant change to the Invisalign proficiency program launched in June 2009 by eliminating the annual case start requirement in order for doctors to maintain their active Invisalign provider status. Doctors are still required to complete a minimum of ten Invisalign continuing education (CE) hours per year. For more information, please see Align's press release titled, "Align Technology Eliminates Annual Case Requirement for Invisalign Providers."

## **Align Web Cast and Conference Call**

Align Technology will host a conference call today, April 22, 2010 at 4:30 p.m. ET, 1:30 p.m. PT, to review its first quarter fiscal 2010 results, discuss future operating trends and 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 Technology's Investor Relations web site at http://investor.aligntech.com. To access the conference call, please dial 201-689-8341 approximately fifteen minutes prior to the start of the call. If you are unable to listen to the call, an archived 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 account number 292 followed by # and conference number 348442 followed by #. The replay must be accessed from international locations by dialing 201-612-74 15 and using the same account and conference numbers referenced above. The telephonic replay will be available through 5:30 p.m. ET on May 5, 2010.

### About Align Technology, Inc.

Align Technology designs, manufactures and markets Invisalign, a proprietary method for treating malocclusion, or the misalignment of teeth. Invisalign corrects malocclusion using a series of clear, nearly invisible, removable appliances that gently move teeth to a desired final position. Because it does not rely on the use of metal or ceramic brackets and wires, Invisalign significantly reduces the aesthetic and other limitations associated with braces. Invisalign is appropriate for treating adults and teens. Align Technology was founded in March 1997 and received FDA clearance to market Invisalign in 1998. Today, the Invisalign product family includes Invisalign, Invisalign Teen, Invisalign Assist, Invisalign Express, and Vivera Retainers.

To learn more about Invisalign or to find an Invisalign trained doctor in your area, please visit www.invisalign.com or call 1-800-INVISIBLE.

#### **About non-GAAP Financial Measures**

To supplement our consolidated financial statements and our business outlook, we use the following non-GAAP financial measures: non-GAAP gross profit, non-GAAP operating expenses, non-GAAP profit from operations, non-GAAP net profit, and non-GAAP earnings per share, which exclude, as applicable, royalties associated with the settlement with Ormco, the effect of charges associated with restructurings, and any related tax effects. The presentation of this financial information is not intended to be considered in isolation or as a substitute for, or superior to, the financial information prepared and presented in accordance with GAAP. For more information on these non-GAAP financial measures, please see the tables captioned "Business Outlook Summary" included at the end of this release.

We use these non-GAAP financial measures for financial and operational decision making and as a means to evaluate period-to-period comparisons. Our management believes that these non-GAAP financial measures provide meaningful supplemental

information regarding our "core operating performance". Management believes that "core operating performance" represents Align's performance in the ordinary, ongoing and customary course of its operations. Accordingly, management excludes from "core operating performance" certain expenditures and other items that may not be indicative of our operating performance including discrete cash and non-cash charges that are infrequent or one-time in nature. We believe that both management and investors benefit from referring to these non-GAAP financial measures in assessing our performance and when planning, forecasting and analyzing future periods. These non-GAAP financial measures also facilitate management's internal evaluation of period-to-period comparisons. We believe these non-GAAP financial measures are useful to investors both because (1) they allow for greater transparency with respect to key metrics used by management in its financial and operational decision making and (2) they are provided to and used by our institutional investors and the analyst community to facilitate comparisons with prior and subsequent reporting periods.

## **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 2010, including anticipated revenue, gross margin, operating expense, operating income, earnings per share, case shipments and cash and statements made by Mr. Arola commenting on our business outlook, including expectations on average selling prices and gross margin in the second quarter and our ability to continue to gain share of the teenage orthodontic market during the summer months. 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 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, continued customer demand for Invisalign 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 Invisalign by consumers and dental professionals, foreign operationa l, political and other risks relating to Align's international manufacturing operations, Align's ability to protect its intellectual property rights, competition from manufacturers of traditional braces 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 fiscal year ended December 31, 2009, which was filed with the Securities and Exchange Commission on February 26, 2010. 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)

	Till Co Months Endou		
	March 31, 2010	March 31, 2009	
Net revenues	\$ 90,090	\$ 70,132	
Cost of revenues	20,380	17,425	
Gross profit	69,710	52,707	
Operating expenses:			
Sales and marketing	27,946	27,854	
General and administrative	14,951	13,468	
Research and development	6,116	5,191	
Restructuring		910	
Total operating expenses	49,013	47,423	
Profit from operations	20,697	5,284	
Interest and other income (expense), net	(553)	148	
Profit before income taxes	20,144	5,432	

Provision for income taxes	5,214	2,796
Net profit	\$ 14,930	\$ 2,636
Net profit per share		
- basic	\$ 0.20	\$ 0.04
- diluted	\$ 0.19	\$ 0.04
Shares used in computing net profit per share		
- basic	75,166	65,983
- diluted	77,597	66,447

ALIGN TECHNOLOGY, INC.

UNAUDITED CONDENSED CONSOLIDATED BALANCE SHEETS (in thousands)

	March 31, 2010	December 31, 2009
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 190,407	\$ 166,487
Marketable securities, short-term	14,991	19,978
Accounts receivable, net	58,801	54,537
Inventories, net	2,356	2,046
Other current assets	18,055	18,251
Total current assets	284,610	261,299
Property and equipment, net	25,418	24,971
Goodwill and intangible assets, net	4,766	5,466
Deferred tax asset	56,560	61,535
Other long-term assets	2,198	1,969
Total assets	\$ 373,552	\$ 355,240

## LIABILITIES AND STOCKHOLDERS' EQUITY

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Current liabilities:		
Accounts payable	\$ 4,513	\$ 6,122
Accrued liabilities	34,690	42,822
Deferred revenue	37,047	32,299
Total current liabilities	76,250	81,243
Other long term liabilities	946	961
Total liabilities	77,196	82,204
Total stockholders' equity	296,356	273,036
Total liabilities and stockholders' equity	\$ 373,552	\$ 355,240

ALIGN TECHNOLOGY, INC.

RECONCILIATION OF GAAP TO NON-GAAP KEY FINANCIAL METRICS

#### **Reconciliation of GAAP to Non-GAAP Gross Profit**

(in thousands)

	Three Months Ended		
	March 31, 2010	December 31, 2009	March 31, 2009
GAAP Gross profit	\$ 69,710	\$ 63,806	\$ 52,707
Ormco royalties	827	4,259	
Non-GAAP Gross profit	\$ 70,537	\$ 68,065	\$ 52,707

#### Reconciliation of GAAP to Non-GAAP Operating Expenses

(in thousands)

	Three Months Ended		
	March 31, 	December 31, 2009	March 31, 2009
GAAP Operating expenses	\$ 49,013	\$ 49,161	\$ 47,423
Restructuring			(910)
Non-GAAP Operating expenses	\$ 49,013	\$ 49,161	\$ 46,513

## Reconciliation of GAAP to Non-GAAP Profit from Operations

(in thousands)

	Three Months Ended		
	March 31, 2010	December 31, 2009	March 31, 2009
GAAP Profit from Operations	\$ 20,697	\$ 14,645	\$ 5,284
Ormco royalties	827	4,259	
Restructuring			910
Non-GAAP Profit from Operations	\$ 21,524	\$ 18,904	\$ 6,194

#### Reconciliation of GAAP to Non-GAAP Net Profit

(in thousands, except per share amounts)

	Three Months Ended		
	March 31, 2010	December 31, 2009	March 31, 2009
GAAP Net profit	\$ 14,930	\$ 11,492	\$ 2,636
Ormco royalties	827	4,259	
Restructuring			910
Tax effect on non-GAAP adjustments	(216)	(3,605)	(355)
Non-GAAP Net profit	\$ 15,541	\$ 12,146	\$ 3,191
Diluted Net profit per share:			
GAAP	\$ 0.19	\$ 0.15	\$ 0.04
Non-GAAP	\$ 0.20	\$ 0.16	\$ 0.05
Shares used in computing diluted non-GAAP net profit per share	77,597	76,831	66,447

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.

#### **Financials**

(in millions, except per share amounts and percentages)

	Q2 2010
Net Revenue	\$88.0 \$91.0
Gross Profit	\$66.5 \$69.5
Gross Margin	75.6% - 76.4%
Operating Expenses	\$52.5 \$53.5
Operating Margin	16.0% - 17.6%
Net Income per Diluted Share	\$0.12 \$0.14
Stock Based Compensation Expense:	
Cost of Revenues	\$0.4
Operating Expenses	\$4.0
Total Stock Based Compensation Expense	\$4.4
Business Metrics:	
	Q2 2010
Case Shipments	63.5K - 65.5K
Cash	\$225M \$230M
Capex	\$3.0M \$5.0M
Depreciation & Amortization	\$2.0M \$3.0M
Diluted Shares Outstanding	78M
Full Year 2010:	FY 2010
Stock Based compensation	\$17.0M
Diluted Shares Outstanding	78M

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