

Align Technology Announces Fourth Quarter and Fiscal 2009 Results

Jan 27, 2010 (GlobeNewswire via COMTEX News Network) -- * Record Q4 Invisalign case shipments of 61.1 thousand increase 8.0% sequentially and 16.0% year-over-year * Record Q4 net revenues of \$86.6 million increase 9.3% sequentially and 16.9% year-over-year

SANTA CLARA, Calif., Jan. 27, 2010 (GLOBE NEWSWIRE) -- Align Technology, Inc. (Nasdaq:ALGN) today reported financial results for the fourth quarter and fiscal year ended December 31, 2009.

Total net revenues for the fourth quarter of fiscal 2009 (Q4 09) were a record \$86.6 million compared to \$79.3 million reported in the third quarter of 2009 (Q3 09) and compared to \$74.1 million reported in the fourth quarter of 2008 (Q4 08). For fiscal 2009 (FY 09), net revenues of \$312.3 million increased 2.7 percent from \$304.0 million reported for fiscal 2008 (FY 08).

Invisalign case shipments for Q4 09 were a record 61.1 thousand, compared to 56.5 thousand in Q3 09 and compared to 52.6 thousand in Q4 08. For fiscal 2009, case shipments of 220.6 thousand increased four percent from 212.1 thousand reported for fiscal 2008.

"The fourth quarter was a strong finish to a better than expected year for Align and I'm very pleased to report sequential and year over year growth for Invisalign," said Thomas M. Prescott, president and CEO. "Our Q4 results reflect strong international growth, increased demand across the GP and Ortho channel in North America, continued adoption of new products including Invisalign Teen and Assist, and diligent expense management."

Net profit for Q4 09 was \$11.5 million, or \$0.15 per diluted share. Q4 net profit includes a benefit of \$1.1 million to net revenues, or approximately \$0.01 per share after taxes, reflecting an updated estimate for the fair value of Invisalign Teen replacement aligners. This is compared to net loss of \$49.9 million, or \$0.72 per diluted share in Q3 09 and net profit of \$65.5 million, or \$0.98 per diluted share in Q4 08. Q3 09 net loss of \$49.9 million 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. Q4 08 net profit of \$65.5 million includes a restructuring charge of \$4.0 million and a favorable impact of approximately \$64.6 million, or \$0.97 per diluted share from the release of a tax valuation allowance on specific deferred tax assets. Stock-based compensation expense included in Q4 09 was \$3.1 million compared to \$4.0 million in Q3 09 and \$3.9 million in Q4 08.

Net loss for fiscal 2009 was \$31.3 million, or \$0.45 per diluted share, which includes litigation settlement costs of \$69.7 million and royalties of \$6.2 million, for a total of \$0.85 per diluted share related to the settlement agreement with Ormco Corporation, and a restructuring charge of \$1.3 million, or \$0.01 per diluted share. This compares to a net profit of \$80.0 million, or \$1.18 per diluted share in fiscal 2008, which includes a restructuring charge of \$6.2 million and the favorable impact of approximately \$64.6 million, or \$0.95 per diluted share from the release of a tax valuation allowance on specific deferred tax assets in Q4 08. Stock-based compensation expense included in FY 09 net profit was \$15.1 million compared to \$17.1 million in FY 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 Q4 09 was \$12.1 million, or \$0.16 per diluted share. This is compared to non-GAAP net profit of \$8.9 million, or \$0.13 per diluted share in Q3 09 and non-GAAP net profit of \$4.9 million, or \$0.07 per diluted share in Q4 08. Non-GAAP net profit for fiscal 2009 was \$29.1 million or \$0.41 per diluted share. This compares to a non-GAAP net profit of \$21.5 million or \$0.32 per diluted share in fiscal 2008.

Q4 09 Operating Results

Key GAAP Operating Results	Q4 09	Q3 09	Q4 08
Gross Margin	73.7%	74.4%	72.7%

Operating Expense Operating Margin Net Profit (Loss)	\$49.2M 16.9% \$11.5M	•	\$52.6M 1.8% \$65.5M
Earnings Per Diluted Share (EPS)	\$0.15	(\$0.72)	\$0.98
Key Non-GAAP Operating Results	Q4 09	Q3 09	Q4 08
Non-GAAP Gross Margin	78.6%	76.8%	72.7%
Non-GAAP Operating Expense	\$49.2M	\$49.5M	\$48.5M
Non-GAAP Operating Margin	21.8%	14.4%	7.2%
Non-GAAP Net Profit	\$12.1M	\$8.9M	\$4.9M
Non-GAAP Earnings Per Diluted			
Share (EPS)	\$0.16	\$0.13	\$0.07

Liquidity and Capital Resources

As of December 31, 2009, Align had \$186.5 million in cash, cash equivalents, and short-term marketable securities compared to \$110.2 million as of December 31, 2008.

Key Business Metrics

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

			Q4
			09/Q3
			09
		% of Total	용
Revenue by Channel (\$M):	Q4 09	Revenue	Change
North American Orthodontists	\$25.0	28.9%	10.2%
North American GP Dentists	\$36.2	41.8%	6.7%
International	\$21.3	24.5%	15.2%
Non-case Revenue*	\$4.1	4.8%	(0.7)%
-			
Total Revenue	\$86.6	100%	9.3%
	=====	=======	=====
*includes training, ancillary and retainers	products,		
and recarners			

Cases Shipped by Channel:

			Q4 09/Q3 09
		% of Total	%
	Q4 09	Cases	Change
North American Orthodontists	19,780	32.4%	5.1%
North American GP Dentists	27,720	45.4%	8.4%
International	13,560	22.2%	11.9%
Total Cases Shipped	61,060	100%	8.0%
	=====	=======	=====

Cases Shipped by Product:

	Q4 09	% of Total Cases	
Invisalign Full Invisalign Express Invisalign Teen	41,570 8,535		7.4% 1.3%
Invisalign Assist	2,770	4.5%	
Total Cases Shipped		100%	
Average Selling Price (ASP), as billed:	Q4 09		
Total Worldwide Blended ASP International ASP	\$1,400 \$1,610		
Number of Doctors Cases were Shipped to:	Q4 09		
North American Orthodontists North American GP Dentists	3,995 11,035		
International	3,595		
Total Doctors Cases were Shipped to Worldwide	18,625		
Number of Doctors Trained Worldwide:	Q4 09	Cumulative	
North American Orthodontists North American GP Dentists		8,935 35,215	
International		15,740	
Total Doctors Trained Worldwide		59,890 =====	
Doctor Utilization Rates*:	Q4 09	Q3 09	Q4 08
North American Orthodontists North American GP Dentists	5.0		4.6 2.3
International	3.8	3.5	
Total Utilization Rate	3.3	3.1	3.0

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

2009 Business Highlights

During 2009, Align continued to make progress with strategic initiatives including the ongoing evolution of Invisalign products, customer channels, brand strategy and international expansion. The following business highlights summarize the company's accomplishments related to these initiatives during the year:

Invisalign Innovation -- New and Improved Features Are Tackling Barriers to Utilization

One of Align's key strategies for increasing adoption is to accelerate product and technology innovation to extend the clinical effectiveness of the Invisalign system. In October, the Company demonstrated significant progress on this front by introducing new and enhanced features for all Invisalign products. The new and improved features are designed to deliver better results across more clinical situations, and to overcome barriers to utilization by addressing clinical issues that doctors have traditionally perceived as challenging in Invisalign treatment, such as extrusions and rotations.

Proficiency Requirements -- Committed to Helping Practices be Successful with Invisalign

In June, Align announced the Invisalign Proficiency Requirements, designed to ensure that every practice that works with Invisalign is successful and every patient that receives Invisalign treatment gets the outcome they wanted. The Proficiency program requires every Invisalign provider in North America start at least 10 Invisalign patients in treatment and complete at least 10 Invisalign-specific continuing education (CE) credits each calendar year to maintain active account status. As of January 2010, approximately 6,400 doctors met the Invisalign Proficiency Requirements and another 15,800 doctors met the criteria for the additional six-month qualification period by starting at least one Invisalign case and completing at least one hour of Invisalign CE in 2009.

New Invisalign Brand Identity -- Reflecting Today's Evolving Invisalign Product Capability

Align recently evolved its brand strategy by updating the Invisalign look and feel, including a new and more modern logo. As part of the re-branding initiative, Align updated its consumer marketing programs, including the Invisalign websites, to direct patients to practices that are committed to being successful with Invisalign. All practices that met the Invisalign Proficiency Requirements for 2009 will receive new marketing materials, including the new Invisalign logo. These practices will be the first customers to be able to utilize the new Invisalign branding for use in their own marketing. In addition to the new branding materials, Preferred Providers will benefit from a new Preferred Provider designation that reflects their annual proficiency commitment.

New International Distributor -- Expanding into Emerging High Potential Countries in EMEA

Earlier this month, Align announced that it is adding an international distributor for the smaller country markets in Europe, the Middle East and Africa (EMEA). As part of the distribution agreement for EMEA, Gil Laks, Align Technology vice president, International will leave Align and take on a new role as owner of the new distributor in the second quarter of 2010.

For further information, please visit the investor relations section of the Company's website: www.investor.aligntech.com.

Q1 Fiscal 2010 Business Outlook

For the first quarter of fiscal 2010 (Q1 10), Align Technology expects net revenues to be in a range of \$85 million to \$88 million. GAAP earnings per diluted share for Q1 10 is expected to be in a range of \$0.11 to \$0.13. Non-GAAP earnings per diluted share for Q1 10 is expected to be in the range of \$0.12 to \$0.14. Stock-based compensation expense for Q1 10 is expected to be approximately \$4.4 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, January 27, 2010 at 4:30 p.m. ET, 1:30 p.m. PT, to review its fourth quarter and fiscal year 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 341731 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 February 10, 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 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, impact of releasing the tax valuation allowance, 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 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 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 first quarter of 2010, 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 meet the Invisalign Proficiency Requirements and the willingness and ability of our customers to maintain and/or increase utilization to meet the Invisalign Proficiency Requirements 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			
	31,	31,	December 31, 2009	31, 2008
Net revenues	\$86,616	\$74,125	\$312,333	\$303,976
Cost of revenues	22,810		78,841	
Gross profit	63,806		233,492	
Operating expenses: Sales and marketing General and administrative Research and development Restructuring	15,487 5,781	16,249 5,951		62,154 26,165
Litigation settlement costs			69,673	
Total operating expenses	49,161			
Profit (loss) from operations	14,645	1,325	(34,012)	15,514
<pre>Interest and other income (expense), net</pre>	(315)	(111)	119	1,562
Profit (loss) before income taxes	14,330	1,214	(33,893)	17,076
Provision for (benefit from) income taxes	2,838		(2,624)	
Net profit (loss)	\$11,492	\$65,496	\$(31,269)	\$79,987

	======	======	=======	======
Net profit (loss) per share				
- basic	\$0.15 ======	\$0.99 =====	\$(0.45) ======	\$1.20 ======
- diluted	\$0.15 ======	\$0.98 ======	\$(0.45) ======	\$1.18 ======
Shares used in computing net profit/loss per share				
- basic	74,482 ======	66,440	69,094	66,812
- diluted	76,831	66,816	69,094	68,064

ALIGN TECHNOLOGY, INC.
UNAUDITED CONDENSED CONSOLIDATED
BALANCE SHEETS
(in thousands)

ASSETS	December 31, 2009	December 31, 2008
Current assets:		
Cash and cash equivalents Marketable securities,	\$166,487	\$87,100
short-term	19,978	23,066
Accounts receivable, net		52,362
Inventories, net	2,046	1,965
Other current assets	18,251	13,414
Total current assets	261,299	177,907
Property and equipment, net Goodwill and intangible	24,971	26,979
assets, net	5,466	8,266
Deferred tax asset	61,535	61,696
Other long-term assets	1,969	4,493
Total assets	\$355,240 =====	\$279,341 =====
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities: Accounts payable Accrued liabilities	\$6,122 42,822	\$5,580 38,282

Deferred revenue	32,299	16,710
Total current liabilities	81,243	60,572
Other long term liabilities	961	229
Total liabilities	82,204	60,801
Total stockholders' equity	273,036	218,540
Total liabilities and stockholders' equity	\$355,240 =====	\$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		
	December 31, 2009	September 30, 2009	December 31, 2008
GAAP Gross profit	\$63,806	\$59,001	\$53,892
Ormco royalties	4,259	1,906	
Non-GAAP Gross profit	\$68,065 ======	\$60,907 =====	\$53,892 ======
Reconciliation of GAAP to			

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

	Three Months Ended		
	December 31, 2009	September 30, 2009	December 31, 2008
GAAP Operating expenses Litigation settlement costs	\$49,161 	\$119,195 (69,673)	\$52,567
Restructuring			(4,042)

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

Three Months Ended

	December 31, 2009	September 30, 2009	December 31, 2008
GAAP Profit (loss) from Operations Ormco royalties Litigation settlement costs	\$14,645 4,259	\$(60,194) 1,906 69,673	\$1,325
Restructuring			4,042
Non-GAAP Profit from Operations	\$18,904 ======	\$11,385 ======	\$5,367 ======

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

Three Months Ended

	December	September	December
	31,	30,	31,
	2009	2009	2008
GAAP Net profit (loss)	\$11,492	\$(49,942)	\$65,496
Ormco royalties	4,259	1,906	
Litigation settlement costs		69,673	
Restructuring			4,042
Release of tax valuation			
allowance			(64,608)
Tax effect on non-GAAP			
adjustments	(3,605)	(12,731)	(43)
Non-GAAP Net profit	\$12,146	\$8,906	\$4,887
	======	=======	======
Diluted Net profit (loss) per share:			
GAAP	\$0.15	\$(0.72)	\$0.98
		=======	
Non-GAAP	¢በ 16	\$0.13	¢n n7
NOIL GAMP	ŞU.16 ======		

	=======	=======	=======
non-GAAP net profit per share	76,831	70,926	66,816
Shares used in computing diluted			
	======	=======	======
GAAP net profit/loss per share	76,831	69,528	66,816
Shares used in computing diluted			

ALIGN TECHNOLOGY, INC.
RECONCILIATION OF GAAP TO NON-GAAP KEY
FINANCIAL METRICS

Reconciliation of GAAP to Non-GAAP Gross Profit (in thousands)

	Year Ended	
	31,	December 31, 2008
GAAP Gross profit	\$233,492	\$225,126
Ormco royalties	6,165	
Non-GAAP Gross profit	\$239,657 ======	\$225,126 ======
Reconciliation of GAAP to Non-GAAP Operating Expenses (in thousands)		

	Year Ended	
		December 31, 2008
GAAP Operating expenses Litigation settlement costs	\$267,504 (69,673)	\$209,612
Restructuring	(1,319)	(6,231)
Non-GAAP Operating expenses	\$196,512 ======	\$203,381 ======
Reconciliation of GAAP to		

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

Year Ended

December December 31, 31,

	2009	2008
GAAP Profit (loss) from Operations Ormco royalties Litigation settlement costs	\$(34,012) 6,165 69,673	\$15,514
Restructuring	1,319	6,231
Non-GAAP Profit from Operations	\$43,145 ======	\$21,745 ======
Reconciliation of GAAP to		

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

	Year Ended	
	31, 2009	December 31, 2008
GAAP Net profit (loss) Ormco royalties Litigation settlement costs Restructuring	\$(31,269) 6,165 69,673 1,319	
Release of tax valuation		(64,608)
Tax effect on non-GAAP		(01/000)
adjustments	(16,818)	(129)
Non-GAAP Net profit	\$29,070 =====	\$21,481 ======
Diluted Net profit (loss) per share:		
GAAP	\$(0.45)	\$1.18
	=======	
Non-GAAP	\$0.41 ======	\$0.32 ======
Shares used in computing diluted GAAP net profit/loss per share		
Shares used in computing diluted non-GAAP net profit per share	70,602	
<u>.</u>	=======	

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)

Full Year 2010:

Q1 2010

	GAAP	Adjustment (a)	Non-GAAP
Net Revenue	\$85.0 \$88.0		\$85.0 \$88.0
Gross Profit	\$64.9 \$67.6	\$0.8	\$65.7 \$68.4
Gross Margin	76.3% - 76.8%	1.0%	77.3% - 77.8%
Operating Expenses	\$51.8 \$52.8		\$51.8 \$52.8
Operating Margin	15.3% - 16.8%	1.0%	16.3% - 17.8%
Net Income per Diluted Share	\$0.11 \$0.13	\$0.01	\$0.12 \$0.14
Stock Based Compensation Expense: Cost of Revenues	\$0.4		\$0.4
Operating Expenses	\$4.0		\$4.0
Total Stock Based Compensation Expense	\$4.4		\$4.4
(a) Ormco Royalties			
Business Metrics:			
	Q1 2010		
Case Shipments Cash Capex Depreciation & Amortization Diluted Shares Outstanding	60K - 62K \$200M \$205M \$4.0M \$6.0M \$2.0M \$3.0M		
2 3	, , , , , ,		

FY 2010

Diluted Shares
Outstanding 78M
Stock Based
Compensation Expense \$20M

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