
UNITED STATES SECURITIES AND EXCHANGE COMMISSION Washington, DC 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 21, 2004

ALIGN TECHNOLOGY, INC.

(Exact name of registrant as specified in its charter)

Delaware 0-32259 94-3267295
-----(State or other jurisdiction of incorporation) File Number) Identification No.)

881 Martin Avenue

Santa Clara, California 95050 (Address of principal executive offices, including 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
- [_] 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 October 21, 2004, Align is issuing a press release and holding a conference call regarding its financial results for the third quarter of fiscal 2004 ended September 30, 2004. A copy of the press release is furnished as Exhibit 99.1 to this Form 8-K and is incorporated by reference.

This information shall not be deemed "filed" for purposes of Section 18 of the Securities 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 these non-GAAP financial measures to the comparable GAAP financial measures is contained in the attached press release.

Item 8.01 Other Events

240.14a-12)

On October 21, 2004, Align is announcing its financial results for the third quarter of fiscal 2004 ended September 30, 2004. These financial results are attached hereto as Exhibit 99.2. Exhibit 99.2 shall be deemed "filed" for

purposes of Section 18 of the Exchange Act and shall be deemed incorporated by reference in filings under the Securities Act of 1933 or the Exchange Act.

Item 9.01. Financial Statements and Exhibits

(c) Exhibits.

Exhibit No.	Description
99.1	Press Release of Align Technology, Inc. dated October 21, 2004
99.2	Financial Results for the Quarter ended September 30, 2004

SIGNATURES

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/ Eldon M. Bullington

Eldon M. Bullington

Vice President of Finance and Chief Financial Officer

Date: October 21, 2004

EXHIBIT INDEX

Exhibit No.	Description
99.1 99.2	Press Release of Align Technology, Inc. dated October 21, 2004 Financial Results for the Quarter ended September 30, 2004

Align Technology, Inc. Reports 9th Consecutive Quarter of Increasing Revenues

- Third Quarter Revenues Increase 35% Year Over Year to \$45.8 Million
- Company Reports GAAP Net Profit of \$3.3 Million, or EPS of \$0.05, and Non-GAAP Net Profit of \$4.7 Million, or EPS of \$0.07
- Company Increases Cash Position by \$16.3 Million Year-to-Date

SANTA CLARA, Calif., Oct. 21 /PRNewswire-FirstCall/ -- Align Technology, Inc. (Nasdaq: ALGN), the inventor of Invisalign(R), a proprietary method of straightening teeth without wires and brackets, today reported financial results for the third quarter of 2004. Total revenues for the third quarter of 2004 were \$45.8 million, compared to \$34.0 million in the third quarter of 2003, an increase of 34.5 percent, and \$44.2 million in the second quarter of 2004, an increase of 3.5 percent.

"We are pleased with our earnings this quarter," stated Thomas M. Prescott, Align Technology's President and CEO. "As we continue building the company, we look forward to strengthening the infrastructure and positioning Align for long-term growth and profitability. Additionally, we believe that year-over-year, revenues will grow by introducing several strategic initiatives including an expanded sales force, enhanced consumer marketing programs and the introduction of new products. "

The net profit for the third quarter of 2004 as determined under generally accepted accounting principles ("GAAP") was \$3.3 million, or earnings per diluted share of \$0.05. This compares to a net loss for the third quarter of 2003 of \$2.1 million, or a net loss of \$0.04 per share, and a net profit for the second quarter of 2004 of \$3.8 million, or earnings per diluted share of \$0.06. Third quarter 2004 profit includes a \$1.1 million severance charge related to the previously announced departure of an executive.

The non-GAAP net profit for the third quarter of 2004, which excludes \$1.4 million of stock-based compensation, was \$4.7 million, or non-GAAP earnings per diluted share of \$0.07. This compares to a non-GAAP net profit of \$1.2 million in the third quarter of 2003, which excludes \$3.4 million of stock-based compensation charges, or a non-GAAP earnings per diluted share of \$0.02. This also compares to a non-GAAP net profit of \$5.6 million in the second quarter of 2004, which excludes \$1.8 million of stock-based compensation, or a non-GAAP earnings per diluted share of \$0.09. The reconciliation of the GAAP to non-GAAP measurements for net profit for the third quarter of 2004 is set forth below within Align Technology's financial statements.

As of September 30, 2004, Align had \$64.0 million in cash, cash equivalents and marketable securities, compared to \$47.7 million as of December 31, 2003.

Conference Call

As previously announced, Align Technology, Inc. will host a live webcast and conference call today, October 21, 2004, at 10:00 a.m. EDT, 7:00 a.m. PDT, to review third quarter of 2004 results and discuss future operating trends and guidance outlook for the future. The webcast of Align's conference call will be accessible through the website at: http://www.aligntech.com/generalapp/us/en/corporate/investor_frameset.jsp .

The webcast will be archived for future on-demand replay. To access the conference call, please dial 201-689-8341 approximately ten 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 through 5:30 p.m. EDT on October 20, 2005. Additionally, a telephonic replay of the call can be accessed by dialing 877-660-6853 with account number 292 followed by # and conference number 119689 followed by #. The replay may be accessed from international locations by dialing 201-612-7415 and using the same account and conference numbers referenced above. The telephonic replay will be available through 5:30 p.m. EDT on November 5, 2004.

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 older teens. Align Technology was founded in March 1997 and received FDA clearance to market Invisalign in 1998.

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

Forward-Looking Statements

This news release contains forward-looking statements, including statements regarding Align's ability to strengthen its infrastructure, position itself for long-term growth and profitability and the anticipated success of Align's initiatives to increase revenue. Forward-looking statements contained in this news release 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, risks relating to Align's history of losses and negative operating cash flows, Align's ability to increase its revenue significantly while controlling expenses, Align's ability to manage growth, loss of key personnel or the inability to attract and retain key personnel, Align's limited operating history, customer demand for Invisalign, acceptance of Invisalign by consumers and dental professionals, competition from manufacturers of traditional braces, Align's third party manufacturing processes and personnel, foreign operational, political and other risks relating to Align's international manufacturing operations, Align's ability to protect its intellectual property rights, potential intellectual property or product liability claims or litigation, and the potential volatility of the market price of Align's common stock. 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, 2003, which was filed with the Securities and Exchange Commission on March 9, 2004, and its Quarterly Reports on Form 10-Q. Align undertakes no obligation to revise or update publicly any forward-looking statements for any reason.

ALIGN TECHNOLOGY, INC. CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (unaudited)

(in thousands, except	Three Months Ended Nine Months Ended			
per share data)	Sept. 30, 2004	Sept. 30, 2003	Sept. 30, 2004	Sept. 30, 2003
Revenues	\$45,766	\$34,038	\$129,175	\$86,223
Cost of revenues	14,922	13,446	42,565	38,639
Gross profit	30,844	20,592	86,610	47,584
Operating expenses:				
Sales and marketing General and administrative Research and development	8, 263	10,505 8,722 3,113	25,196	25,630
Total operating expenses	26,993	22,340	77,501	67,991
Profit (loss) from operations	3,851	(1,748)	9,109	(20,407)
Interest and other income (expense), net Provision for income taxes		(359) (37)		(129) (38)
Net profit (loss)	\$3,318	\$(2,144)	\$7,647	\$(20,574)
Net profit (loss) per share bas	ic \$0.06	\$(0.04)	\$0.13	\$(0.36)
Weighted-average shares used in computing basic net profit (loss) per share	60,319	57,948	59,703	57,543
Net profit (loss) per share diluted	\$0.05	\$(0.04)	\$0.12	\$(0.36)

ALIGN TECHNOLOGY, INC. CONDENSED CONSOLIDATED BALANCE SHEETS (unaudited)

(in thousands)	September 30, 2004	December 31, 2003
ASSETS		
Current assets: Cash and cash equivalents Restricted cash Marketable securities, short-term Accounts receivable, net Inventories, net Other current assets Total current assets	\$63,215 281 519 27,663 2,150 5,855 99,683	\$44,939 439 2,292 21,265 2,334 5,845 77,114
Property and equipment, net Other long-term assets	23,304 2,197	23,121 1,967
Total assets	\$125,184	\$102,202
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities: Accounts payable Accrued liabilities Deferred revenue Debt, current portion Total current liabilities	\$3,899 21,733 13,798 1,932 41,362	\$3,095 19,180 13,113 1,989 37,377
Debt, long-term portion	428	1,849
Total liabilities	41,790	39,226
Total stockholders' equity	83,394	62,976
Total liabilities and stockholders' equity	\$125,184	\$102,202

ALIGN TECHNOLOGY, INC.
NON-GAAP CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (unaudited)

Use of Non-GAAP Financial Information

To supplement our condensed consolidated financial statements presented on a GAAP basis, Align uses a non-GAAP measure of net profit (loss), which is adjusted to exclude certain costs and expenses and any associated tax effects of such adjustments. We believe that our non-GAAP net profit (loss) gives an indication of our baseline performance before other charges that are considered by management to be outside of our core operating results. In addition, our non-GAAP net profit (loss) is among the primary indicators management uses as a basis for our planning and forecasting of future periods. The presentation of this additional information should not be considered in isolation or as a substitute for net profit (loss) prepared in accordance with generally accepted accounting principles in the United States of America.

	Three Mon Sept.		Nine Mon Sept.	
<pre>(in thousands, except per share data)</pre>	30, 2004	30, 2003	30, 2004	30, 2003
Revenues	\$45,766	\$34,038	\$129,175	\$86,223
Cost of revenues	14,784	12,830	41,710	36,619
Gross profit	30,982	21,208	87,465	49,604
Operating expenses:				
Sales and marketing General and administrative Research and development	13,770 7,754 4,206	9,984 7,117 2,470	39,920 22,588 10,448	30,798 19,439 7,264

Total operating expenses	25,730	19,571	72,956	57,501
Profit (loss) from operations	5,252	1,637	14,509	(7,897)
Interest and other income (expense), net Provision for income taxes	,	(359) (37)	(619) (843)	` ,
Net profit (loss)	\$4,719	\$1,241	\$13,047	\$(8,064)
Net profit (loss) per share basic	\$0.08	\$0.02	\$0.22	\$(0.14)
Weighted-average shares used in computing basic net profit (loss) per share	60,319	57,948	59,703	57,543
Net profit (loss) per share diluted	\$0.07	\$0.02	\$0.20	\$(0.14)
Weighted-average shares used in computing diluted net profit (loss) per share	64,055	62,912	64,298	57,543

ALIGN TECHNOLOGY, INC.
RECONCILIATION OF GAAP NET PROFIT (LOSS) TO ADJUSTED NON-GAAP NET PROFIT (LOSS)
(unaudited)

(in thousands)				nths Ended , Sept. 30, 2003
Net profit (loss)	\$3,318	\$(2,144)	\$7,647	\$(20,574)
Stock-based compensation expense included in: (1) - cost of revenues - sales and marketing - general and administrative - research and development	138 114 509 640	616 521 1,605 643	855 635 2,608 1,302	2,020 1,753 5,684 2,546
Restructuring costs included in general and administrative: (2)				507
Non-GAAP net profit (loss)	\$4,719	\$1,241	\$13,047	\$(8,064)

(1)Stock-based compensation expense primarily represents the amortization of deferred stock-based compensation recorded in connection with the granting of stock options to employees and non-employees. Stock-based compensation expense also includes, in connection with severance packages for several employees, accelerated vesting of options granted prior to the company's initial public offering.

(2)Restructuring costs represented residual restructuring charges related to the transition of operations from the United Arab Emirates and Pakistan to Costa Rica during the first quarter of 2003.

Contact: investor relations, Barbara Domingo of Align Technology, Inc., +1-408-470-1000, or investorinfo@aligntech.com; or press, Shannon Henderson of Ethos Communications, Inc., +1-678-417-1767, or shannon@ethoscommunication.com.

SOURCE Align Technology, Inc.

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/Web site: http://www.invisalign.com/(ALGN)

CO: Align Technology, Inc.

ST: California IN: MTC HEA SU: ERN CCA ALIGN TECHNOLOGY, INC. CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (unaudited)

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