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Align Technology Announces Third Quarter Fiscal 2009 Results

Oct 22, 2009 (GlobeNewswire via COMTEX News Network) --

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-- Q3 net revenues of $79.3 million increase 3.9% sequentially and 5.4% from the prior year
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-- Q3 record case shipments of 56.5 thousand increase 6.6% sequentially and 7.0% from the prior year

SANTA CLARA, Calif., Oct. 22, 2009 (GLOBE NEWSWIRE) -- Align Technology, Inc. (Nasdaq:ALGN) today reported financial results for the third quarter, ended September 30, 2009.

Total net revenues for the third quarter of fiscal 2009 (Q3 09) were \$79.3 million compared to \$76.3 million reported in the second quarter of 2009 (Q2 09) and compared to \$75.2 million reported in the third quarter of 2008 (Q3 08). Invisalign case shipments for Q3 09 were 56.5 thousand, compared to 53.0 thousand in Q2 09 and compared to 52.8 thousand in Q3 08.

Net loss for Q3 09 was \$49.9 million, or \$0.72 per diluted share, which includes litigation settlement costs of \$69.7 million and royalties of \$1.9 million, for a total of \$0.85 per diluted share related to the settlement agreement with Ormco Corporation announced on August 17, 2009. This is compared to net profit of \$4.5 million, or \$0.07 per diluted share in Q2 09 and net profit of \$5.2 million, or \$0.08 per diluted share in Q3 08. Stock-based compensation expense included in Q3 09 was \$4.0 million compared to \$4.3 million in Q2 09 and \$4.4 million in Q3 08.

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 Q3 09 was \$8.9 million, or \$0.13 per diluted share. This is compared to non-GAAP net profit of \$4.8 million, or \$0.07 per diluted share in Q2 09 and non-GAAP net profit of \$7.3 million, or \$0.11 per diluted share in Q3 08.

Commenting on Align's third quarter financial results, Thomas M. Prescott, president and CEO said, "I'm pleased to report a very good quarter with better than expected results across the board. Third quarter revenues were driven by sequential growth in the Ortho and GP channels in North America, as well as continued adoption of Invisalign Teen worldwide. Our financial performance highlights the operating leverage possible in our business when we drive sufficient volume into our more productive cost structure, and it reaffirms the tough actions we took over the last twelve months."

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Q3 09 Operating Results
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Key GAAP Operating Results	Q3 09	Q2 09	Q3 08
Gross Margin	74.4%	76.0%	75.0%
Operating Expense	\$ 119.2M	\$ 51.7M	\$ 50.7M
Operating Margin	(75.9%)	8.2%	7.6%
Net Profit (Loss)	(\$49.9)	\$ 4.5M	\$ 5.2M
Earnings Per Diluted Share (EPS)	(\$0.72)	\$ 0.07	\$ 0.08
Key Non-GAAP Operating Results	Q3 09	Q2 09	Q3 08
Non-GAAP Gross Margin	76.8%	76.0%	75.0%
Non-GAAP Operating Expense	\$ 49.5M	\$ 51.3M	\$ 48.5M

Non-GAAP Operating Margin	14.4%	8.7%	10.5%
Non-GAAP Net Profit	\$ 8.9M	\$ 4.8M	\$ 7.3M
Non-GAAP Earnings Per Diluted			
Share (EPS)	\$ 0.13	\$ 0.07	\$ 0.11

Liquidity and Capital Resources

As of September 30, 2009, Align had \$154.9 million in cash, cash equivalents, and short-term marketable securities compared to \$110.2 million as of December 31, 2008.

Q309 Business Highlights

During the quarter, Align made several major announcements. For further information, please visit the investor relations section of the Company's website: <u>http://investor.aligntech.com</u>.

- -- Align reached a settlement agreement with Ormco Corporation ending all litigation between the two companies and formed a new strategic relationship to jointly develop a combination orthodontic product. As part of the settlement, Align made a cash payment of approximately \$13.1 million to Ormco and issued approximately 7.6 million shares of Align's Common Stock to Danaher Corporation, Ormco's ultimate parent.
- -- Align introduced new and enhanced product features for all Invisalign products designed to provide improved results for everyday clinical demands. Features include optimized attachments, power ridges, velocity optimization selection, interproximal reduction (IPR) improvements, and a new attachment kit. Also, additional features have been added or enhanced in Invisalign Assist, expanding its capabilities and giving doctors the confidence and control necessary to treat a wider range of patients.
- -- Align announced program updates to its Invisalign Proficiency Requirements including an additional qualification period of six months, as well as a new Invisalign Preferred Provider designation for doctors who achieve the proficiency requirements by the end 2009

Key Business Metrics

The following table highlights business metrics for Align's third quarter of 2009. Additional historical information is available on the Company's website at http://investor.aligntech.com.

Revenue by Channel (\$M):	Q3 09	% of Total Revenue	Q3 09/Q2 09 % Change
North American Orthodontists	\$ 22.7	28.7%	5.3%
North American GP Dentists	\$ 33.9	42.8%	6.8%
International	\$ 18.5	23.3%	2.2%
Non-case Revenue*	\$ 4.2	5.2%	(15.2%)
Total Revenue	\$ 79.3	100%	3.9%
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* includes training, ancillary products, and retainers

Cases Shipped by Channel:	Q3 09	% of Total Cases	Q3 09/Q2 09 % Change
North American Orthodontists North American GP Dentists International	18,830 25,565 12,120	33.3% 45.2% 21.5%	8.7%
Total Cases Shipped	56,515 ======	100%	6.6% ======
Cases Shipped by Product:	Q3 09	% of Total Cases	Q3 09/Q2 09 % Change
Invisalign Full	38,705	68.5%	2.3%
Invisalign Express	8,425	14.9%	5.3%
Invisalign Teen	7,850	13.9%	32.2%
Invisalign Assist	1,535	2.7%	25.3%
Total Cases Shipped	56,515	100%	6.6%
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Average Selling Price (ASP),	
as billed:	Q3 09
Total Worldwide Blended ASP	\$ 1,390
International ASP	\$ 1,560

Number of Doctors Cases were Shipped to:	Q3 09
North American Orthodontists North American GP Dentists International	3,835 11,060 3,470
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Total Doctors Cases were Shipped to Worldwide	18,365

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Number of Doctors Trained Worldwide:	Q3 09	Cumulative	
North American Orthodontists North American GP Dentists International	75 430 300	8,885 34,805 15,330	
Total Doctors Trained Worldwide	805	59,020 =====	
Doctor Utilization Rates*:	Q3 09	Q2 09	Q3 08

North American Orthodontists	4.9	4.7	4.8
North American GP Dentists	2.3	2.2	2.4
International	3.5	3.6	3.2
Total Utilization Rate	3.1	3.0	3.0
	========	===========	===========

* Utilization = # of cases shipped/# of doctors to whom cases were shipped

Total Invisalign Patients		
(cases shipped):	Q3 09	Cumulative
Number of Patients Treated		
or in Treatment (cases)	56,515	1,103,635
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Q4 Fiscal 2009 Business Outlook

For the fourth quarter of fiscal 2009 (Q4 09), Align Technology expects net revenues to be in a range of \$77.5 million to \$81.0 million. GAAP earnings per diluted share for Q4 09 is expected to be in a range of \$0.07 to \$0.09. Non-GAAP earnings per diluted share for Q4 09 is expected to be in the range of \$0.10. Stock-based compensation expense for Q4 09 is expected to be approximately \$3.9 million.

A more comprehensive business outlook is available following the financial tables of this release.

Align Web Cast and Conference Call

Align Technology will host a conference call today, October 22, 2009 at 4:30 p.m. ET, 1:30 p.m. PT, to review its third quarter fiscal 2009 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 333971 followed by #. The replay must 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. ET on November 5, 2009.

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 a certified Invisalign doctor in your area, please visit <u>www.invisalign.com</u> 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 operating expenses, non-GAAP profit from operations, non-GAAP net profit, and non-GAAP earnings per share, which exclude, as applicable, litigation settlement costs and royalties associated with the settlement with Ormco, the effect of charges associated with restructurings, and the related tax effect. 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 periodto-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 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 periodto-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 fourth guarter of 2009, including anticipated revenue, gross margin, operating expense, operating income, earnings per share, case shipments and cash. 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 as well as the willingness and ability of our customers to adopt the expected baseline requirements set forth in our recently announced proficiency program and the willingness and ability of our customers to maintain and/or increase utilization to meet the new proficiency standards 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, 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, 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, 2008, which was filed with the Securities and Exchange Commission on February 27, 2009. 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		
	Sept. 30, 2009	Sept. 30, 2008	- ·	Sept. 30, 2008	
Net revenues	\$ 79,269	\$ 75,173	\$225,717	\$229,851	
Cost of revenues	20,268	18,766	56,031	58,617	
Gross profit	59,001	56,407	169,686	171,234	
Operating expenses: Sales and marketing General and administrative Research and development	27,687 16,224 5,611	•		45,905	

Destructuring		2 1 9 0	1 210	0 1 0 0
Restructuring Litigation			1,319	
settlement costs	69,673		69,673	
Total operating expenses	119,195		218,343	
Profit (loss) from operations	(60,194)	5,691	(48,657)	14,189
Interest and other income (expense), net	(271)	264	434	1,673
Profit (loss) before income taxes	(60,465)	5,955	(48,223)	15,862
Provision for (benefit from) income taxes	(10,523)	798	(5,462)	1,371
Net profit (loss)			\$(42,761)	
Net profit (loss) per share				
- basic			\$ (0.64)	
- diluted	\$ (0.72)\$ 0.08	\$ (0.64) ========	\$ 0.21
Shares used in computing net profit/loss per share				
- basic			67,278	
- diluted	69,528	68,704	67,278	69,906
ALIGN TECHNOLOGY, INC. UNAUDITED CONDENSED CONSOLIDA (in thousands)		E SHEETS ept. 30, 2009	Dec. 31, 2008	
ASSETS				
Current assets: Cash and cash equivalents Marketable securities, shor Accounts receivable, net Inventories, net Other current assets Total current assets Property and equipment, net Goodwill and intangible assets	t-term -	55,035 1,892 25,671 237,538 24,429	23,066 52,362 1,965 13,414 177,907 26,979	
Deferred tax asset Other long-term assets	- ,	61,048		

Total assets

LIABILITIES AND STOCKHOLDERS' EQUITY

Current liabilities: Accounts payable Accrued liabilities Deferred revenue	\$ 7,498 37,484 27,920	1 1
Total current liabilities	72,902	60,572
Other long term liabilities	202	229
Total liabilities	73,104	60,801
Total stockholders' equity	257,680	218,540
Total liabilities and stockholders' equity	\$330,784 ========	\$279,341 =======

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		
	Sept. 30,	June 30,	Sept. 30,
	2009	2009	2008
GAAP Gross profit	\$ 59,001	\$ 57,978	\$ 56,407
Ormco royalties	1,906		
Non-GAAP Gross profit	\$ 60,907 ======	\$57,978 ========	\$56,407

Reconciliation of GAAP to Non-GAAP Operating Expenses (in thousands)

	Three Months Ended		
	Sept. 30,	June 30,	Sept. 30,
	2009	2009	2008
GAAP Operating expenses	\$ 119,195	\$ 51,725	\$ 50,716
Litigation settlement costs	(69,673)		
Restructuring		(409)	(2,189)
Non-GAAP Operating expenses	\$ 49,522	\$ 51,316	\$ 48,527

Reconciliation of GAAP to Non-GAAP Profit from Operations (in thousands)

	Three Months Ended		
	Sept. 30, 2009	June 30, 2009	Sept. 30, 2008
GAAP Profit (loss) from			
Operations	\$ (60,194)	\$6,253	\$ 5,691
Ormco royalties	1,906		
Litigation settlement costs	69,673		
Restructuring		409	2,189
Non-GAAP Profit from Operations	\$ 11,385	\$ 6,662	\$7,880
	==========	==========	=========

Reconciliation of GAAP to Non-GAAP Net Profit (in thousands, except per share amounts)

	Three Months Ended		
	Sept. 30, 2009	June 30, 2009	Sept. 30, 2008
GAAP Net profit (loss) Ormco royalties Litigation settlement costs Restructuring Tax effect on non-GAAP adjustments	\$ (49,942) 1,906 69,673 	\$ 4,545	\$ 5,157 2,189
Non-GAAP Net profit		\$ 4,827	
Diluted Net profit (loss) per share:			
GAAP		\$ 0.07	
Non-GAAP	\$ 0.13	======== \$ 0.07 ========	\$ 0.11
Shares used in computing diluted GAAP net profit/loss per share	69,528	67,373	
Shares used in computing diluted non-GAAP net profit per share		67,373	68,704

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.

(in millions, except per share amounts and percentages)

		Q4 2009	
	GAAP	Adjustment (a)	Non-GAAP
Net Revenue	\$77.5-\$81.0		\$77.5 - \$81.0
Gross Profit	\$55.1-\$58.1	\$3.8	\$58.9 - \$61.9
Gross Margin	71.1%-71.8%	4.7%-4.9%	76.0% - 76.5%
Operating Expenses	\$49.0-\$50.0		\$49.0 - \$50.0
Operating Margin	7.9%-10.1%	4.7%-4.9%	12.8% - 14.8%
Net Income per Diluted Share	\$0.07-\$0.09	\$0.01	\$0.08 - \$0.10
Stock Based Compensation Expense: Cost of Revenues Operating Expenses	\$0.3 \$3.5		\$0.3 \$3.5
Total Stock Based Compensation Expense	\$3.9		\$3.9
(a) Ormco Royalties			
Business Metrics:	Q4 2009		
Case Shipments Cash DSO Capex Depreciation & Amortization Diluted Shares Outstanding	57.0K - 59. \$170M - \$17 mid 60's \$2.0M - \$4. \$2.0M - \$3. 76M	0М	
Full Year 2009:	FY 2009		
Stock Based compensation Diluted Shares Outstanding	\$15.9M 70M		

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SOURCE: Align Technology

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