

invisalign

Securities and Exchange Commission Division of Corporation Finance Mail Stop 3030 100 F Street, N.E. Washington, D.C. 20549

November 4, 2009

Re:

Attention:	Mr. Todd Mr. Kartholy Mr. Cascio

Align Technology, Inc. Form 10-K for the fiscal year ended December 31, 2008 File No. 000-32259

Ladies and Gentlemen:

On behalf of Align Technology, Inc. ("Align"), we respectfully submit this letter in response to comments from the staff (the "Staff") of the Securities and Exchange Commission (the "Commission") received by letter dated October 22, 2009 relating to Align's Annual Report on Form 10-K for the fiscal year ended December 31, 2008 (the "Form 10-K").

In this letter, we have recited the comments from the Staff in italicized, bold type and have followed each comment with Align's response. Capitalized terms used but not defined herein shall have the meanings ascribed thereto in the Form 10-K, as applicable.

## Form 10-K for the Fiscal Year Ended December 31, 2008

<u>Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations</u> <u>Restructurings, page 48</u>

1. We see that you have implemented restructuring plans in 2008 and 2009. In future filings please provide quantified disclosure of the expected cost savings from the restructuring plans and identify the period when you expect to first realize those benefits. For guidance on MD&A disclosures about exit plans please refer to SAB Topic 5-P.

Align acknowledges the Staff's comment and will, in the Form 10-Q for the period ending September 30, 2009 and future filings as appropriate, provide a quantified disclosure of the expected cost savings from the restructuring plans as described in the guidance noted.

## Provisions for (benefit from) income taxes, page 50

2. We see that you released a significant portion of the deferred income tax asset valuation allowance in 2008. Please tell us and in future filings provide a discussion of the specific factors on which your determination was based. In this regard, describe the specific positive and negative evidence you considered highlighting changes in assumptions and environmental factors leading to the change in the conclusion about recoverability. Refer to Section II-B of the "Division of Corporation Finance: Frequently Requested Accounting and Financial Reporting Interpretations and Guidance," which is available on our website.

Align acknowledges the Staff's comment and will provide, in the Form 10-Q for the period ending September 30, 2009 and the Form 10-K for 2009, a discussion of the specific factors supporting the assessment of the deferred income tax asset valuation.

In the Company's assessment of the valuation of deferred tax assets, we estimated future market growth, forecasted earnings, projected taxable income, future capital gains and losses and foreign source income. In that regard, the Company considered the following positive evidence:

- · Four consecutive quarters (Q1-Q4 of 2008) and seven of the last eight quarters (Q1-Q3 2007) of pre-tax operating profitability
- Then projected fiscal 2009 pre-tax book income of \$7.2 million for the US entity and \$8.8 million for the consolidated Company
- · Pre-tax book income outlook beyond 2009 suggested that the deferred tax assets related to US temporary differences would be utilized

The Company also considered the following negative evidence:

- History of operating losses in 2006 and prior to 2003
- The cyclical nature of the business and price volatility
- Uncertainty as to the impact of new product launches on profitability

The weight of the positive evidence was far greater than the weight of the negative evidence. The Company released the valuation allowance because Align's history and outlook on profitability in the US would show it is more likely than not that the deferred tax assets related to US temporary differences will be utilized.

The following additional information will be disclosed in the Form 10-Q for the period ending September 30, 2009 and in future filings, as appropriate:

At December 31, 2008, based on an evaluation of the available positive and negative evidence, we determined that most of our deferred tax assets would be realized with the exception of certain capital loss and foreign net operating loss carryforwards. In making that determination, we considered the historical and projected pretax operating profit, excluding stock-based compensation, as well as the cyclical nature of our business and the uncertainty as to the impact

2

of new product launches. Specifically, at December 31, 2008, we considered the following positive evidence:

- · cumulative seven quarters of pretax operating profitability plus permanent items
- the then-projected pretax book income for 2009 and beyond suggesting that deferred tax assets will be utilized

We also considered the following negative evidence:

- history of operating losses in 2006 and prior to 2003
- · cyclical nature of the business and price volatility

We believe that the positive evidence is of sufficient quality and quantity to overcome the negative evidence and as a result, we released our tax valuation allowance of \$64.6 million in the fourth quarter of 2008. The remaining valuation allowance of approximately \$6.2 million is related to capital loss and foreign net operating loss carryforwards as of December 31, 2008 because we cannot forecast sufficient future capital gains or foreign source income to realize these deferred tax assets. These net operating loss carryforwards will result in an income tax benefit if and when we conclude it is more likely than not that the related deferred tax assets will be realized.

## Item 8. Financial Statements

## <u>Note 1. Summary of Significant Accounting Policies</u> <u>Foreign Currency</u>

3. We see that in 2007 you concluded that as a result of changed economic facts and circumstances you concluded that the functional currency of certain subsidiaries in Europe is now the local currency. In future filings please provide a description of the primary economic factors you considered in reaching your determinations. Please refer to FASB ASC 830-10-45-7 and 830-10-55-4 and -5. Also refer to Section I-D of the "Division of Corporation Finance: Frequently Requested Accounting and Financial Reporting Interpretations and Guidance," which is available on our website.

Align acknowledges the Staff's comment and will, in the Form 10-K for 2009, provide a discussion of the specific factors supporting the determination of the functional currency of the subsidiaries as described in the guidance noted.

## Note 7. Legal Proceedings, page 78

4. We see the discussion of the two legal matters. Tell us how your disclosures consider the guidance from FASB ASC 450-20-50-4b. Under that guidance you should disclose an estimate of the possible loss or range of loss or provide a statement that such estimate cannot be made when there is a reasonable possibility that a loss has been incurred as provided in FASB ASC 450-20-50-3.

3

Align acknowledges the Staff's comment and confirms that the Company considered the guidance from FASB ASC 450-20-50-4b. With respect to the two pending legal matters, Align supplementally advises the Staff that at the time the 10-K was filed, there was not sufficient evidence to conclude that a reasonable possibility existed that a loss had been incurred.

In connection to the Ormco matter, the case was scheduled to go to jury trial in June 2009. At the time the 2008 Form 10-K was filed, the Company intended to vigorously defend its position and ultimately succeed in convincing the jury to decide in favor of Align. When the trial took place during the second quarter of 2009 and the jury returned a verdict in favor of Ormco, the Company concluded that there existed a reasonable possibility of loss. However, due to the complicated factors in the case and the lengthy discovery process to assess damages that had not yet begun, the Company believed the amount of the loss could not reasonably be estimated at that time. A statement to this effect was disclosed in the Form 10-Q for the period ended June 30, 2009.

In connection to the Class Action matter, at the time the 2008 Form 10-K was filed, all discovery in the case had been stayed pending the Court's decision on the motion for class certification, the motion to dismiss and the motion for summary judgment. The most recent of these motions was filed in October 2007. Because all activity related to the case had been stayed there was no indication of a potential loss. To date, the court still has not made any decisions on the motions filed nor has there been any other activity of note in the case. Thus, the Company still contends that there is not sufficient evidence to conclude that a reasonable possibility exists that a loss had been incurred.

The following will be disclosed in the Form 10-Q for the period ending September 30, 2009 and in future filings, as appropriate, related to legal proceedings pending as of the end of the most recent quarter-end:

# Consumer Class Action

On May 18, 2007, Debra A. Weber filed a consumer class action lawsuit against Align, OrthoClear, Inc. and OrthoClear Holdings, Inc. (d/b/a OrthoClear, Inc.) in Syracuse, New York, U.S. District Court. The complaint alleges two causes of action against the OrthoClear defendants and one cause of action against Align for breach of contract. The cause of action against the Company, titled "Breach of Third Party Benefit Contract" references Align's agreement to make Invisalign treatment available to OrthoClear patients, alleging that the Company failed "to provide the promised treatment to Plaintiff or any of the class members".

On July 3, 2007, the Company filed an answer to the complaint and asserted 17 affirmative defenses. On July 20, 2007, the Company filed a motion for summary judgment on the Third Cause of Action (the only cause of action alleged against Align). On August 24, 2007, Weber filed a motion for class certification. On October 1, 2007, the Company filed an opposition to the motion for class certification and it is currently awaiting rulings from the Court. OrthoClear has filed a motion to dismiss. The initial case management conference and all discovery has been stayed pending the Court's decision on the motion for class certification, OrthoClear's motion to dismiss and the Company's motion for summary judgment. The Company believes the lawsuit

to be without merit and intends to vigorously defend itself. Accordingly, the Company believes there is not sufficient evidence to conclude that a reasonable possibility exists that a loss had been incurred as of September 30, 2009.

### Securities Litigation

In August 2009, Plaintiff Charles Wozniak filed a lawsuit against the Company and its Chief Executive Officer and President, Thomas M. Prescott ("Mr. Prescott"), in District Court for the Northern District of California on behalf of a claimed class consisting of all persons or entities who purchased the common stock of Align between January 30, 2007 and October 24, 2007. The complaint alleges that Align and Mr. Prescott violated Section 10(b) of the Securities Exchange Act of 1934 and that Mr. Prescott violated Section 20(a) of the Securities Exchange Act of 1934. Specifically, the complaint alleges that during the class period Align failed to disclose that it had shifted the focus of the sales force to clearing backlog, causing a significant decrease in the number of new case starts.

Two plaintiffs have filed motions to be appointed lead plaintiff. A hearing on these two motions is set for November 20, 2009. The Company believes the lawsuit to be without merit and intends to vigorously defend itself. Accordingly, the Company believes there is not sufficient evidence to conclude that a reasonable possibility exists that a loss had been incurred as of September 30, 2009.

### Note 13. Income Taxes, page 87

### 5. In future filings please disclose the domestic and foreign amounts of pre-tax accounting income. Please refer to Rule 4-08(h) of Regulation S-X.

Align acknowledges the Staff's comment and will, in the Form 10-K for 2009, disclose the domestic and foreign amounts of pre-tax accounting income as described in the guidance noted.

6. We see that you have received tax incentives in the form of a reduced income tax rate from the government of Costa Rica. In future filings please provide the quantified disclosure about the impact of those incentives as called for by SAB Topic 11-C.

Align acknowledges the Staff's comment and will, in the Form 10-K for 2009, quantify and disclose the impact of the tax incentives provided by the government of Costa Rica as described in the guidance noted.

#### Form 8-K dated August 16, 2009

7. Please tell us how you intend on accounting for the settlement with Ormco and explain the rationale in GAAP to the extent necessary for an understanding of the planned accounting.

On August 16, 2009, Align entered into three agreements with Ormco Corporation ("Ormco"), an affiliate of Danaher Corporation ("Danaher"): a Settlement Agreement, a Stock Purchase Agreement,

5	

and a Joint Development, Marketing and Sales agreement ("Collaboration Agreement"). The Settlement Agreement ended all pending litigation between the parties, and Align agreed to (1) make a cash payment of \$13.2 million upon the execution of the agreement and (2) issue a total of 7.6 million non-assessable shares of common stock pursuant to the Stock Purchase Agreement. Under the Collaboration Agreement, Align and Ormco agreed to jointly develop and market an orthodontic product for the most complex orthodontic cases that combine the Invisalign system with Ormco's orthodontic brackets and arch wire systems over the next seven years. Because the Company entered into several agreements with Ormco on the same date, the guidance related to multiple element arrangements was considered in determining the allocation of the total settlement amount to the various elements of this arrangement.

In accordance with the Collaboration Agreement, each party will retain ownership of its pre-existing intellectual property, and each party will be granted intellectual property licenses in their respective field for jointly-developed combination products. The Collaboration Agreement, among other things, ensures mutual and equal participation, and equal share of the risks, costs, and benefits associated with developing the combination product. With the assistance of a third party valuation firm, Align concluded there was no value on the execution date of this agreement, as the Company has not contributed any assets or tendered any consideration. In addition, as part of its long-term strategic plan, the Company had the intention of collaborating with other orthodontic industry leaders to offer Invisalign in combination with traditional wires and brackets therapy, and it believes that the terms of such an agreement would have been similar to those it reached with Ormco.

Upon execution of the Settlement Agreement, 5.6 million shares were issued to Danaher and the remaining 2.0 million shares were issued upon the expiration of the waiting period under the provisions of the Hart-Scott-Rodino Antitrust Improvements Act, which occurred on September 21, 2009. In addition to other provisions of the Settlement Agreement, these shares may not be resold except pursuant to an effective registration statement under the Securities Act or an available exemption from registration. The Company is not obligated to affect any such registration prior to the one year anniversary of this agreement. In order to determine the fair value of the stock issued to Danaher, the Company considered the fair value guidance from FASB ASC 820-10-55-52. The fair value of the shares should reflect the value that market participants would demand because of the risk relating to the inability to access a public market for these securities for the specified period. With the assistance of a third party valuation firm, Align has concluded that 25% is an appropriate discount based on review of published restricted stock studies, comparison to restricted stock transactions of other companies in the industry in which Align operates, and the cost of hedging the restricted stock using the Black-Scholes option pricing model. The fair value of the unregistered shares was determined as of the market

closing price on the dates the share were issued less the 25% discount rate, for a total value of \$76.7 million, including the cash payment. The settlement transaction value is summarized as follows:

6

	Number of shares issued	Stock at Close	Stock Price with 25% Discount	Total Amount
August 14, 2009(1)	5,561,489	\$ 10.13	\$ 7.60	\$ 42,253,413
September 22, 2009	2,025,000	14.00	10.50	 21,262,500
Subtotal stock	7,586,489			63,515,913
Cash payment				 13,148,866
Total transaction value				\$ 76,664,779
				\$ · · · ·

In accordance with the Settlement Agreement, Ormco released Align from any and all past and future claims of infringement for the period September 9, 2003 through the expiration of the patent on January 19, 2010 ("infringement period"). In order to determine how to allocate the settlement value between past infringement and the future use of the patent, Align referred to a speech by Eric West, Associate Chief Accountant, Office of the Chief Accountant, on December 10, 2007 at the 2007 AICPA National Conference on Current SEC and PCAOB Developments. The Company considered both past and estimated future case shipment volumes during the infringement period, and allocated the total settlement value across all case shipments. The value attributed to past infringement claims was recorded as litigation settlement costs and was based on case shipments from September 9, 2003 through August 16, 2009, totaling \$69.7 million. The remaining \$7.0 million was recorded to the balance sheet as prepaid royalties, and will be amortized to cost of revenues until the expiration of the patent in January 2010.

Align acknowledges that the Company is responsible for the adequacy and accuracy of the disclosures in its filings with the Securities and Exchange Commission. Align further acknowledges that staff comments or changes to disclosures in response to staff comments do not foreclose the Commission from taking any action with respect to the filing and that the company may not assert staff comments as a defense in any proceeding initiated by the Commission or any person under the federal securities laws of the United States.

Very truly yours,

/s/ Kenneth B. Arola

Kenneth B. Arola Vice President and Chief Financial Officer Align Technology, Inc.

(1) Since the settlement agreement was executed on Sunday, August 16, 2009, the Company used the closing price from the last day of trading activity, Friday, August 14, 2009.

7