

ALIGN TECHNOLOGY INC

FORM 10-Q

(Quarterly Report)

Filed 11/05/09 for the Period Ending 09/30/09

| | |
|-------------|---|
| Address | 851 MARTIN AVENUE SANTA CLARA, CA 95050 |
| Telephone | 4087381500 |
| CIK | 0001097149 |
| Symbol | ALGN |
| SIC Code | 3842 - Orthopedic, Prosthetic, and Surgical Appliances and Supplies |
| Industry | Medical Equipment & Supplies |
| Sector | Healthcare |
| Fiscal Year | 12/31 |

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES
EXCHANGE ACT OF 1934**

For the quarterly period ended September 30, 2009

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES
EXCHANGE ACT OF 1934**

For the transition period from to

Commission file number: 0-32259

Align Technology, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of
incorporation or organization)

94-3267295

(I.R.S. Employer
Identification Number)

881 Martin Avenue

Santa Clara, California 95050

(Address of principal executive offices)

(408) 470-1000

(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☐ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definitions of "large accelerated filer," "accelerated filer," and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ☒

Accelerated filer ☐

Non-accelerated filer ☐

Smaller reporting company ☐

(Do not check if a smaller reporting company)

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The number of shares outstanding of the registrant's Common Stock, \$0.0001 par value, as of October 30, 2009 was 74,461,321.



ALIGN TECHNOLOGY, INC.

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Invisalign, Align, ClinCheck, Invisalign Assist, Invisalign Teen and Viverra, amongst others, are trademarks belonging to Align Technology, Inc. and are pending or registered in the United States and other countries.

PART I—FINANCIAL INFORMATION

ITEM 1 FINANCIAL STATEMENTS ALIGN TECHNOLOGY, INC. CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (in thousands, except per share data) (unaudited)

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|-------------------------------------|-----------|------------------------------------|------------|
| | 2009 | 2008 | 2009 | 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 | 27,687 | 28,214 | 84,649 | 88,737 |
| General and administrative | 16,224 | 14,395 | 46,231 | 45,905 |
| Research and development | 5,611 | 5,918 | 16,471 | 20,214 |
| Restructurings | — | 2,189 | 1,319 | 2,189 |
| Litigation settlement | 69,673 | — | 69,673 | — |
| Total operating expenses | 119,195 | 50,716 | 218,343 | 157,045 |
| Profit (loss) from operations | (60,194) | 5,691 | (48,657) | 14,189 |
| Interest and other income (expense), net | (271) | 264 | 434 | 1,673 |
| Net profit (loss) before provision for 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) | \$ (49,942) | \$ 5,157 | \$ (42,761) | \$ 14,491 |
| Net profit (loss) per share: | | | | |
| Basic | \$ (0.72) | \$ 0.08 | \$ (0.64) | \$ 0.21 |
| Diluted | \$ (0.72) | \$ 0.08 | \$ (0.64) | \$ 0.21 |
| Shares used in computing net profit (loss) per share: | | | | |
| Basic | 69,528 | 67,367 | 67,278 | 68,330 |
| Diluted | 69,528 | 68,704 | 67,278 | 69,906 |

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

ALIGN TECHNOLOGY, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands, except per share data)
(unaudited)

| | September 30, 2009 | December 31, 2008 |
|--|-----------------------|----------------------|
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 135,961 | \$ 87,100 |
| Marketable securities, short-term | 18,979 | 23,066 |
| Accounts receivable, net of allowance for doubtful accounts of \$1,446 and \$612, respectively | 55,035 | 52,362 |
| Inventories, net | 1,892 | 1,965 |
| Prepaid expenses and other current assets | 25,671 | 13,414 |
| Total current assets | <u>237,538</u> | <u>177,907</u> |
| Property and equipment, net | 24,429 | 26,979 |
| Goodwill | 478 | 478 |
| Intangible assets, net | 5,688 | 7,788 |
| Deferred tax asset | 61,048 | 61,696 |
| Other assets | 1,603 | 4,493 |
| Total assets | <u>\$ 330,784</u> | <u>\$ 279,341</u> |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current liabilities: | | |
| Accounts payable | \$ 7,498 | \$ 5,580 |
| Accrued liabilities | 37,484 | 38,282 |
| Deferred revenues | 27,920 | 16,710 |
| Total current liabilities | 72,902 | 60,572 |
| Other long-term liabilities | 202 | 229 |
| Total liabilities | 73,104 | 60,801 |
| Commitments and contingencies (Notes 5 and 8) | | |
| Stockholders' equity: | | |
| Preferred stock, \$0.0001 par value (5,000 shares authorized; none issued) | — | — |
| Common stock, \$0.0001 par value (200,000 shares authorized; 74,329 and 65,633 shares issued and outstanding, respectively.) | 7 | 7 |
| Additional paid-in capital | 521,133 | 439,494 |
| Accumulated other comprehensive income, net | 531 | 269 |
| Accumulated deficit | (263,991) | (221,230) |
| Total stockholders' equity | 257,680 | 218,540 |
| Total liabilities and stockholders' equity | <u>\$ 330,784</u> | <u>\$ 279,341</u> |

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

ALIGN TECHNOLOGY, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)
(unaudited)

| | Nine Months Ended September 30, | |
|--|------------------------------------|------------------|
| | 2009 | 2008 |
| Cash Flows from Operating Activities: | | |
| Net profit (loss) | \$ (42,761) | \$ 14,491 |
| Adjustments to reconcile net profit (loss) to net cash provided by operating activities: | | |
| Deferred taxes | 740 | — |
| Depreciation and amortization | 7,582 | 7,365 |
| Amortization of intangibles | 2,100 | 2,127 |
| Stock-based compensation | 12,011 | 13,176 |
| Litigation settlement costs and amortization of prepaid royalties | 58,430 | — |
| Provision from doubtful accounts | 958 | — |
| Loss on retirement and disposal of fixed assets | 20 | 206 |
| Excess tax benefit from share-based payment arrangements | — | (188) |
| Non-cash restructuring charges | — | 411 |
| Changes in assets and liabilities: | | |
| Accounts receivable | (3,167) | (4,093) |
| Inventories | 74 | (109) |
| Prepaid expenses and other current assets | (7,036) | 1,491 |
| Accounts payable | 816 | (733) |
| Accrued and other long-term liabilities | (912) | (6,269) |
| Deferred revenues | 11,051 | 3,116 |
| Net cash provided by operating activities | <u>39,906</u> | <u>30,991</u> |
| Cash Flows from Investing Activities: | | |
| Purchase of property and equipment | (4,084) | (12,361) |
| Proceeds from sale of equipment | — | 189 |
| Purchases of marketable securities | (33,940) | (65,094) |
| Maturities of marketable securities | 40,910 | 66,463 |
| Other assets | 35 | 272 |
| Net cash provided by (used in) investing activities | <u>2,921</u> | <u>(10,531)</u> |
| Cash Flows from Financing Activities: | | |
| Proceeds from issuance of common stock | 6,376 | 10,222 |
| Payments on short-term obligations | (136) | (271) |
| Repurchased shares of common stock | — | (39,432) |
| Excess tax benefit from share-based payment arrangements | — | 188 |
| Employees' taxes paid upon the vesting of restricted stock units | (264) | (347) |
| Net cash provided by (used in) financing activities | <u>5,976</u> | <u>(29,640)</u> |
| Effect of foreign exchange rate changes on cash and cash equivalents | 58 | (204) |
| Net increase (decrease) in cash and cash equivalents | 48,861 | (9,384) |
| Cash and cash equivalents at beginning of period | 87,100 | 89,140 |
| Cash and cash equivalents at end of period | <u>\$ 135,961</u> | <u>\$ 79,756</u> |

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

ALIGN TECHNOLOGY, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(unaudited)

Note 1. Summary of Significant Accounting Policies

Basis of presentation

The accompanying unaudited Condensed Consolidated Financial Statements have been prepared by Align Technology, Inc. (the “Company” or “Align”) in accordance with the rules and regulations of the Securities and Exchange Commission (“SEC”) and contain all adjustments, including normal recurring adjustments, necessary to present fairly Align’s financial position as of September 30, 2009, its results of operations for the three and nine months ended September 30, 2009 and 2008, and its cash flows for the nine months ended September 30, 2009 and 2008. The Condensed Consolidated Balance Sheet as of December 31, 2008 was derived from the December 31, 2008 audited financial statements. Certain prior period amounts have been reclassified to conform with the current period presentation. These reclassifications had no impact on previously reported net earnings or financial position.

The results of operations for the three and nine months ended September 30, 2009 are not necessarily indicative of the results that may be expected for the year ending December 31, 2009 or any other future period, and the Company makes no representations related thereto. The information included in this Quarterly Report on Form 10-Q should be read in conjunction with “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” “Quantitative and Qualitative Disclosures About Market Risk” and the Consolidated Financial Statements and notes thereto included in Items 7, 7A and 8, respectively, of the Company’s Annual Report on Form 10-K for the year ended December 31, 2008.

In connection with the preparation of the condensed consolidated financial statements, the Company evaluated events subsequent to the balance sheet date of September 30, 2009 through the financial statement issuance date of November 5, 2009.

The preparation of financial statements in accordance with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the amounts reported in Align’s Condensed Consolidated Financial Statements and accompanying notes. Actual results could differ materially from those estimates.

Recent Accounting Pronouncements

In September 2006, the Financial Accounting Standards Board (“FASB”) issued Financial Accounting Standard No. 157 (“FAS 157”) or Accounting Standard Codification (“ASC”) 820 which provides guidance for using fair value to measure assets and liabilities. It also responds to investors’ requests for expanded information about the extent to which companies measure assets and liabilities at fair value, the information used to measure fair value, and the effect of fair value measurements on earnings. FAS 157 (ASC 820) applies whenever other standards require (or permit) assets or liabilities to be measured at fair value, and does not expand the use of fair value in any new circumstances. FAS 157 (ASC 820), as originally issued, was effective for fiscal years beginning after November 15, 2007, except that under FASB Staff Position, or, “Effective Date of FASB Statement 157” (“FSP 157-2) or ASC 820 companies are allowed to delay the effective date of FAS 157 (ASC 820) for non-financial assets and non-financial liabilities that are not recognized or disclosed at fair value on a recurring basis until fiscal years beginning after November 15, 2008. In October 2008, FASB Staff Position 157-3 “Determining the Fair Value of a Financial Asset When the Market for that Asset is not Active,” (FAS 157-3 or ASC 820), was issued and effective upon issuance, including prior periods for which financial statements have not been issued FSP 157-3(ASC 820), clarified the application of FAS 157 (ASC 820) in a market that is not active. Effective January 1, 2008, the Company adopted the provisions of FAS 157(ASC 820) for all financial assets and liabilities. Effective January 1, 2009, the Company adopted FSP 157-2 (ASC 820) and 157-3(ASC 820). The adoption of these Topics did not have a material impact on the Company’s consolidated financial statements.

In April 2009, the FASB issued FSP No. 157-4 “FSP 157-4” or ASC 820 “Determining Fair Value When the Volume and Level of Activity for the Asset or Liability Have Significantly Decreased and Identifying Transactions That Are Not Orderly”, which provides guidance on determining fair value when there is no active market or where the price inputs being used represent distressed sales. FSP 157-4 (ASC 820) is effective for interim and annual periods ending after June 15, 2009 and was adopted by the Company in the second quarter of 2009. The adoption did not have a material impact on the Company’s consolidated financial statements.

In April 2009, the FASB issued FSP No. 115-2 “FSP 115-2” or ASC 320, “ Recognition and Presentation of Other-Than-Temporary Impairments”, which is effective for the Company for the quarterly period beginning April 1, 2009. FSP 115-2 (ASC 320) amends existing guidance for determining whether an other than temporary impairment of debt securities has occurred. Among other changes, the FASB replaced the existing requirement that an entity’s management assert it has both the intent and ability to hold an impaired security until recovery with a requirement that management assert (a) it does not have the intent to sell the security, and (b) it is more likely than not it will not have to sell the security before recovery of its cost basis. The adoption of this pronouncement did not have a material effect on the Company’s consolidated financial statements.

In April 2009, the FASB issued FSP 107-1 and ABP 28-1 or ASC 825 , “ Interim Disclosures about Fair Value of Financial Instruments.” This pronouncement require disclosures about fair value of financial instruments for interim reporting periods of publicly traded companies as well as in annual financial statements and also requires those disclosures in summarized financial information at interim reporting periods. FSP 107-1 and ABP 28 (ASC 825) are effective for interim and annual reporting periods ending after June 15, 2009. The Company adopted this pronouncement and provided the required disclosures in Note 2.

In April 2009, the FASB issued FSP 141(R)-1 or ASC 805, “ Accounting for Assets Acquired and Liabilities Assumed in a Business Combination That Arise from Contingencies .” FSP 141(R)-1 (ASC 805) requires that assets acquired and liabilities assumed in a business combination that arise from contingencies be recognized at fair value if fair value can be reasonably estimated. If fair value of such an asset or liability cannot be reasonably estimated, the asset or liability would generally be recognized in accordance with FASB Statement No. 5 or ASC 450 , “ Accounting for Contingencies”, and FASB Interpretation No. 14, “ Reasonable Estimation of the Amount of a Loss.” This pronouncement is effective for assets or liabilities arising from contingencies in business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008. The adoption of FSP 141(R)-1 (ASC 805) did not have a material effect on the Company’s consolidated financial statements.

In May 2009, the FASB issued FAS 165, “Subsequent Events” (FAS 165”) or ASC 855. FAS 165 (ASC 855) establishes general standards of accounting for and disclosure of events that occur after the balance sheet date but before financial statements are issued or are available to be issued. FAS 165 (ASC 855), which includes a new required disclosure of the date through which an entity has evaluated subsequent events, is effective for interim or annual periods ending after June 15, 2009. The Company has adopted this standard as of June 30, 2009; however, the adoption of FAS 165 (ASC 855) had no impact to the Company’s consolidated financial statements.

In June 2009, the FASB issued FAS No. 166, “Accounting for Transfers of Financial Assets—an amendment of FASB 140” (“FAS 166”). FAS 166 eliminates the concept of a qualifying special-purpose entity, creates more stringent conditions for reporting a transfer of a portion of a financial asset as a sale, clarifies other sale-accounting criteria, and changes the initial measurement of a transferor’s interest in transferred financial assets. FAS 166 will be effective for transfers of financial assets in annual reporting periods beginning after November 15, 2009 and in interim periods within those first annual reporting periods with earlier adoption prohibited. The Company is currently assessing the potential impact, if any, on the adoption of FAS 166 on its consolidated financial statements.

In June 2009, the FASB issued FAS No. 167, “Amendments to FASB Interpretation No. 46(R)” (“FAS 167”). FAS 167 amends FIN 46 (R), “Consolidation of Variable Interest Entities (revised December 2003)—an interpretation of ARB No. 51” (“FIN 46(R)”) to require an enterprise to perform an analysis to determine whether the enterprise’s variable interest or interests give it a controlling financial interest in a variable interest entity. This analysis identifies the primary beneficiary of a variable interest entity as one with the power to direct the activities of a variable interest entity that most significantly impact the entity’s economic performance and the obligation to absorb losses of the entity that could potentially be significant to the variable interest. FAS 167 will be effective as of the beginning of the annual reporting period commencing after November 15, 2009. The Company is assessing the potential impact, if any, of the adoption of FAS 167 on its consolidated financial statements.

In June 2009, the FASB issued FAS No. 168 “FAS 168” or ASC 105, “The FASB Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting Principles, a replacement of FASB No. 162”. FAS 168 (ASC 105) establishes the FASB Accounting Standards Codification (“Codification”), as the single source of authoritative accounting and reporting standards in the United States for all non-government entities, with the exception of the Securities and Exchange Commission and its staff. It does not include any new guidance or interpretations of US GAAP, but merely eliminates the existing hierarchy and codifies the previously issued standards and pronouncements into specific topic areas. The Codification was adopted on July 1, 2009 for the Company’s consolidated financial statements for the period ended

September 30, 2009.

In September 2009, FASB amended the ASC as summarized in Accounting Standards Update (“ASU”) 2009-13, “Revenue Recognition (ASC 605): Multiple-Deliverable Revenue Arrangements.” Guidance in ASC 605-25 on revenue arrangements with multiple deliverables has been amended to require an entity to allocate revenue to deliverables in an arrangement using its best estimate of selling prices if the vendor does not have vendor-specific objective evidence or third-party evidence of selling prices, and to eliminate the use of the residual method and require the entity to allocate revenue using the relative selling price method. The new guidance also requires expanded quantitative and qualitative disclosures about revenue from arrangements with multiple deliverables. The update is effective for fiscal years beginning on or after June 15, 2010, with early adoption permitted. Adoption may either be on a prospective basis for new revenue arrangements entered into after adoption of the update, or by retrospective application. The Company is assessing the potential impact of the update on its consolidated financial statements and is planning to adopt the update effective January 1, 2011.

Other recent accounting pronouncements issued by the FASB (including its Emerging Issues Task Force), the American Institute of Certified Public Accountants and the SEC did not or are not believed by management to have a material impact on the Company’s present or future consolidated financial statements.

Note 2. Marketable Securities and Fair Value Measurements

The Company’s short-term marketable securities as of September 30, 2009 and December 31, 2008 are as follows (in thousands):

| September 30, 2009 | Amortized Costs | Gross Unrealized Gains | Fair Value |
|---------------------------------|--------------------|------------------------------|------------------|
| U.S. government notes and bonds | \$ 17,971 | \$ 6 | \$ 17,977 |
| Corporate bonds | 1,000 | 2 | 1,002 |
| Total | <u>\$ 18,971</u> | <u>\$ 8</u> | <u>\$ 18,979</u> |

| December 31, 2008 | Amortized Costs | Gross Unrealized Gains | Gross Unrealized Losses | Fair Value |
|---|--------------------|------------------------------|-------------------------------|------------------|
| U.S. government notes and bonds | \$ 9,971 | \$ 25 | \$ — | \$ 9,996 |
| Corporate bonds and certificates of deposit | 3,774 | 1 | (24) | 3,751 |
| Agency bonds and discount notes | 8,499 | 20 | — | 8,519 |
| Commercial paper | 800 | — | — | 800 |
| Total | <u>\$ 23,044</u> | <u>\$ 46</u> | <u>\$ (24)</u> | <u>\$ 23,066</u> |

As of September 30, 2009, all short-term investments have maturity dates of less than one year. For the nine months ended September 30, 2009 and 2008, no significant losses were realized on the sale of marketable securities.

The Company’s long-term marketable securities as of December 31, 2008 are as follows (in thousands):

| December 31, 2008 | Amortized Costs | Gross Unrealized Gains | Gross Unrealized Losses | Fair Value |
|-------------------|--------------------|------------------------------|-------------------------------|-----------------|
| Agency bonds | \$ 1,000 | \$ 1 | \$ — | \$ 1,001 |
| Corporate bonds | 1,897 | — | (35) | 1,862 |
| Total | <u>\$ 2,897</u> | <u>\$ 1</u> | <u>\$ (35)</u> | <u>\$ 2,863</u> |

The long-term marketable securities are included in Other assets in the consolidated balance sheet. As of September 30, 2009, the Company did not hold any long-term marketable securities.

Fair Value Measurements

The Company measures the fair value of its cash equivalents and marketable securities as the price that would be received from selling an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The Company uses the GAAP fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. This hierarchy requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. The three levels of inputs that may be used to measure fair value:

Level 1— Quoted (unadjusted) prices in active markets for identical assets or liabilities.

The Company's Level 1 assets consist of U.S. government debt securities and money market funds. The Company does not hold any Level 1 liabilities.

Level 2 —Observable inputs other than quoted prices included in Level 1, such as quoted prices for similar assets or liabilities in active markets; quoted prices for identical or similar assets or liabilities in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the asset or liability.

The Company's Level 2 assets consist of agency bonds and discount notes, corporate bonds, and certificates of deposit. The Company does not hold any Level 2 liabilities.

Level 3 —Unobservable inputs to the valuation methodology that are supported by little or no market activity and that are significant to the measurement of the fair value of the assets or liabilities. Level 3 assets and liabilities include those whose fair value measurements are determined using pricing models, discounted cash flow methodologies or similar valuation techniques, as well as significant management judgment or estimation.

The Company did not hold any Level 3 assets or liabilities during the quarter ended September 30, 2009.

The following table summarizes the Company's financial assets measured at fair value on a recurring basis as of September 30, 2009 (in thousands):

| Description | Balance as of September 30, 2009 | Quoted Prices in Active Markets for Identical Assets (Level 1) | Significant Other Observable Inputs (Level 2) |
|---------------------------------|-------------------------------------|---|---|
| Cash equivalents: | | | |
| Money market funds | \$ 99,464 | \$ 99,464 | \$ — |
| U.S. government debt securities | 7,000 | 7,000 | |
| Short-term investments: | | | |
| U.S. government debt securities | 17,977 | 17,977 | — |
| Corporate bonds | 1,002 | — | 1,002 |
| | <u>\$ 125,443</u> | <u>\$ 124,441</u> | <u>\$ 1,002</u> |

Note 3. Balance Sheet Components

Inventories, net are comprised of (in thousands):

| | September 30, 2009 | December 31, 2008 |
|-----------------|-----------------------|----------------------|
| Raw materials | \$ 1,000 | \$ 1,066 |
| Work in process | 399 | 416 |
| Finished goods | 493 | 483 |
| | <u>\$ 1,892</u> | <u>\$ 1,965</u> |

Work in process includes costs to produce the Invisalign product. Finished goods primarily represent ancillary products that support the Invisalign system.

Accrued liabilities consist of the following (in thousands):

| | September 30, 2009 | December 31, 2008 |
|---------------------------------------|-----------------------|----------------------|
| Accrued payroll and benefits | \$ 20,873 | \$ 17,795 |
| Accrued income taxes | 2,300 | 2,492 |
| Accrued sales and marketing expenses | 3,108 | 2,449 |
| Accrued sales rebate | 2,082 | 2,205 |
| Accrued sales tax and value added tax | 2,153 | 1,823 |
| Accrued warranty | 2,115 | 2,031 |
| Accrued professional fees | 872 | 922 |
| Accrued restructuring | 292 | 2,501 |
| Other | 3,689 | 6,064 |
| | <u>\$ 37,484</u> | <u>\$ 38,282</u> |

Note 4. Intangible Assets

The intangible assets represent non-compete agreements received in conjunction with the October 2006 OrthoClear Agreement at gross value of \$14 million. These assets are amortized on a straight-line basis over the expected useful life of five years. As of September 30, 2009 and December 31, 2008, the net carrying value of these non-compete agreements was \$5.7 million (net of \$8.3 million of accumulated amortization) and \$7.8 million (net of \$6.2 million of accumulated amortization), respectively.

The Company performs an impairment test whenever events or changes in circumstances indicate that the carrying value of such assets may not be recoverable. Examples of such events or circumstances include significant underperformance relative to historical or projected future operating results, significant changes in the manner of use of acquired assets or the strategy for its business, significant negative industry or economic trends, and/or a significant decline in the Company's stock price for a sustained period. Impairments are recognized based on the difference between the fair value of the asset and its carrying value, and fair value is generally measured based on discounted cash flow analyses. There were no impairments of intangible assets during the periods presented.

The total estimated annual future amortization expense for these intangible assets as of September 30, 2009 is as follows (in thousands):

| Fiscal Year | |
|---------------------------|-----------------|
| 2009 (remaining 3 months) | \$ 700 |
| 2010 | 2,800 |
| 2011 | 2,188 |
| Total | <u>\$ 5,688</u> |

Note 5. Legal Proceedings

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 6. Ormco Litigation Settlement

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, 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.

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 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.

Note 7. Credit Facilities

On December 5, 2008, the Company renegotiated and amended its existing credit facility with Comerica Bank. Under this revolving line of credit, the Company has \$25.0 million of available borrowings with a maturity date of December 31, 2010. This credit facility requires a quick ratio covenant and also requires the Company to maintain a minimum unrestricted cash balance of \$10.0 million. The interest rate on borrowings will range from Libor plus 1.5% to 2.0% depending upon the amount of unrestricted cash the Company maintains at Comerica Bank above the \$10.0 million minimum.

As of September 30, 2009, the Company had no outstanding borrowings under this credit facility and is in compliance with the financial covenants.

Note 8. Commitments and Contingencies

As of September 30, 2009, minimum future lease payments for non-cancelable leases are as follow (in thousands):

| Years Ending December 31, | |
|----------------------------------|-----------------|
| 2009 (remaining 3 months) | \$ 1,166 |
| 2010 | 3,156 |
| 2011 | 2,741 |
| 2012 | 1,813 |
| 2013 and thereafter | 973 |
| Total | <u>\$ 9,849</u> |

In April 2009, the Company terminated its third party shelter services arrangement with IMS for order acquisition, the fabrication of aligner molds and finished aligners and the shipment of the completed product to customers. The Company is now a direct manufacturer of its clear aligners at the facility in Juarez, Mexico and directly coordinates order acquisition, including, (1) order entry, (2) digital scanning, (3) aligner manufacturing as well as product shipment from this location. IMS has assigned the lease for the facility in Juarez, Mexico to Align Mexico, a wholly-owned subsidiary of Align, and the Company guarantees the lease payments for its subsidiary which are included in the table above.

The Company warrants its products against material defects until the Invisalign case is completed. The Company accrues for warranty costs in cost of revenues upon shipment of products. The amount of accrued estimated warranty costs is primarily based on historical experience as to product failures as well as current information on replacement costs. The Company regularly reviews the accrued balances and updates these balances based on historical warranty trends. Actual warranty costs incurred have not materially differed from those accrued. However, future actual warranty costs could differ from the estimated amounts.

The following table reflects the change in the Company’s warranty accrual during the nine months ended September 30, 2009 and 2008, respectively (in thousands):

| | Nine Months Ended September 30, | |
|--------------------------------|------------------------------------|-----------------|
| | 2009 | 2008 |
| Balance at beginning of period | \$ 2,031 | \$ 2,035 |
| Charged to cost of revenues | 2,046 | 1,910 |
| Actual warranty expenses | (1,962) | (1,850) |
| Balance at end of period | <u>\$ 2,115</u> | <u>\$ 2,095</u> |

Note 9. Stock-based Compensation*Summary of stock-based compensation expense*

Stock-based compensation expense recognized in the Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2009 and 2008 is based on options ultimately expected to vest and has been reduced for estimated forfeitures. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Forfeitures were estimated based on historical experience. The following table summarizes stock-based compensation expense related to all of the Company's stock-based options and employee stock purchases for the three and nine months ended September 30, 2009 and 2008:

| (In thousands) | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|--|-------------------------------------|-----------------|------------------------------------|------------------|
| | 2009 | 2008 | 2009 | 2008 |
| Cost of revenues | \$ 359 | \$ 437 | \$ 1,150 | \$ 1,298 |
| Sales and marketing | 1,243 | 1,390 | 3,559 | 4,069 |
| General and administrative | 1,885 | 2,009 | 5,839 | 6,122 |
| Research and development | 500 | 554 | 1,463 | 1,687 |
| Total stock-based compensation expense | <u>\$ 3,987</u> | <u>\$ 4,390</u> | <u>\$ 12,011</u> | <u>\$ 13,176</u> |

The fair value of stock options granted and the option component of the Purchase Plan shares were estimated at the grant date using the Black-Scholes option pricing model with the following weighted average assumptions:

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|-------------------------------------|---------|------------------------------------|---------|
| | 2009 | 2008 | 2009 | 2008 |
| Stock Options: | | | | |
| Expected term (in years) | 4.4 | 4.4 | 4.4 | 4.4 |
| Expected volatility | 64.0% | 60.2% | 61.6% | 59.8% |
| Risk-free interest rate | 2.1% | 3.1% | 1.6% | 2.8% |
| Expected dividend | — | — | — | — |
| Weighted average fair value at grant date | \$ 5.42 | \$ 5.49 | \$ 4.15 | \$ 6.46 |
| Employee Stock Purchase Plan: | | | | |
| Expected term (in years) | 1.2 | 1.2 | 1.3 | 1.2 |
| Expected volatility | 72.8% | 64.7% | 74.6% | 67.2% |
| Risk-free interest rate | 0.68% | 2.2% | 0.63% | 2.2% |
| Expected dividend | — | — | — | — |
| Weighted average fair value at grant date | \$ 5.10 | \$ 4.49 | \$ 3.78 | \$ 4.89 |

Options

The Company grants options for periods not exceeding ten years and generally vest over 4 years with 25% vesting one year from the date of grant and 1/48th each month thereafter. Stock option activity for the nine months ended September 30, 2009 under the stock incentive plans is set forth below:

| | Total Shares Underlying Stock Options | | | In-The-Money Options | | |
|---|--|---------------------------------|--|--|---------------------------------|--|
| | Number of Shares Underlying Stock Options (in thousands) | Weighted Average Exercise Price | Weighted Average Remaining Contractual Term (in years) | Number of Shares Underlying Stock Options (in thousands) | Weighted Average Exercise Price | Aggregate Intrinsic Value (in thousands) |
| Outstanding as of December 31, 2008 | 7,309 | \$ 11.63 | | | | |
| Granted | 1,088 | 8.30 | | | | |
| Cancelled or expired | (309) | 12.35 | | | | |
| Exercised | (389) | 6.19 | | | | |
| Outstanding as of September 30, 2009 | <u>7,699</u> | <u>\$ 11.40</u> | <u>6.58</u> | <u>5,797</u> | <u>\$ 9.07</u> | <u>\$ 29,826</u> |
| Vested and expected to vest at September 30, 2009 | <u>7,499</u> | <u>\$ 11.41</u> | <u>6.52</u> | <u>5,619</u> | <u>\$ 9.03</u> | <u>\$ 29,139</u> |
| Exercisable at September 30, 2009 | <u>4,897</u> | <u>\$ 11.21</u> | <u>5.46</u> | <u>3,424</u> | <u>\$ 8.04</u> | <u>\$ 21,169</u> |

The aggregate intrinsic value in the table above represents the total pre-tax intrinsic value (the difference between the Company's closing stock price on the last trading day of the third quarter of 2009 of \$14.22 and the number of in-the-money options multiplied by the respective exercise price) that would have been received by the option holders had all option holders exercised their options on September 30, 2009. This amount changes based on the fair market value of the Company's stock.

The total intrinsic value of stock options exercised for the three and nine months ended September 30, 2009 was \$0.6 million and \$1.7 million, respectively. As of September 30, 2009, the Company expects to recognize \$15.7 million of total unamortized compensation cost related to stock options over a weighted average period of 2.3 years. The Company did not recognize tax benefits from exercised options for the nine months ended September 30, 2009 as the amount was not material to the consolidated financial statements.

Restricted Stock Units

The Company grants restricted stock units (RSUs) that generally vest over 4 years. Prior to October 2007, 25% of the grant vested on the one year anniversary of the date of grant and 6.25% vested quarterly thereafter. In October 2007, the Compensation Committee of the Board of Directors approved to change the vesting for prospective grants of RSUs to 25% annually. The fair value of each award is based on the Company's closing stock price on the date of grant. A summary of the nonvested shares for the nine months ended September 30, 2009 is as follows:

| | Number of Shares Underlying RSUs (in thousands) | Weighted Average Grant Date Fair Value | Weighted Average Remaining Contractual Term (in years) | Aggregate Intrinsic Value (in thousands) |
|------------------------------------|---|--|--|--|
| Nonvested as of December 31, 2008 | 872 | \$ 13.69 | | |
| Granted | 314 | 8.25 | | |
| Vested and released | (202) | 13.01 | | |
| Forfeited | (50) | 12.45 | | |
| Nonvested as of September 30, 2009 | <u>934</u> | <u>\$ 12.08</u> | <u>1.37</u> | <u>\$ 13,281</u> |

The aggregate intrinsic value in the table above represents the total pre-tax intrinsic value (calculated by using Align's closing stock price on the last trading day of the third quarter of 2009 of \$14.22 multiplied by the number of nonvested restricted stock units) that would have been received by the award holders had all restricted stock units been vested and released on September 30, 2009. This amount changes based on the fair market value of the Company's stock.

The total intrinsic value of restricted stock units vested and released for the three and nine months ended September 30, 2009 was \$0.5 million and \$2.0 million, respectively. As of September 30, 2009, the total unamortized compensation cost related to restricted stock units was \$10.9 million, which the Company expects to recognize over a weighted average period of 2.3 years. The Company did not recognize tax benefits from restricted stock units that vested during the nine months ended September 30, 2009 as the amount was not material to the consolidated financial statements.

Employee Stock Purchase Plan

Align's Employee Stock Purchase Plan (the "Purchase Plan") consists of overlapping twenty-four month offering periods with four six-month purchase periods in each offering period. Employees purchase shares at 85% of the fair market value of the common stock at either the beginning of the purchase period or the end of the purchase period, whichever price is lower. The Company accounts for the Purchase Plan as a compensatory plan and has valued the option component of the Purchase Plan shares at the date of grant using the Black-Scholes option pricing model.

As of September 30, 2009, the Company expects to recognize \$2.2 million of total unamortized compensation cost related to employee stock purchases over a weighted average period of 0.4 years.

Note 10. Accounting for Income Taxes

The financial statement recognition of the benefit for an uncertain tax position is dependent upon the benefit being more-likely-than-not to be sustainable upon audit by the applicable taxing authority. If this threshold is met, the tax benefit is then measured and recognized at the largest amount that is greater than 50 percent likely of being realized upon ultimate settlement.

During the third quarter of fiscal 2009, the amount of unrecognized tax benefits was increased by approximately \$0.5 million. The total amount of unrecognized tax benefits was \$4.2 million as of September 30, 2009, which would impact the Company's effective tax rate if recognized. The Company recognizes interest and penalties related to unrecognized tax benefits as a component of income taxes. Interest and penalties are immaterial and are included in the unrecognized tax benefits. There were no significant changes to this amount as of September 30, 2009.

The Company is subject to taxation in the U.S. and various states and foreign jurisdictions. All of the Company's tax years will be open to examination by the U.S. federal and most state tax authorities due to the Company's net operating loss and overall credit carryforward position. With few exceptions, the Company is no longer subject to examination by foreign tax authorities for years before 2005.

Note 11. Net Profit (Loss) Per Share

Basic net profit (loss) per share is computed using the weighted average number of shares of common stock outstanding during the period. Diluted net profit (loss) per share is computed using the weighted average number of shares of common stock, adjusted for the dilutive effect of potential common stock. Potential common stock, computed using the treasury stock method, include options, restricted stock units, and the dilutive component of Purchase Plan shares.

The following table sets forth the computation of basic and diluted net profit (loss) per share attributable to common stock (in thousands, except per share amounts):

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|-------------------------------------|----------|------------------------------------|-----------|
| | 2009 | 2008 | 2009 | 2008 |
| Net profit (loss) | \$ (49,942) | \$ 5,157 | \$ (42,761) | \$ 14,491 |
| Weighted-average common shares outstanding, basic | 69,528 | 67,367 | 67,278 | 68,330 |
| Effect of potential dilutive common shares | — | 1,337 | — | 1,576 |
| Total shares, diluted | 69,528 | 68,704 | 67,278 | 69,906 |
| Basic net profit (loss) per share | \$ (0.72) | \$ 0.08 | \$ (0.64) | \$ 0.21 |
| Diluted net profit (loss) per share | \$ (0.72) | \$ 0.08 | \$ (0.64) | \$ 0.21 |

For the three and nine months ended September 30, 2009, stock options and restricted stock units totaling 4.0 million and 5.1 million, respectively, were excluded from diluted net profit per share because of their anti-dilutive effect. For the three and nine months ended September 30, 2008, stock options and restricted stock units totaling 5.0 million and 4.5 million, respectively, were excluded from diluted net profit per share because of their anti-dilutive effect.

Note 12. Comprehensive Income

Comprehensive income includes net profit, foreign currency translation adjustments and unrealized gains and losses on available-for-sale securities. The components of comprehensive income are as follows (in thousands):

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|-------------------------------------|----------|------------------------------------|-----------|
| | 2009 | 2008 | 2009 | 2008 |
| Net profit | \$ (49,942) | \$ 5,157 | \$ (42,761) | \$ 14,491 |
| Foreign currency translation adjustments | 214 | (429) | 20 | (176) |
| Change in unrealized gain/(loss) on available-for-sale securities | — | (43) | 242 | (34) |
| Comprehensive income | \$ (49,728) | \$ 4,685 | \$ (42,499) | \$ 14,281 |

Note 13. Segments and Geographical Information

Segment

The Company reports segment data based on the internal reporting that is used by management for making operating decisions and assessing performance. During all periods presented, the Company operated as a single business segment.

Geographical Information

Net revenues and long-lived assets are presented below by geographic area (in thousands):

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|-------------------------|-------------------------------------|-------------------|------------------------------------|-------------------|
| | 2009 | 2008 | 2009 | 2008 |
| Net revenues: | | | | |
| North America | \$ 60,054 | \$ 59,627 | \$ 172,577 | \$ 182,910 |
| Europe | 18,206 | 15,056 | 50,986 | 45,522 |
| Other international | 1,009 | 490 | 2,154 | 1,419 |
| Total net revenues | <u>\$ 79,269</u> | <u>\$ 75,173</u> | <u>\$ 225,717</u> | <u>\$ 229,851</u> |
| | | | | |
| | As of September 30, 2009 | | As of December 31, 2008 | |
| | | | | |
| Long-lived assets: | | | | |
| North America | \$ 90,893 | \$ 99,086 | | |
| Europe | 1,113 | 960 | | |
| Other international | 1,240 | 1,388 | | |
| Total long-lived assets | <u>\$ 93,246</u> | <u>\$ 101,434</u> | | |

Note 14. Restructuring

In July and October 2008, the Company announced restructuring plans to increase efficiencies across the organization and lower the overall cost structure. The July 2008 plan reduced full time headcount primarily through a phased-consolidation of order acquisition operations from the corporate headquarters in Santa Clara, California to Juarez, Mexico, which was completed by the end of 2008. In addition to headcount reductions, the October restructuring plan included the phased relocation of the Company's shared services organizations from Santa Clara, California to its facility in Costa Rica, which was completed during the second quarter of 2009.

Activity and liability balances related to restructuring activity for nine months ended September 30, 2009 are as follows (in thousands):

| | Severance and Benefits |
|-------------------------------|------------------------|
| Balance at December 31, 2008 | \$ 2,501 |
| Restructuring accrual | 1,319 |
| Cash payments | (3,528) |
| Balance at September 30, 2009 | <u>\$ 292</u> |

The Company has included this amount in Accrued liabilities in the Consolidated Balance Sheets.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

In addition to historical information, this quarterly report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. These statements include, among other things, our expectations regarding the Proficiency Requirements and its impact on our case volume and revenues, including our belief that the Proficiency Requirements will not have a material impact on our 2009 revenues and results of operations, the anticipated impact our new products and product enhancements will have on doctor utilization and our market share, our expectations regarding product mix and product adoption, our expectations regarding the existence and impact of seasonality, our expectation that our utilization rate will improve over time, our expectations regarding our average selling prices and gross profits in 2009, our expectations regarding the continued growth of our international markets, our expectations regarding the impact of increased consumer marketing programs in Europe, our expectations that the decline in general economic conditions in 2009 may result in a decline in our North America product volumes and revenues, particularly in the GP channel, compared to 2008, the anticipated level of our

operating expenses, and other factors beyond our control, as well as other statements regarding our future operations, financial condition and prospects and business strategies. These statements may contain words such as “expects,” “anticipates,” “intends,” “plans,” “believes,” “estimates,” or other words indicating future results. These forward-looking statements are subject to certain risks and uncertainties that could cause actual results to differ materially from those reflected in the forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in Item 2 “Management’s Discussion and Analysis of Financial Condition and Results of Operations”, and in particular, the risks discussed below in Part II, Item 1A “Risk Factors”. We undertake no obligation to revise or update these forward-looking statements. Given these risks and uncertainties, readers are cautioned not to place undue reliance on such forward-looking statements.

The following discussion and analysis of our financial condition and results of operations should be read together with our Condensed Consolidated Financial Statements and related notes included elsewhere in this Quarterly Report on Form 10-Q.

Align Technology, Inc. designs, manufactures and markets the Invisalign system, 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 metal arch wires and brackets, commonly referred to as braces. We received the United States Food and Drug Administration (“FDA”) clearance to market Invisalign in 1998. The Invisalign system is regulated by the FDA as a Class II medical device.

We distribute the vast majority of our products directly to our customers: the orthodontist and the general practitioner dentist, or GP. Orthodontists and GPs must complete an Invisalign training course in order to provide the Invisalign treatment solution to their patients. The Invisalign system is sold in North America, Europe, Asia Pacific, Latin America and Japan. We use a distributor model for the sale of our products in parts of the Asia Pacific and Latin American region.

Each Invisalign treatment plan is unique to the individual patient. Our Invisalign Full treatment consists of as many aligners as indicated by ClinCheck in order to achieve the doctors’ treatment goals. Our Invisalign Express is a dual arch orthodontic treatment for cases that meet certain predetermined clinical criteria and consist of up to ten sets of aligners. Invisalign Express treatment is intended to assist dental professionals to treat a broader range of patients by providing a lower-cost option for adult relapse cases, for minor crowding and spacing, or as a pre-cursor to restorative or cosmetic treatments such as veneers. Invisalign Teen, which was launched in July 2008, is designed to meet the specific needs of the non-adult comprehensive or teen treatment market. Invisalign Assist, launched in October 2008, is intended to help newly-trained and low volume Invisalign GPs accelerate the adoption and frequency of use of Invisalign into their practice. Upon completion of an Invisalign or non-Invisalign treatment, the patient may be prescribed our traditional retainer product, or our Viverra retainers, a clear aligner set designed for ongoing retention.

Our goal is to establish Invisalign as the standard method for treating malocclusion ultimately driving increased product adoption by dental professionals by focusing on four key objectives: driving product innovation, enhancing the customer experience, generating consumer demand and expanding into international markets.

Product innovation and enhancements to existing products. We believe that product performance and innovation is a cornerstone to our future long-term goal to drive and sustain product adoption. Until 2008, the Invisalign system was a single offering used by our primary channels—GPs and orthodontists—each with distinct and separate needs. In 2008, we launched additional products to better meet those distinct needs. Specifically, orthodontists want a more robust set of tools for greater predictability, wider applicability and more flexibility in the use of the Invisalign system. On the other hand, typical GPs want greater ease of use, more efficient and simplified diagnostic tools, guidance through the case set-up process, minimal treatment intervention and self-help tools designed to simplify treatment of cases of mild to moderate malocclusion. Based on this knowledge, in July 2008, we announced the release of Invisalign Teen, predominantly marketed to the orthodontist. In October 2008, we announced the release of Invisalign Assist, predominantly marketed to the GP. More recently, in September 2009, we introduced new and enhanced features in all Invisalign products: Invisalign Full, Invisalign Teen, Invisalign Assist and Invisalign Express. The new product line features are designed to overcome barriers to treatment by addressing clinical issues that some orthodontists and GPs have traditionally perceived as challenging in Invisalign treatment, such as extrusion and rotation of teeth, root movements and interproximal reduction (IPR). These new and enhanced features include:

- New optimized attachments for extrusions and rotations custom designed to be patient-specific and tooth-specific to consistently deliver the correct aligner forces to the teeth, helping to increase predictability of the movement.
- Power Ridges™, previously available only with Invisalign Teen, have been expanded across all products for cases requiring certain types of movements, including lingual root torque.
- Velocity Optimization designed to provide more controlled movements for the entire tooth, including the root, and is designed to limit the speed of tooth movements to optimal ranges.
- Interproximal Reduction (IPR) Protocol Improvements designed to address a frequent doctor request regarding timing of IPR during treatment. IPR can now be set up in later stages of treatment when teeth are better aligned and contact points may be easier to access.
- New Invisalign Attachment Kit and attachment material designed to deliver greater bond strength, wear resistance, accuracy and ease of use.

Invisalign Teen

With the introduction of Invisalign Teen, our Invisalign product family includes a product designed to meet the specific needs of the non-adult comprehensive or younger teen market. Invisalign Teen features include an aligner wear indicator to help gauge patient compliance and specially engineered aligner features to address the natural eruption of key teeth and lingual root control. Predominantly marketed to orthodontists who treat the vast majority of malocclusion in teen patients, these features make it easier and more efficient for orthodontists to treat those younger patients. The launch of a teen-specific product makes the Invisalign system more applicable to an orthodontist's patient base, which we believe will increase our penetration into and our share of the teen treatment market over time. In addition, some of our customers believe the additional product features included in Invisalign Teen are desirable to use on all of their patients regardless of age. As a result, these customers are increasingly using Invisalign Teen rather than Invisalign Full on their adult patients. Although Invisalign Teen has grown from 11% of our total case volume in the second quarter of 2009 to 14% of our total case volume in the third quarter of 2009, we expect that orthodontists will continue to adopt Invisalign Teen slowly, after they experience multiple successful treatment outcomes.

Invisalign Assist

Invisalign Assist, is intended to help newly-trained and lower volume Invisalign GPs accelerate the adoption and frequency of use of Invisalign into their practice. Invisalign Assist features are intended to make it easier for doctors to select appropriate cases for their experience level or treatment approach. In addition, GPs can plan and submit cases efficiently, manage appointments with suggested tasks, and receive batch shipments of aligners based on treatment progress. In addition to the new features announced in September 2009 to our entire product line, additional features were added or enhanced in Invisalign Assist. These features are intended to expand the capabilities of Invisalign Assist and give doctors the confidence and control necessary to treat a wider range of patients. To date, Invisalign Assist has been used primarily for simple anterior alignment and aesthetically-oriented cases that can be treated with aligners only. We believe that with the introduction of these new and enhanced product features, Invisalign Assist can now be used to treat a broader range of cases while maintaining the benefits of built-in support. Additional enhancements include:

- More doctor input and control regarding case set-up and ClinCheck modifications.
- Improved progress tracking reports with more tooth-specific detail.
- More information for case-specific clinical tasks, including bonding attachments, performing IPR, and monitoring treatment progress.
- More tooth-specific details explaining why a case falls outside the Invisalign Assist treatment parameters.

We believe that Invisalign Assist will help GPs increase their confidence in prescribing Invisalign treatment.

We believe continuing to introduce new products and product features as well as enhancing the user experience will keep us at the forefront of the market and increase adoption of Invisalign. The launch of Invisalign Teen, Invisalign Assist and the recent launch of the new and enhanced features in all Invisalign products as well as other future products will rely on new features, tools and delivery options to meet specific clinical demands while providing a family of end-to-end solutions for our customers. Enhanced product performance and innovation should continue to drive the adoption and frequency of use (what we call utilization). Although we believe new product introduction to be a cornerstone to our future long-term growth, we expect that adoption of these new products will increase gradually over a number of years.

Enhancing the customer experience. We are committed to enhancing the customer experience by focusing on specific customer “touch points”, or areas where we interact directly with our customers. Specifically, we are focused on improving our pre-selection process in order to attract new doctors that are motivated to become Invisalign providers and committed to making Invisalign a key part of their practices and strengthening our training programs in order to increase the rate that these newly trained customers submit Invisalign cases, as well as increase the rate that they move up the adoption curve to ultimately become leading Invisalign providers, or what we call promoters.

- *Improving Training Programs.* Ensuring Invisalign trained doctors are confident in using the Invisalign system is a key driver toward our ultimate goal of increasing product adoption. We continuously update our training programs to address the needs of our customers. For instance, we developed a pre-training course intended to familiarize doctors with the Invisalign system prior to attending the full training course. In addition, we recently updated our initial training program by focusing on Invisalign Assist, instead of Invisalign Full, since we believe Invisalign Assist is the right product for newly trained GPs. We anticipate that by using Invisalign Assist, newly trained GPs will exit this initial training program with increased confidence in prescribing Invisalign treatment. We have also incorporated the Invisalign technique into the curriculum of 38 university programs. By educating dental students and orthodontic residents on the benefits of the Invisalign technique, we believe they will be more likely to use this technology in their future practices and offer Invisalign as a treatment option.
- *Moving from Invisalign provider to a leading Invisalign provider.* Once a doctor is trained, our goal is to assist the doctor to move up the adoption curve to ultimately become a leading Invisalign provider, or a promoter. In order to increase the number of Invisalign promoters, we provide additional services to help our customers increase their confidence in using the Invisalign system through continuing education and clinical support as well as improving their practice management skills.

Furthermore, on June 2, 2009, we announced the implementation of the Invisalign Product Proficiency Requirements (or the Proficiency Requirements) in North America to help ensure that Invisalign-trained doctors have the experience and confidence necessary to achieve high quality treatment outcomes for Invisalign patients. Under the Proficiency Requirements, every Invisalign provider in North America must start 10 Invisalign cases (measured by case shipments) and complete at least 10 Invisalign-specific continuing education (CE) credits each calendar year. Doctors who do not meet the annual case start and CE requirements by the end of each calendar year will be able to continue treating in-progress cases but will not be able to submit new Invisalign cases or use Invisalign branding or marketing resources.

In September 2009, we updated the Proficiency Requirements in order to further support our customers through this significant change, (1) including launching a program to recognize doctors who achieve the annual proficiency requirements by December 31, 2009 and (2) providing an additional six-month qualification period to assist doctors who are unable to meet the proficiency requirements by December 31, 2009, but demonstrate a desire to continue using Invisalign. Doctors who achieve the annual proficiency requirements as of December 31, 2009, will benefit from a new addition to our consumer marketing program that encourages prospective patients to seek out “Invisalign Preferred Providers” on the Invisalign website and in television ads as a way to recognize doctors’ commitment to proficiency with Invisalign. For those doctors who are unable to achieve the proficiency requirements by December 31, 2009, we announced a one-time, additional six-month qualification period that will enable those doctors to secure their Invisalign provider status for 2010. The additional six-month qualification period stipulates that:

- Doctors who do not meet the proficiency requirements for 2009 but have at least one shipped case and at least one Invisalign CE hour at the end of calendar year 2009 will be allowed to maintain their active provider status through June 30, 2010.
- Doctors who qualify for the additional six-month qualification period can secure their provider status for the second half of 2010 by meeting half of the annual proficiency requirements (at least five shipped cases and five Invisalign CE hours) between January 1 and June 30, 2010.
- Doctors will still be responsible for meeting the total annual requirements of at least ten shipped cases and ten Invisalign CE hours by the end of 2010 to qualify as providers for the following year.
- Doctors that have not submitted any cases nor obtained any Invisalign CE hours during 2009 will not be eligible for the additional qualification period.

Doctors can reactivate their provider status by retaking Invisalign Clear Essentials I training and meeting the Proficiency Requirements during the new calendar year. In conjunction with the Proficiency Requirements, we have defined a Proficiency Pathway consisting of Invisalign educational opportunities that matches clinical education to case experience levels in order to help doctor’s gain confidence with case selection and treatment planning, case submission and treatment management. We expect that the Proficiency Requirements will enable us to focus more effectively on those doctors who want to make Invisalign a key part of their practice and consequently increase the rate that they move up the adoption curve to ultimately become promoters.

Other resources that we offer our doctors include the Aligntech Institute program (www.aligntechinstitute.com), which is an interactive website that provides clinical education and practice development training. These clinical education and practice development training opportunities include instructor-led training classes, seminars and workshops, conference calls, web-based videos, case studies, and other clinical resources. Many of these courses and resources are eligible for continuing education (CE) credits. Additionally, our VIP portal (Virtual Invisalign Practice) provides our trained doctors and their staff access to thousands of Invisalign cases and best practices as well as up-to-date support information, programs and marketing materials for continuous support and information access. By participating in these programs and the various events and educational offerings, we believe that our customers will emerge with a better understanding of the product and its applicability, and with a greater aptitude for starting and finishing Invisalign cases successfully.

Consumer demand generation for Invisalign. Marketing to the consumer and creating demand is one of our key strategic objectives to driving long-term growth. Our market research indicates that the majority of people with malocclusion who desire treatment forgo treatment rather than elect traditional treatment due to its many limitations, such as compromised aesthetics and oral discomfort. By communicating the benefits of Invisalign to both dental professionals and consumers, we intend to increase the number of patients who seek treatment using Invisalign. Historically, our marketing programs have been directed to an adult audience, however, with the introduction of Invisalign Teen, we will for the first time direct our communication efforts directly to teens and their parents. Despite the continuing challenges in the U.S. economy and weak consumer spending, we believe that consumer demand creation is a key component to our long-term growth. As a result, we will continue to invest in efforts to increase consumer awareness of Invisalign through a variety of media outlets. We will continue to drive consumer demand among the adult population through our traditional TV advertising, as well as digital online media. In 2009, we are focusing our efforts on the introduction of a new public relations program for Invisalign Teen intended to access print, TV and online media. We also have a teen specific website and will increasingly leverage online and mobile widgets, social media and blogs to directly target teens.

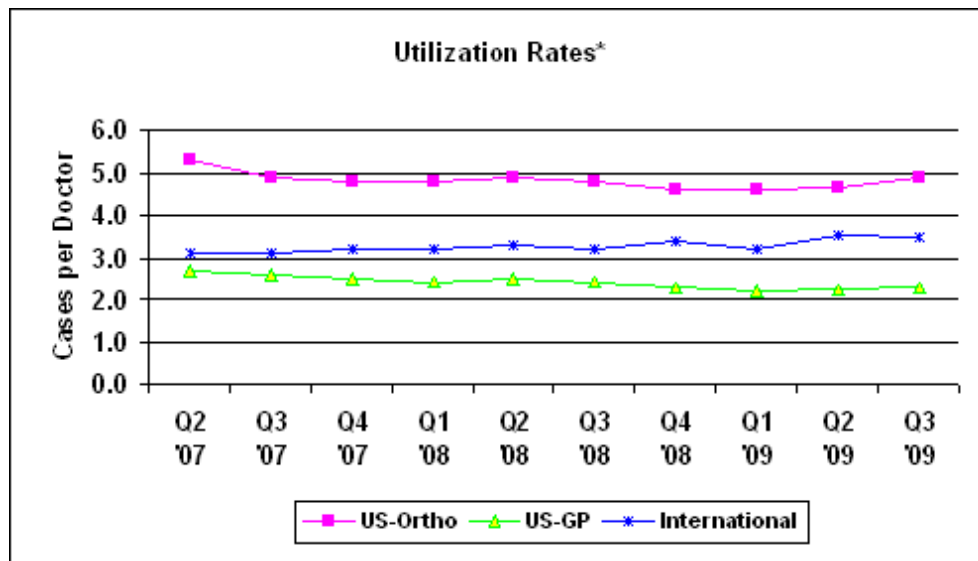
Growth of international markets. We will continue to focus our efforts towards increasing adoption of Invisalign by dental professionals in our key international markets, Europe and Japan. Similar to the North America market, our objective internationally is to increase the number of doctors that are motivated to becoming an Invisalign provider and committed to making Invisalign a key part of their practices. Through September 30, 2009, we have trained over 15,300 doctors, predominantly orthodontists in Europe, our primary international market. Product line expansion is key to providing doctors a solution that addresses a wider range of potential patient needs with greater treatment flexibility. In October 2008, we launched Invisalign Express in Europe expanding our international product offerings. In Europe, the vast majority of orthodontic case starts are children and teens. With the introduction of Invisalign Teen in Europe in March 2009, we expect the addressable market for our product to expand and ultimately increase adoption. In addition, we will carry on our efforts to increase brand awareness and consumer demand in Europe by continuing our consumer advertising campaign. Our overall brand awareness and consumer demand is lower in Europe, and thus, we expect customers to adopt Invisalign Teen more slowly than in North America. Additionally, although the vast majority of our international revenues are from direct sales, approximately 10% of our international sales are through distributors covering smaller international markets, specifically Asia Pacific and Latin America. We will consider selling through distributors in other markets as well as consider expanding directly into additional countries on a case-by-case basis. With these efforts, we expect our international revenues and case volumes to continue to increase in the foreseeable future.

In addition to whether we successfully execute our business strategy, a number of other factors, the most important of which are set forth below, may affect our results during the remainder of 2009 and beyond.

- *Introduction of Proficiency Requirements.* We have a large number of low volume doctors that make up a significant portion of our customer base. As awareness and acceptance of Invisalign has grown, so has consumer demand and the size of our trained doctor base. Today, there are more than 44,000 Invisalign-trained doctors in North America, and approximately 3,000,000 prospective patients visit our web site during the 12 month period. We want to direct these potential patients to an Invisalign practice and feel comfortable that the patient will receive the best treatment experience possible. To further this goal, on June 2, 2009, we announced the implementation of the Invisalign Product Proficiency Requirements in North America to help ensure that Invisalign-trained doctors have the experience and confidence necessary to achieve high quality treatment outcomes for Invisalign patients. *For a further description of the Proficiency Requirements see “Moving from Invisalign provider to a leading Invisalign provider” above.* Although we want every doctor to achieve and maintain the Proficiency

Requirements with Invisalign, we expect that a number of our lower volume doctors may be unwilling or unable to meet the requirements by the June 2010 qualification deadline. Although we believe that the Proficiency Requirements will not have a material impact on our results of operations in fiscal year 2009, if the number of customers that meet the Proficiency Requirements is less than we anticipate, our case volumes will decrease and our revenues will be harmed. *See Part I, Item 1A—“Risk Factors” for risks related to our Proficiency Requirements.*

- *Impact on consumer spending due to a decline in the U.S. economy.* Consumer spending habits are affected by, among other things, prevailing economic conditions, levels of employment, salaries and wage rates, gas prices, consumer confidence and consumer perception of economic conditions. A general slowdown in the United States economy as well as an uncertain economic outlook have adversely affected U.S. consumer spending habits. As a result of the decline in general economic conditions, we expect that our North American product volumes and revenues will decline in 2009 compared to 2008, particularly in the GP channel.
- *Utilization Rates.* Our goal is to establish Invisalign as the standard method for treating malocclusion ultimately driving increased product adoption and frequency of use by dental professionals, or utilization. Our quarterly utilization rates from the second quarter of 2007 through the third quarter 2009 are as follows.



Utilization rates = # of cases shipped divided by # of doctors cases were shipped to

As set forth in the chart above, utilization rates improved sequentially for our North America channels from the second quarter to the third quarter of 2009, whereas utilization rates historically declined between the second to third quarters in both 2007 and 2008. The availability of Invisalign Teen and doctors striving to meet the Proficiency Requirements were the primary factors for the increase in the third quarter of 2009. For our international channel our utilization rate has declined slightly due to the summer holiday schedules in Europe. In addition, although we believe that the introduction of the Proficiency Requirements will not have a material impact on our results of operations in 2009, if a lesser number of our customers than we anticipate fail to maintain and/or increase utilization to meet the Proficiency Requirements, our utilization will decrease further and our revenues will be harmed.

- *Impact of new products on deferred revenue.* We launched three new products in 2008: Viverra retainers in January 2008, Invisalign Teen in July 2008, and Invisalign Assist in October 2008. As a result of and depending upon customer adoption of these new products, our mix of products is shifting gradually. These new products will have a significantly higher amount of deferred revenue as a percentage of their average selling prices compared to Invisalign Full. The Viverra retainer includes four shipments per year; revenue is deferred upon the first shipment and then recognized as each shipment occurs. Revenue for the six replacement aligners included in the price of Invisalign Teen is deferred based on their fair market value until the earlier of the replacement aligners being used or until the case is completed. For Invisalign Assist, when the progress tracking feature is selected, aligners are shipped to the dental professional after every nine stages. As a result, for these cases, revenue and cost are deferred upon the first staged shipment and are recognized upon shipment of the final

staged shipment. In addition, included in the price of Invisalign Full treatment, we offer case refinement, which is a finishing tool used to adjust a patient's teeth to the desired final position. Invisalign Teen, Invisalign Assist, and Invisalign Full include a deferral for case refinement. As these new products increase as a percentage of our total case volume, deferred revenue on our balance sheet will increase.

- *Reliance on international manufacturing operations.* Our manufacturing efficiency has been and will continue to be an important factor in our future profitability. Currently, two of our key production steps are performed in operations located outside of the U.S.—San Jose, Costa Rica and Juarez, Mexico. At our facility in Costa Rica, dental technicians use a sophisticated, internally developed computer-modeling program to prepare digital treatment plans. In April 2009, we terminated our third party shelter services arrangement with IMS for order acquisition, the fabrication of aligner molds and finished aligners and the shipment of the completed product to customers. We are now a direct manufacturer of our clear aligners at our facility in Juarez, Mexico with approximately 495 employees and directly coordinate order acquisition and product shipment from this location. Our success will depend in part on the efforts and abilities of management to effectively manage these international operations, including any difficulties encountered by us with respect to a transition from a third party shelter services arrangement to a direct manufacturer, including difficulties hiring and retaining qualified personnel. If our management fails in any of these respects, we could experience production delays and lost or delayed revenue. In addition, even if we have case submissions, we may not have a sufficient number of trained dental technicians in Costa Rica to create the ClinCheck treatments, or if we are unable to ship our product to our customers on a timely basis, our revenue will be delayed or lost, which will cause our operating results to fluctuate. *See Part I, Item 1A—“Risk Factors” for risks related to our international operations.*
- *Seasonal Fluctuations.* Seasonal fluctuations in the number of doctors in their offices and available to take appointments have affected, and are likely to continue to affect our business. Specifically, our customers often take vacation during the summer months and therefore tend to start fewer cases. In addition, summer is typically the busiest season for orthodontists with practices that have a high percentage of adolescent and teenage patients. Many parents want to get their teens started in treatment before the start of the school year. As a result, adult appointments, including adult Invisalign patient starts, are often pushed further into late summer or early fall. This year we did not experience the normal seasonality in our business and had sequential case growth in both the North American orthodontic and International channels. This year, with the availability of Invisalign Teen, was the first summer we were able to actively compete for a share of teen patient starts and believe that Invisalign Teen may have helped moderate the historical trend we have typically seen for our North American orthodontic and International customers during the summer months. We expect teenage case starts to be seasonally down in the fourth quarter of 2009, which is consistent with historical trends. These seasonal trends have caused and will likely continue to cause, fluctuations in our quarterly results, including fluctuations in sequential revenue growth rates.
- *Foreign Exchange Rates.* Although the U.S. dollar is our reporting currency, a portion of our revenues and profits are generated in foreign currencies. Revenues and profits generated by subsidiaries operating outside of the United States are translated into U.S. dollars using exchange rates effective during the respective period and as a result are affected by changes in exchange rates. We have generally accepted the exposure to exchange rate movements without using derivative financial instruments to manage this risk. Therefore, both positive and negative movements in currency exchanges rates against the U.S. dollar will continue to affect the reported amount of revenues and profits in our consolidated financial statements.
- *Restructuring.* During 2008, we announced restructuring plans in July and October to increase efficiencies across the organization and lower the overall cost structure. In July 2008, we implemented a restructuring plan to reduce our full time headcount including a phased consolidation of order acquisition from our corporate headquarters in Santa Clara, California, to Juarez, Mexico, which was completed by the end of 2008. In October 2008, we implemented a restructuring plan to reduce full time headcount in Santa Clara, California and created a new shared services organization in our existing Costa Rica facility that consolidates customer care, accounts receivable, credit and collections, and customer event registration organizations, which were previously located in Santa Clara, California. The relocation was completed during the second quarter of 2009. The relocation is accompanied by a number of risks and uncertainties that may affect our results of operations and statement of cash flows. *See Part II, Item 1A—“Risk Factors” for risks related to the October restructuring, including the phased-relocation of our customer facing operations to Costa Rica.*

- *Ormco Litigation Settlement*. On August 16, 2009, the Company and Ormco entered into a Settlement Agreement, pursuant to which the Company (1) paid Ormco a cash amount equal to approximately \$13.2 million, and (2) agreed to issue to Danaher Corporation (“Danaher”), an affiliate of Ormco, 7.6 million fully paid and nonassessable shares of the Company’s Common Stock, 5.6 million and 2.0 million of which were issued to Danaher on August 16, 2009 and September 22, 2009, respectively, pursuant to the Stock Purchase Agreement entered into between the Company and Danaher on August 16, 2009.

Joint Development, Marketing and Sales Agreement. In connection with the settlement reached with Ormco, on August 16, 2009, Align and Ormco entered into the Joint Development, Marketing and Sales Agreement, pursuant to which the parties have agreed to an exclusive collaboration over the next seven years to jointly develop and commercialize a combination orthodontic treatment system involving the use of both Align’s clear aligner system and Ormco’s brackets and arch wire system, which system will be capable of treating even the most complex orthodontic cases. A copy of the Joint Development, Marketing and Sales Agreement is attached as an exhibit to this Form 10-Q.

See Footnote 6 “Ormco Litigation Settlement” for additional information about the settlement accounting.

- *Effective Tax Rate.* Our effective tax rate may vary significantly from period to period. Various internal and external factors may have favorable or unfavorable effects on our future effective tax rate. These factors include, but are not limited to, changes in tax laws, regulations and /or rates, changing interpretations of existing tax laws or regulations, the future levels of tax benefits of stock option deductions relating to incentive stock options and employee stock purchase plans and changes in overall levels of pretax earnings.

Results of Operations

Net revenues:

Invisalign product revenues by channel and other non-case revenues, which represents training, retainer and ancillary products, for the three and nine months ended September 30, 2009 and 2008 are as follows (in millions):

| Net revenues | Three Months Ended September 30, | | | | Nine Months Ended September 30, | | | |
|---------------------------|----------------------------------|---------|------------|----------|---------------------------------|----------|------------|----------|
| | 2009 | 2008 | Net Change | % Change | 2009 | 2008 | Net Change | % Change |
| North America: | | | | | | | | |
| Ortho | \$ 22.7 | \$ 22.0 | \$ 0.7 | 3.2% | \$ 65.4 | \$ 67.5 | \$ (2.1) | (3.1%) |
| GP | 33.9 | 33.9 | — | 0.0% | 96.6 | 103.4 | (6.8) | (6.6%) |
| Total North American | | | | | | | | |
| Invisalign | 56.6 | 55.9 | 0.7 | 1.3% | 162.0 | 170.9 | (8.9) | (5.2%) |
| International Invisalign | 18.5 | 15.1 | 3.4 | 22.5% | 50.8 | 45.8 | 5.0 | 10.9% |
| Total Invisalign revenues | 75.1 | 71.0 | 4.1 | 5.8% | 212.8 | 216.7 | (3.9) | (1.8%) |
| Non-case revenues | 4.2 | 4.2 | — | 0.0% | 12.9 | 13.2 | (0.3) | (2.3%) |
| Total net revenues | \$ 79.3 | \$ 75.2 | \$ 4.1 | 5.5% | \$ 225.7 | \$ 229.9 | \$ (4.2) | (1.8%) |

Case volume data which represents Invisalign case shipments by channel, for the three and nine months ended September 30, 2009 and 2008 are as follows (in thousands):

| Invisalign case volume | Three Months Ended September 30, | | | | Nine Months Ended September 30, | | | |
|---------------------------------|----------------------------------|------|------------|----------|---------------------------------|-------|------------|----------|
| | 2009 | 2008 | Net Change | % Change | 2009 | 2008 | Net Change | % Change |
| North America: | | | | | | | | |
| Ortho | 18.8 | 18.0 | 0.8 | 4.4% | 53.2 | 53.6 | (0.4) | (0.7%) |
| GP | 25.6 | 25.7 | (0.1) | (0.4%) | 72.4 | 78.7 | (6.3) | (8.0%) |
| Total North American Invisalign | 44.4 | 43.7 | 0.7 | 1.6% | 125.6 | 132.3 | (6.7) | (5.1%) |
| International Invisalign | 12.1 | 9.1 | 3.0 | 33.0% | 33.9 | 27.1 | 6.8 | 25.1% |
| Total Invisalign case volume | 56.5 | 52.8 | 3.7 | 7.0% | 159.5 | 159.4 | 0.1 | 0.1% |

Our total net revenues increased for the three months ended September 30, 2009 compared to the same period in 2008 mainly due to higher International Invisalign volumes partially offset by unfavorable exchange rates against the US dollar. Revenues for North American Invisalign improved slightly due to increased case volume and the impact of the price increases effective at the beginning of 2009 partially offset by the mix shift towards new products which have a greater proportion of revenue that is deferred.

Our total net revenues decreased slightly for the nine months period ended September 30, 2009 compared to the same period in 2008. In North America, revenue decreased due to lower case volumes particularly in the GP channel as well as higher promotional discounts. The price increases effective at the beginning of 2009 partially offset the reduction in revenue. International Invisalign revenue increased over the prior period mainly due to improved case volumes partially offset by unfavorable exchange rates.

For 2009, we expect our total net revenues to be comparable to 2008. North American revenues are expected to decrease due to lower case volumes and product mix shift toward products with higher amounts of deferred revenue. International revenue is expected to increase compared to 2008 due to increased case shipments.

Cost of revenues and gross profit:

| (In millions) | Three Months Ended September 30, | | | Nine Months Ended September 30, | | |
|-------------------|----------------------------------|---------|--------|---------------------------------|----------|----------|
| | 2009 | 2008 | Change | 2009 | 2008 | Change |
| Cost of revenues | \$ 20.3 | \$ 18.8 | \$ 1.5 | \$ 56.0 | \$ 58.6 | \$ (2.6) |
| % of net revenues | 25.6% | 25.0% | | 24.8% | 25.5% | |
| Gross profit | \$ 59.0 | \$ 56.4 | \$ 2.6 | \$ 169.7 | \$ 171.2 | \$ (1.5) |
| Gross margin | 74.4% | 75.0% | | 75.2% | 74.5% | |

Cost of revenues includes salaries for staff involved in the production process, the cost of materials, packaging, shipping costs, depreciation on capital equipment used in the production process, training costs and stock-based compensation expense. Cost of revenues also includes the cost of the third party shelter service provider, we utilized in Juarez, Mexico until April 2009.

Gross margin declined slightly for the three months ended September 30, 2009 compared to the same period in 2008 primarily due to the amortization of royalties of \$1.9 million that were paid to Ormco in August 2009 in connection with the litigation settlement. This decrease was partially offset by reduced headcount and cost savings relating to the phased-consolidation of our order acquisition operations from Santa Clara, California to Juarez, Mexico, which was completed in December 2008. Furthermore, since the termination of our relationship with IMS in April 2009, we became a direct manufacturer of our aligners, which resulted in additional cost savings.

Gross margin improved for the nine months ended September 30, 2009 compared to the same period in 2008 primarily due to improved manufacturing efficiencies, including reduced headcount and cost savings relating to the phased-consolidation of order acquisition operations from Santa Clara, California to Juarez, Mexico, which was completed in December 2008. Furthermore, since the termination of our relationship with IMS in April 2009, we became a direct manufacturer of our aligners, which resulted in additional cost savings. These savings were reduced by the amortization of royalties paid to Ormco.

We anticipate our gross margin in 2009 to be consistent with 2008 as we benefit from the 2008 restructuring and the transition from a third party shelter service provider to directly manufacturing our clear aligners. However, those benefits will be offset by the amortization of the prepaid Ormco royalties.

Sales and marketing :

| (In millions) | Three Months Ended September 30, | | | Nine Months Ended September 30, | | |
|---------------------|-------------------------------------|---------|----------|------------------------------------|---------|----------|
| | 2009 | 2008 | Change | 2009 | 2008 | Change |
| Sales and marketing | \$ 27.7 | \$ 28.2 | \$ (0.5) | \$ 84.6 | \$ 88.7 | \$ (4.1) |
| % of net revenues | 34.9% | 37.5% | | 37.5% | 38.6% | |

Sales and marketing expense includes sales force compensation (including travel-related costs), marketing personnel-related costs, media and advertising, clinical education, product marketing, customer care and stock-based compensation expense.

Our sales and marketing expense decreased in the three months ended September 30, 2009 as compared to the same period in 2008, as a result of a reduction of \$1.8 million in marketing, travel, and other sales and marketing administrative costs. These costs were primarily offset by increases of \$1.3 million related to media, clinical education, and public relations expenses.

For the nine months ended September 30, 2009 compared to the same period in 2008, the decrease in sales and marketing expense was due to a \$3.5 million decrease in media and marketing, and \$1.5 million decrease in other sales and marketing administrative costs. These decreases were partially offset by higher public relations expenses and payroll related costs.

We expect sales and marketing expense levels in 2009 to be slightly lower than 2008 as we benefit from the transition of our customer care organization from Santa Clara, California to Costa Rica, which was completed in the second quarter of 2009. These benefits will be partially offset by the continued investment in our international channel and consumer marketing programs.

General and administrative:

| (In millions) | Three Months Ended September 30, | | | Nine Months Ended September 30, | | |
|----------------------------|-------------------------------------|---------|--------|------------------------------------|---------|--------|
| | 2009 | 2008 | Change | 2009 | 2008 | Change |
| General and administrative | \$ 16.2 | \$ 14.4 | \$ 1.8 | \$ 46.2 | \$ 45.9 | \$ 0.3 |
| % of net revenues | 20.5% | 19.1% | | 20.5% | 20.0% | |

General and administrative expense includes salaries for administrative personnel, outside consulting services, legal expenses and stock-based compensation expense.

General and administrative expense increased for the three months ended September 30, 2009 as compared to the same period in 2008 primarily due to increased legal fees and outside consulting services of approximately \$0.8 million related to the Ormco litigation, and bad debt and other general and administration expenses of \$0.7 million.

General and administrative expense increased slightly for the nine months ended September 30, 2009 compared to the same period in 2008. Increased depreciation, bad debt, and other general expenses of \$3.7 million was offset by a reduction in payroll-related expenses of \$1.5 million, resulting from a decrease in headcount and lower legal expense due to an insurance reimbursement of \$1.5 million received in the first quarter of 2009.

We expect general and administrative expense for 2009 to be comparable to 2008 levels as we benefit from the October 2008 restructuring, including the transition of our shared services organizations to Costa Rica, which was completed in the second quarter of 2009.

Research and development:

| (In millions) | Three Months Ended September 30, | | | Nine Months Ended September 30, | | |
|--------------------------|-------------------------------------|--------|----------|------------------------------------|---------|----------|
| | 2009 | 2008 | Change | 2009 | 2008 | Change |
| Research and development | \$ 5.6 | \$ 5.9 | \$ (0.3) | \$ 16.5 | \$ 20.2 | \$ (3.7) |
| % of net revenues | 7.1% | 7.8% | | 7.3% | 8.8% | |

Research and development expense includes the personnel-related costs and outside consulting expenses associated with the research and development of new products and enhancements to existing products, conducting clinical and post-marketing trials and stock-based compensation expense.

Research and development expense was comparable for the three months ended September 30, 2009 compared to the same period in 2008.

Research and development expense decreased during the nine months ended September 30, 2009 compared to the same period in 2008 primarily due to decreases in payroll-related expenses of \$2.4 million, as well as decreases in outside consulting, depreciation and other administration costs totaling approximately \$1.2 million.

We expect research and development expense levels in 2009 will be lower than 2008 as a result of reduced headcount from the 2008 restructuring programs and lower consulting expenses.

Restructuring :

| (In millions) | Three Months Ended September 30, | | | Nine Months Ended September 30, | | |
|-------------------|-------------------------------------|--------|----------|------------------------------------|--------|----------|
| | 2009 | 2008 | Change | 2009 | 2008 | Change |
| Restructuring | \$ — | \$ 2.2 | \$ (2.2) | \$ 1.3 | \$ 2.2 | \$ (0.9) |
| % of net revenues | 0.0% | 2.9% | | 0.6% | 1.0% | |

During 2008, we announced restructuring plans in July and October to increase efficiencies across the organization and lower the overall cost structure. In July 2008, we implemented a restructuring plan to reduce our full time headcount including a phased-consolidation of order acquisition operations from our corporate headquarters in Santa Clara, California to Juarez, Mexico, which was completed by the end of 2008.

In addition to headcount reductions, the October restructuring plan included the phased relocation of our shared services organizations from Santa Clara, California to our facility in Costa Rica, which we completed during the second quarter of 2009. For the three months ended September 30, 2009, we did not incur any restructuring expenses. We incurred approximately \$1.3 million during the nine months ended September 30, 2009, which were related to severance and termination benefits. We do not expect to incur any additional restructuring charges under the October 2008 Plan for the remainder of 2009. Additionally, at the time the plans were implemented, we expected total net cost savings of approximately \$3.5 million per quarter starting in the first quarter of 2009 as a result these restructuring plans.

Litigation settlement:

| (In millions) | Three Months Ended September 30, | | | Nine Months Ended September 30, | | |
|-----------------------|-------------------------------------|------|---------|------------------------------------|------|---------|
| | 2009 | 2008 | Change | 2009 | 2008 | Change |
| Litigation settlement | \$ 69.7 | \$ — | \$ 69.7 | \$ 69.7 | \$ — | \$ 69.7 |
| % of net revenues | 87.9% | 0.0% | | 30.9% | 0.0% | |

On August 16, 2009, we entered into a litigation settlement with Ormco valued at \$76.7 million which was comprised of a cash payment of \$13.2 million and a stock issuance of approximately 7.6 million shares of common stock. We recognized the litigation settlement of \$69.7 million in our operating expenses for the quarter ended September 30, 2009. The remaining \$7.0 million was recorded to prepaid expenses, of which \$1.9 million was recognized in cost of sales during the quarter ended September 30, 2009. The remaining \$5.1 million will be amortized based on case shipments during the fourth quarter of 2009 and first quarter of 2010.

See Footnote 6 “Ormco Litigation Settlement” for additional information about the settlement accounting.

Interest and other income, net :

| (In millions) | Three Months Ended September 30, | | | Nine Months Ended September 30, | | |
|-------------------------------|-------------------------------------|---------------|-----------------|------------------------------------|---------------|-----------------|
| | 2009 | 2008 | Change | 2009 | 2008 | Change |
| Interest income | \$ 0.1 | \$ 0.7 | \$ (0.6) | \$ 0.5 | \$ 2.6 | \$ (2.1) |
| Other income (expense), net | (0.4) | (0.4) | — | (0.1) | (0.9) | 0.8 |
| Total interest and other, net | <u>\$ (0.3)</u> | <u>\$ 0.3</u> | <u>\$ (0.6)</u> | <u>\$ 0.4</u> | <u>\$ 1.7</u> | <u>\$ (1.3)</u> |

Total interest and other income, net includes interest income earned on cash balances, and interest expense on debt, foreign currency translation gains and losses and other miscellaneous charges.

Interest income, net decreased for both the three and nine months ended September 30, 2009 compared to the same periods in 2008 primarily due to lower returns on our investments. We shifted our investments into more conservative securities with shorter durations, principally money market and US government securities, which generally bear lower interest rates than other securities. Furthermore, interest rates for investments throughout the marketplace are lower due to the low Federal Funds Rate established by the Federal Reserve.

Other income (expense), net for the three months ended September 30, 2009 was consistent with the same period in 2008. Other expense, net for the nine months ended September 30, 2009 decrease compared with the same period in 2008 due to the increase in foreign exchange gains during 2009.

Income tax :

| (In millions) | Three Months Ended September 30, | | | Nine Months Ended September 30, | | |
|---|-------------------------------------|--------|-----------|------------------------------------|--------|----------|
| | 2009 | 2008 | Change | 2009 | 2008 | Change |
| Provision for (benefit) from income taxes | \$ (10.5) | \$ 0.8 | \$ (11.3) | \$ (5.5) | \$ 1.4 | \$ (6.9) |

We recorded an income tax provision (benefit) of \$(10.5) million and \$0.8 million for the three months ended September 30, 2009 and 2008, respectively, representing effective tax rates of 17.4% and 13.4%. We recorded an income tax provision (benefit) of \$(5.5) million and \$1.4 million for the nine months ended September 30, 2009 and 2008, respectively, representing effective tax rates of 11.3% and 8.6%. Our effective tax rate for the remainder of 2009 may fluctuate based upon our operating results for each taxable jurisdiction in which we operate and the amount of statutory tax that we incur in each jurisdiction.

We exercised significant judgment in regards to estimates of future market growth, forecasted earnings and projected taxable income, in determining the provision for income taxes, and for purposes of assessing our ability to utilize any future benefit from deferred tax assets. 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 of new product launches. Specifically, at December 31, 2008, the Company 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

The Company 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.

In February 2009, the California 2009-2010 budget legislation was signed into law. One of the major components of this legislation is the ability to elect to apply a single sales factor apportionment for years beginning after January 1, 2011. As a result of our anticipated election of the single sales factor, we are required to re-measure our deferred taxes taking into account the reversal pattern and the expected California tax rate under the elective single sales factor. We have determined that by electing a single sales factor apportionment, our deferred tax assets will decrease by approximately \$0.6 million (net of federal benefit). The tax impact of \$0.6 million has been recorded as a discrete item in the first quarter of fiscal year 2009.

Liquidity and Capital Resources

We fund our operations from product sales and proceeds from the sale of common stock. As of September 30, 2009 and December 31, 2008 we had the following cash and cash equivalents, and short-term marketable securities (in thousands):

| | September 30, 2009 | December 31, 2008 |
|-----------------------------------|-----------------------|----------------------|
| Cash and cash equivalents | \$ 135,961 | \$ 87,100 |
| Marketable securities, short-term | 18,979 | 23,066 |
| Total | <u>\$ 154,940</u> | <u>\$ 110,166</u> |

Net cash provided by operating activities was \$39.9 million for the nine months ended September 30, 2009 resulting primarily from our net loss of \$42.8 million adjusted by \$81.8 million for non-cash items such as, litigation settlement costs, stock based compensation expense, depreciation, and amortization of intangibles, as well as an \$11.1 million increase in deferred revenue related to our new Invisalign Teen and Invisalign Assist products. These changes were offset by a \$10.2 million increase in accounts receivable, prepaids, and other assets.

Net cash provided by operating activities was \$31.0 million for the nine months ended September 30, 2008 resulting primarily from our net profit of \$14.5 million adjusted by \$23.1 million for non-cash items such as, stock-based compensation expense, depreciation, and amortization of intangibles, as well as a \$3.1 million increase in deferred revenue. These changes were offset by a \$4.1 million increase in accounts receivable and a decrease in accrued liabilities of \$6.3 million.

Net cash provided by investing activities was \$2.9 million for the nine months ended September 30, 2009, consisting largely of \$7.0 million of net maturities of marketable securities partially offset by \$4.1 million for the purchase of property, plant, and equipment.

Net cash used in investing activities was \$10.5 million for the nine months ended September 30, 2008, largely consisted of \$12.4 million used for the purchase of property and equipment and offset by \$1.4 million of net maturities of marketable securities.

As a result of adverse financial market conditions, investments in some financial instruments may pose risks arising from liquidity and credit concerns. Although we believe our current investment portfolio has little risk of impairment, we cannot predict future market conditions or market liquidity and can provide no assurance that our investment portfolio will remain unimpaired.

Net cash provided by financing activities was \$6.0 million for the nine months ended September 30, 2009, which primarily resulted from \$6.4 million in proceeds from the issuance of our common stock for employee stock option exercises.

Net cash used in financing activities was \$29.6 million for the nine months ended September 30, 2008, which resulted primarily from our \$39.4 million stock repurchase offset by \$10.2 million in proceeds from the issuance of our common stock, primarily from exercises of employee stock options.

Contractual Obligations

In April 2009, we terminated our third party shelter services arrangement with IMS for order acquisition, the fabrication of aligner molds and finished aligners and the shipment of the completed product to customers. We are now a direct manufacturer of our clear aligners at the facility in Juarez, Mexico and directly coordinate order acquisition and product shipment from this location. IMS has assigned the lease to Align Mexico, a wholly-owned subsidiary of Align, and we guarantee the lease payments for our subsidiary.

There were no other material changes to our contractual obligations outside the ordinary course of business from those disclosed in our Annual Report on Form 10-K for the year ended December 31, 2008.

We believe that our current cash and cash equivalents combined with our existing borrowing capacity will be sufficient to fund our operations for at least the next 12 months. If we are unable to generate adequate operating cash flows, we may need to seek additional sources of capital through equity or debt financing, collaborative or other arrangements with other companies, bank financing and other sources in order to realize our objectives and to continue our operations. There can be no assurance that we will be able to obtain additional debt or equity financing on terms acceptable to us, or at all. If adequate funds are not available, we may need to make business decisions that could adversely affect our operating results such as modifications to our pricing policy, business structure or operations. Accordingly, the failure to obtain sufficient funds on acceptable terms when needed could have a material adverse effect on our business, results of operations and financial condition.

Critical Accounting Policies

Management's discussion and analysis of our financial condition and results of operations is based upon our Condensed Consolidated Financial Statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of financial statements requires our management to make estimates and judgments that affect the reported amounts of assets and liabilities, revenues and expenses and disclosures at the date of the financial statements. We evaluate our estimates on an on-going basis, including those related to revenue recognition, accounts receivable, legal contingencies and income taxes. We use authoritative pronouncements, historical experience and other assumptions as the basis for making estimates. Actual results could differ from those estimates.

We believe the following critical accounting policies reflect our most significant estimates, judgments and assumptions used in the preparation of our consolidated financial statements. These critical accounting policies and related disclosures appear in our Annual Report on Form 10-K for the year ended December 31, 2008.

- Revenue recognition;
- Stock-based compensation expense;
- Long-lived assets, including finite lived purchased intangible assets;
- Deferred tax valuation allowance.

There have been no significant changes in our critical accounting policies during the three months ended September 30, 2009 compared to what was previously disclosed in Item 7, *Management's Discussion and Analysis of Financial Condition and Results of Operations* included in our Annual Report on Form 10-K for the year ended December 31, 2008.

Recent Accounting Pronouncements

See Note 1 "Summary of Significant Accounting Policies" of the Notes to Condensed Consolidated Financial Statements for a discussion of recent accounting pronouncements.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

For quantitative and qualitative disclosures about market risk affecting us, see Item 7A, “Quantitative and Qualitative Disclosures About Market Risk,” in our Annual Report on Form 10-K for the year ended December 31, 2008, which is incorporated herein by reference. Our exposure to market risk has not changed materially since December 31, 2008.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of disclosure controls and procedures .

Under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, we have evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15 (e) and 15d-15(e) under the Exchange Act) as of the end of the period covered by this Quarterly Report on Form 10-Q. Based upon that evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that our disclosure controls and procedures are effective as of September 30, 2009 to provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our Chief Executive Officer and our Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure, and that such information is recorded, processed, summarized and reported within the time periods specified in the SEC rules and forms.

Changes in internal control over financial reporting .

There was no change in our internal control over financial reporting that occurred during the period covered by this Quarterly Report on Form 10-Q that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

Ormco

On January 6, 2003, Ormco Corporation (“Ormco”), a division of Sybron Dental Specialties (a Danaher Corporation subsidiary), filed suit against us in the United States District Court for the Central District, Orange County Division, asserting infringement of U.S. Patent Nos. 5,447,432, 5,683,243 and 6,244,861. The complaint sought unspecified monetary damages and injunctive relief. Also in 2003, we counterclaimed for infringement of our U.S. Patent No. 6,398,548, seeking unspecified monetary damages and injunctive relief. Ormco filed a first amended complaint for infringement of U.S. Patent No. 6,616,444 and we filed an answer to Ormco’s first amended complaint and a counterclaim for invalidity and non-infringement of U.S. Patent No. 6,616,444 and for infringement of U.S. Patent No. 6,554,611.

In connection with these claims, in 2004, the Court granted five motions for summary judgment that we filed. First, the Court granted our motion for summary judgment of non-infringement, finding that our Invisalign system does not infringe any of the asserted Ormco patents (5,447,432, 5,683,243, 6,244,861 and 6,616,444). Second, the Court granted in part our motion for summary judgment of infringement, finding that Ormco and its subsidiary, Allesee Orthodontic Appliances, Inc. (“AOA”) infringe certain, but not all, claims of our patents Nos. 6,398,548 and 6,554,611 through the manufacture and sale of Red, White & Blue appliances. Third, the Court granted our motion for summary judgment of invalidity of Ormco’s asserted patents claims (5,447,432, 5,683,243, 6,244,861 and 6,616,444). As noted above, the Court earlier found that we do not infringe these patents. In addition, the Court also denied Ormco’s and AOA’s motion for summary judgment seeking a finding of invalidity of our asserted patent claims (6,398,548 and 6,554,611). Fourth, the Court granted our summary judgment motion that our asserted patent claims are not invalid based on the evidence currently before the Court. Although the Court granted that motion, it reopened discovery on two additional invalidity arguments Ormco and AOA asserted. Fifth, the Court also granted our summary judgment motion that our patents are not unenforceable and granted Ormco’s and AOA’s summary judgment motion that Ormco and AOA did not willfully infringe our patents.

On February 24, 2005, the Court, on further summary judgment, confirmed the validity of all of the asserted claims of our 6,554,611 patent and two of the asserted claims of our 6,398,548 patent. The Court also found certain claims of our 6,398,548 patent to be invalid in view of prior use evidence. On May 26, 2005, the Court issued a permanent injunction (the “Permanent Injunction”) to enjoin Ormco and AOA from further infringement of Claims 10 and 17 of our 6,398,548 patent and Claims 1-3 and 7 of our 6,554,611 patent. On May 31, 2005, Ormco and AOA filed a notice of appeal with the Federal Circuit from the Permanent Injunction.

There have been two appeals. After the Permanent Injunction was entered, Ormco and AOA appealed that injunction and the orders of the District Court on summary judgment on which the injunction was based. In April 2006, the U.S. Court of Appeals for the Federal Circuit (“CAFC”) issued a ruling declaring two out of a total of seventy-one claims in our US Patent No. 6,398,548 and four out of a total of ten claims in US Patent No. 6,554,611 to be invalid as “obvious.” The CAFC’s decision reverses the California District Court summary judgment order of validity.

The 6,398,548 patent consists of 71 claims; only claims 10 and 17 were at issue in the first appeal and CAFC ruling. These two claims are directed to a system of appliances and method of repositioning teeth from an initial to a final tooth arrangement where at least some of the appliances are marked to show order of use. These claims contain further limitations requiring instructions as to the order in which the appliances are to be worn and use of the appliances in intervals of 2-20 days.

The 6,554,611 patent consists of ten claims directed to a system for repositioning teeth that includes one or more intermediate appliances and a final appliance, provided in a single package, as well as instructions which set forth the order in which the appliances are to be worn. The CAFC’s ruling pertains only to claims 1, 2, 3 and 7 in the patent.

The second appeal was from the final judgment. Ormco appealed the ruling of the District Court that 92 claims in four of its patents are not infringed by us and that the asserted claims are invalid. We appealed the ruling of the District Court that certain claims of our 6,398,548 patent which were found to be infringed by Ormco’s and AOA’s Red, White & Blue appliances were invalid. The CAFC issued a ruling on August 24, 2007, affirming the District Court’s ruling that 86 out of 92 claims in Ormco’s 5,447,432, 5,683,243, 6,244,861 and 6,616,444 patents are invalid and not infringed by us. The CAFC reversed the District Court’s non-infringement and invalidity rulings on six claims in Ormco’s 6,616,444 patent. Ormco filed a petition for review with the U.S. Supreme Court with respect to the portion of the CAFC’s opinion that affirmed the District Court’s ruling of non-infringement and non-enablement of Ormco’s 86 claims. The Supreme Court denied Ormco’s petition, and the case on the six claims in Ormco’s 6,616,444 patent were returned to the District Court for a determination of validity and infringement of those claims. The District Court issued orders construing the claim terms at issue and granting our motion to amend our answer and counterclaim to assert Ormco’s 6,616,444 patent is unenforceable due to inequitable conduct.

On February 25, 2009, the District Court issued rulings on various Summary Judgment and expert related motions. In summary, the District Court granted one of Ormco’s motions on one theory of infringement and granted our motion on two theories of non-infringement. Our invalidity argument supported by over fifty prior art references was unaffected. The District Court also ruled that one of our inequitable conduct theories should be resolved at trial.

Trial on liability issues took place between June 9, 2009 and June 25, 2009. The jury returned a verdict finding (i) infringement under 35 U.S.C. §271(g), (ii) finding the six claims in Ormco’s 6,616,444 patent to be not invalid and (iii) providing an advisory verdict on the equitable issues that Ormco did not commit prosecution laches or engage in unclean hands. On July 28, 2009, the Court entered judgment in favor of Ormco on our defenses of prosecution laches and unclean hands. Subsequent to the jury verdict, we filed a motion for judgment as a matter of law on all issues seeking to set aside the jury’s verdict of liability. On August 3, 2009, the court denied our motion for judgment as a matter of law.

On July 13, 2009, Ormco filed a motion for permanent injunction against us seeking to enjoin the sale of the Invisalign system through the January 2010 expiration of the 6,616,44 patent, as well as other injunctive relief against us including (i) the destruction of all material, including software, created by Align from September 2003 to the present; (ii) the discontinuation of certification programs and the decertification of doctors certified from September 2003 to the present; and (iii) the destruction of sales representatives’ records developed during this time period. A hearing on the motion for permanent injunction was scheduled on August 17, 2009.

On August 16, 2009, Align and Ormco entered into a Settlement Agreement (the “Settlement Agreement”), pursuant to which we (1) paid Ormco a cash amount equal to approximately \$13.15 million, and (2) agreed to issue to Danaher Corporation (“Danaher”), an affiliate of Ormco, up to 7,586,489 fully paid and nonassessable shares of our Common Stock (the “Shares”), 5,561,489 and 2,025,000 of which were issued to Danaher on August 16, 2009 and September 22, 2009, respectively, pursuant to the Stock Purchase Agreement entered into between Align and Danaher on August 16, 2009

Pursuant to the terms of the Settlement Agreement, judgment was entered on the claims resolved by the jury in the litigation involving the parties that was pending in the U.S. District Court for the Central District of California, Western Division, Case No. SACV 03-16 CAS (ANx), and all remaining claims in the Litigation were dismissed with prejudice.

In addition, the Settlement Agreement includes the following terms:

- A release by Ormco of all past claims asserted by it against us based upon Ormco’s U.S. Patent Number 6,616,444 (the “Patent”) and an agreement by Ormco not to assert against us any claim of infringement based upon the Patent as a result of our activities relating to removable aligners.
- A release by us of any and all past and future claims that claims 37, 38, 39, 40, and 69 of the Patent are not infringed by us, that claims 37, 38, 39, 40, 45 and 69 of the Patent are invalid, and that the Patent is unenforceable and a waiver by us of any right to appeal from or contest any of the findings, judgments, rulings or orders made by the court in the litigation;
- A covenant by Ormco that, with respect to our current products and processes (including any enhancements), it will not, anywhere in the world, initiate or cause to be initiated against us any claim of infringement of any claim in any patent owned or controlled by Ormco that is existing as of August 16, 2009, or that issues from any patent application having a filing date, or claiming priority to any patent application having a filing date with the applicable government authority, no later than August 16, 2009, solely with respect to any activities relating to removable dental aligners and/or processes for making removable dental aligners, including attachments, buttons and similar auxiliaries for use in connection with the removable dental aligners (and for the avoidance of doubt not to include any activities relating to non-removable appliances).
- A covenant by us that it will not, anywhere in the world, initiate or cause to be initiated against Ormco any claim of infringement of any patent owned or controlled by us that is existing as of August 16, 2009, or that issues from any patent application having a filing date, or claiming priority to any patent application having a filing date, no later than August 16, 2009, for any activities relating to those products currently being manufactured and/or sold by Ormco, including any enhancements to those products; provided, however, that those removable aligner products are created without using a computer or other digital means to create the physical model of the teeth on which the aligners are formed; and

A copy of the Settlement Agreement is filed as exhibits to this quarterly report on Form 10-Q.

- A Joint Development, Marketing and Sales Agreement with Ormco.

See Footnote 6 “Ormco Litigation Settlement” for additional information about the settlement accounting.

Other matters

USPTO

During fiscal 2005 and 2006, requests were filed with the United States Patent and Trademark Office (“USPTO”) by a San Francisco, California, law firm, acting on behalf of an unnamed party, requesting Ex Parte re-examination of our patents. A Reexamination Certificate has been issued regarding the 6,309,215, 6,398,548, 6,705,863, 6,217,325, 6,722,880, 6,318,994 and 5,975,893 patents and therefore these patents are no longer in reexamination. We received an Action Closing Prosecution on the 6,685,469 patent. The status of the 6,629,840 patent is as follows:

| Patent No. | Request for Reexamination Granted? | Initial Office Actions Received? | Status |
|------------|------------------------------------|----------------------------------|---|
| 6,629,840 | Yes | Yes | In this initial Office Action dated June 13, 2006, the examiners confirmed the validity of eight of the eleven claims of U.S. Patent No. 6,629,840 (the ‘840 patent) without amendment and preliminarily rejected the remaining claims of the patents. The non-final initial Office Action presented us with the first opportunity to respond to the USPTO’s review and interpretation of the prior art. On September 13, 2006, we submitted a response to the initial Office Action. A petition seeking a waiver was filed on February 15, 2007 and was granted on April 17, 2007, granting a single interview. The interview was held on May 22, 2007, and an Interview Summary was filed with the USPTO on June 21, 2007. We are awaiting further action by the USPTO. |

As part of the OrthoClear Agreement, OrthoClear agreed to take no further action with respect to the Inter Parte Requests, including the 6,629,840 patent.

Consumer Class Action

On May 18, 2007, Debra A. Weber filed a consumer class action lawsuit against us, 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 us for breach of contract. The cause of action against us titled “Breach of Third Party Benefit Contract” references our agreement to make Invisalign treatment available to OrthoClear patients, alleging that we failed “to provide the promised treatment to Plaintiff or any of the class members”.

On July 3, 2007, we filed our answer to the complaint and asserted 17 affirmative defenses. On July 20, 2007, we filed a motion for summary judgment on the Third Cause of Action (the only cause of action alleged against us). On August 24, 2007, Weber filed a motion for class certification. On October 1, 2007, we filed an opposition to the motion of class certification and we are 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 our motion for summary judgment. The Company believes the lawsuit to be without merit and intends to vigorously defend itself.

Securities Litigation

In August 2009, Plaintiff Charles Wozniak filed a lawsuit against the Company and our 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 we failed to disclose that we had shifted the focus of our 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. We believe the lawsuit to be without merit and intend to vigorously defend ourselves.

Litigating claims of the types discussed in this Quarterly Report on Form 10-Q, whether or not ultimately determined in our favor or settled by us, is costly and diverts the efforts and attention of our management and technical personnel from normal business operations. Any of these results from litigation could adversely affect our results of operations and stock price. From time to time, we have received, and may again receive, letters from third parties drawing our attention to their patent rights. While we do not believe that we infringe any such rights that have been brought to our attention, there may be other more pertinent proprietary rights of which we are presently unaware.

ITEM 1A. RISK FACTORS

We depend on the sale of the Invisalign system for the vast majority of our revenues, and any decline in sales of Invisalign for any reason, including as a result of the introduction of the Proficiency Requirements or a decline in general economic conditions, or a decline in average selling prices would adversely affect revenues, gross margin and net profits.

We expect that revenues from the sale of the Invisalign system will continue to account for the vast majority of our total revenues for the foreseeable future. Continued and widespread market acceptance of Invisalign by orthodontists, GPs and consumers is critical to our future success. If orthodontists and GPs experience a reduction in consumer demand for orthodontic services, if consumers prove unwilling to adopt Invisalign as rapidly as we anticipate or in the volume that we anticipate, if orthodontists or GPs choose to use a competitive product rather than Invisalign or if the average selling price of our product declines, our operating results would be harmed. Factors that could cause the adoption of Invisalign to occur at a lower rate than we expect, as well as the risk related to declining average selling prices are described more fully below.

Consumers may not adopt Invisalign as rapidly as we anticipate due to a variety of factors including a continued decline in general economic conditions.

Consumer spending habits are affected by, among other things, prevailing economic conditions, levels of employment, salaries and wage rates, gas prices, consumer confidence and consumer perception of economic conditions. A general slowdown in the United States economy and certain international economies or an uncertain economic outlook would adversely affect consumer spending habits which may, among other things, result in a decrease in the number of overall orthodontic case starts or a reduction in the demand for Invisalign generally either of which would have a material adverse effect on our sales and operating results. In addition, Invisalign represents a significant change from traditional orthodontic treatment, and consumers may be reluctant to accept it or may not find it preferable to traditional treatment. We have generally received positive feedback from orthodontists, GPs and consumers regarding Invisalign as both an alternative to braces and as a clinical method for treatment of malocclusion, but a number of dental professionals believe that Invisalign is appropriate for only a limited percentage of their patients. Market acceptance will depend in part upon the recommendations of dental professionals, as well as other factors including effectiveness, safety, ease of use, reliability, aesthetics, greater comfort and hygiene compared to traditional orthodontic products and price for Invisalign compared to competing products.

Orthodontists and GPs may not adopt Invisalign in sufficient numbers or as rapidly as we anticipate for a number of reasons, including the introduction of the Proficiency Requirements or declining general economic conditions.

Our success depends upon increasing acceptance and frequency of use of the Invisalign system by dental professionals (what we refer to as utilization). We have a large number of low volume doctors that make up a large portion of our customer base. We want every Invisalign provider to be one we can comfortably direct a prospective patient to with an expectation of knowledgeable treatment and a great outcome. To further this goal, on June 2, 2009, we announced the implementation of the Invisalign Product Proficiency Requirements in North America to help ensure that Invisalign-trained doctors have the experience and confidence necessary to achieve high quality treatment outcomes for Invisalign patients. Under the Proficiency Requirements, every Invisalign provider in North America must start 10 Invisalign cases and complete at least 10 Invisalign-specific continuing education (CE) credits each calendar year. We announced in September 2009, updates to the Proficiency Requirements, including a new designation for doctors who meet the annual requirements and an additional qualification period in 2010. Under the updated Proficiency Requirements, doctors with zero cases shipped or zero Invisalign CE hours at the end of 2009 and doctors who ultimately do not meet the annual case and CE requirements in 2010 will be able to continue treating their in-progress cases, but will not be eligible to submit new Invisalign cases or to use Invisalign marketing resources. Doctors can reactivate their provider status by retaking Invisalign Clear Essentials I training and meeting the Proficiency Requirements in the new calendar year. Although we want every doctor to achieve and maintain the Proficiency Requirements with Invisalign, we expect that a number of our lower volume doctors may be unwilling or unable to meet these requirements. If the number of our other customers who fail to maintain and/or increase utilization to meet the Proficiency Requirements is greater than we anticipate, our case volumes will decrease and our revenues will be harmed. In addition, if GPs and Orthos do not attend our training courses in sufficient numbers for any reason, including the introduction of the Proficiency Requirements, or declining general economic conditions, our revenue may fail to grow as expected. In addition, increased competition from direct competitors could cause us to lose market share and reduce dental professionals' efforts and commitment to expand their Invisalign practice. If adoption and utilization does not increase as we anticipate, our revenues may fail to grow as expected and our operating results may be harmed.

The frequency of use by orthodontists or GPs may not increase at the rate that we anticipate or at all.

One of our key objectives is to continue to increase utilization, or the adoption and frequency of use, of the Invisalign system by new and existing customers. If utilization of Invisalign by our existing and newly trained orthodontists or GPs does not occur or does not occur as quickly as we anticipate, our operating results could be harmed.

We may experience declines in average selling prices of our products.

In response to challenges in our business, including increased competition, we have in the past reduced the list price of our products. We also provide volume based discount programs to our doctors. In addition, we sell a number of products at different list prices. If we introduce any price reductions, expand our discount programs in the future, if participation in these programs increases or if our product mix shifts to newer products with a higher percentage of deferred revenue, our average selling price would be adversely affected and our revenues, gross margin and net profits (losses) may be reduced. Furthermore, although the U.S. dollar is our reporting currency, a portion of our revenues and profits are generated in foreign currencies. Revenues and profits generated by subsidiaries operating outside of the United States are translated into U.S. dollars using exchange rates effective during the respective period and are affected by changes in exchange rates. As a result, negative movements in currency exchange rates against the U.S. dollar will adversely affect our average selling price and consequently the amount of revenues and profits in our consolidated financial statements.

If we fail to sustain or increase profitability or revenue growth in future periods, the market price for our common stock may decline.

If we are to sustain or increase profitability in future periods, we will need to continue to increase our revenues, while controlling our expenses. While we generated positive operating cash flow in 2008 and in 2009, we cannot be certain that we will be able to achieve positive cash flow from operations, from period to period, in the future. Because our business is evolving, it is difficult to predict our future operating results or levels of growth, and we have in the past not been and may in the future not be able to sustain our historical growth rates. If we do not increase profitability or revenue growth or otherwise meet the expectations of securities analysts or investors, the market price of our common stock will likely decline.

Our financial results have fluctuated in the past and may fluctuate in the future which may cause volatility in our stock price.

Our operating results have fluctuated in the past and we expect our future quarterly and annual operating results to fluctuate as we focus on increasing doctor and consumer demand for our products. These fluctuations could cause our stock price to decline. Some of the factors that could cause our operating results to fluctuate include:

- limited visibility into and difficulty predicting the level of activity in our customers' practices from quarter to quarter;
- disruptions to our business due to the impact on H1N1 virus, commonly referred to as "swine flu" or any other such epidemic that results in changes in consumer spending habits, consumers unable or unwilling to visit the orthodontist or general practitioners office, as well as any impact on workforce absenteeism;
- weakness in consumer spending as a result of the slowdown in the United States economy and global economies;
- changes in the timing of receipt of case product orders during a given quarter which, given our cycle time and the delay between case receipts and case shipments, could have an impact on which quarter revenue can be recognized;
- fluctuations in currency exchange rates against the U.S. dollar
- changes in product mix;
- seasonal fluctuations in the number of doctors in their offices and their availability to take appointments;
- success of marketing programs from quarter to quarter;
- changes in the timing of when revenue is recognized, including as a result of the introduction of new products or promotions;
- changes to our effective tax rate;
- unanticipated delays in production caused by insufficient capacity;
- any disruptions in the manufacturing process, including unexpected turnover in the labor force or the introduction of new production processes or natural or other disasters beyond our control;
- the development and marketing of directly competitive products by existing and new competitors;
- aggressive price competition from competitors;
- costs and expenditures in connection with litigation;
- inaccurate forecasting of revenues, production and other operating costs; and
- investments in research and development to develop new products and enhancements to Invisalign.

To respond to these and other factors, we may need to make business decisions that could adversely affect our operating results such as modifications to our pricing policy, business structure or operations. Most of our expenses, such as employee compensation and lease payment obligations, are relatively fixed in the short term. Moreover, our expense levels are based, in part, on our expectations regarding future revenue levels. As a result, if our revenues for a particular period fall below our expectations, whether caused by changes in consumer spending, consumer preferences, weakness in the U.S. or

global economies, changes in customer behavior related to advertising and prescribing our product, or other factors, we may be unable to adjust spending quickly enough to offset any shortfall in revenues. Due to these and other factors, we believe that quarter-to-quarter comparisons of our operating results may not be meaningful. You should not rely on our results for any one quarter as an indication of our future performance.

Our future success may depend on our ability to develop, successfully introduce and achieve market acceptance of new products.

Our future success may depend on our ability to develop, manufacture, market, and obtain regulatory approval or clearance of new products. We launched Invisalign Teen in July 2008 and Invisalign Assist in October 2008. In September 2009, we introduced new and enhanced features in all Invisalign products. There can be no assurance that we will be able to successfully develop, sell and achieve market acceptance of these and other new products and applications and enhanced versions of our existing product. The extent of, and rate at which, market acceptance and penetration are achieved by future products is a function of many variables, which include, among other things, our ability to include functionality and features that address customer requirements, the availability of third-party reimbursement of procedures using our new products, the existence of competing products and general economic conditions affecting purchasing patterns. In addition, even if our new products are successfully introduced, it is unlikely that they will rapidly gain market share and acceptance primarily due to the relatively long period of time it takes to successfully treat a patient. Since it takes approximately 12 to 24 months to treat a patient, our customers may be unwilling to rapidly adopt our new products until they successfully complete at least one case or until more historical clinical results are available.

Our ability to market and sell new products may also be subject to government regulation, including approval or clearance by the United States Food and Drug Administration (“FDA”), and foreign government agencies. Any failure in our ability to successfully develop and introduce or achieve market acceptance of our new products or enhanced versions of existing products could have a material adverse effect on our operating results and could cause our revenues to decline.

A disruption in the operations of our primary freight carrier or higher shipping costs could cause a decline in our revenues or a reduction in our earnings.

We are dependent on commercial freight carriers, primarily UPS, to deliver our products. If the operations of these carriers are disrupted for any reason, we may be unable to deliver our products to our customers on a timely basis. If we cannot deliver our products in an efficient and timely manner, our customers may reduce their orders from us and our revenues and operating profits could materially decline. In a rising fuel cost environment, our freight costs will increase. If freight costs materially increase and we are unable to pass that increase along to our customers for any reason or otherwise offset such increases in our cost of revenues, our gross margin and financial results could be adversely affected.

We are dependent on our international operations, which exposes us to foreign operational, political and other risks that may harm our business.

Our key production steps are performed in operations located outside of the U.S. At our facility in Costa Rica, technicians use a sophisticated, internally developed computer-modeling program to prepare digital treatment plans, which are then transmitted electronically to Juarez, Mexico. These digital files form the basis of ClinCheck and are used to manufacture aligner molds. Our order acquisition, aligner fabrication and shipping operations are conducted in Juarez, Mexico. In addition to the research and development efforts conducted in our Santa Clara, California facility, we also carry out research and development at locations in San Jose, Costa Rica and Moscow, Russia. In October 2008, we announced the phased-consolidation of our customer-care, accounts receivable, credit and collections and customer event registration organizations, which was previously located in Santa Clara, California, to our facility in Costa Rica. We completed this relocation in the second quarter of 2009. Our increasing reliance on international operations exposes us to risks and uncertainties that may affect our business or results of operation, including:

- difficulties in hiring and retaining employees generally, as well as difficulties in hiring and retaining employees with the necessary skills to perform the more technical aspects of our operations;
- difficulties in managing international operations;
- fluctuations in currency exchange rates;
- import and export license requirements and restrictions;

- controlling production volume and quality of the manufacturing process;
- political, social and economic instability, including as a result of increased levels of violence in Juarez, Mexico;
- acts of terrorism and acts of war;
- interruptions and limitations in telecommunication services;
- product or material transportation delays or disruption, including as a result of health epidemics such as the outbreak of the H1N1 virus commonly referred to as the “Swine Flu” in the event travel to and from Mexico is restricted;
- burdens of complying with a wide variety of local country and regional laws;
- trade restrictions and changes in tariffs; and
- potential adverse tax consequences.

If any of these risks materialize in the future, we could experience production delays and lost or delayed revenue.

We recently completed the transition from reliance on a shelter service arrangement to become a direct manufacturer of our products. If we fail to successfully manage our operations in Juarez, Mexico, our business may be harmed.

In April 2009, we terminated our third party shelter services arrangement with IMS, for order acquisition, fabrication of aligner molds and finished aligners and the shipment of the completed product to customers. In addition to the risks related to international operations described in the risk factor above, any difficulties encountered by us with respect to directly manufacturing our products, including difficulties hiring and retaining qualified personnel could disrupt our ability to deliver our products in a timely manner which could harm our business.

We recently completed the relocation of our customer facing organizations to Costa Rica.

In October 2008, we announced a restructuring plan to increase efficiencies across the organization and lower our overall cost structure. In addition to headcount reduction, the restructuring plan included the phased-relocation of our customer care, accounts receivable, credit and collections and customer event registration organizations from Santa Clara, California, to our facility in Costa Rica. We completed this relocation in the second quarter of 2009. In addition to the risks related to international operations described in the risk factor above, this relocation is accompanied by a number of risks and uncertainties that may affect our results of operations and statement of cash flows, including:

- due to the large number of new employees in these customer facing organizations, our customers may experience a decrease in service levels for a period of time;
- the relocation may continue to absorb the attention and resources of management and key employees that would otherwise be available for the ongoing business operations; and
- difficulties in hiring or retaining employees in Costa Rica with the necessary skills to perform these customer facing functions.

If any of these risks materialize in the future, our operating results, statement of operations and cash flows may be adversely affected.

A key step in our manufacturing process relies on sophisticated computer technology that requires new technicians to undergo a relatively long training process. If we are unable to accurately predict our volume growth, and fail to hire a sufficient number of technicians in advance of such demand, the delivery time of our products could be delayed which could adversely affect our results of operations.

Training technicians to use our sophisticated computer modeling program that produces the digital treatment plan that forms the basis of ClinCheck takes approximately 90 to 120 days. As a result, if we are unable to accurately predict our volume growth, we may not have a sufficient number of trained technicians to timely create ClinCheck treatment plans within the timeframe our customers expect. Any delay in ClinCheck processing time could delay the ultimate delivery of finished aligners to our customers. Such a delay could cause us to lose existing customers or fail to attract new customers. This could cause a decline in our revenues and net profits and could adversely affect our results of operations.

Our headquarters, digital dental modeling processes, and other manufacturing processes are all principally located in regions that are subject to earthquakes and other natural disasters.

Our digital dental modeling is processed in our facility located in San Jose, Costa Rica. The operations team in Costa Rica creates ClinCheck treatment plans using sophisticated computer software. We recently completed the transition of our customer facing operations from Santa Clara, California to Costa Rica. In addition, our aligner molds and finished aligners are fabricated in Juarez, Mexico. Both Costa Rica and Mexico are in earthquake zones and may be subject to other natural disasters. If there is a major earthquake or any other natural disaster in a region where one of these facilities is located, our ability to create ClinCheck treatment plans or manufacture and ship our aligners could be compromised which could result in our customers experiencing a significant delay in receiving their completed aligners. In addition, our headquarters facility is located in the San Francisco Bay Area. An earthquake or other natural disaster in this region could result in a disruption in our operations. Any such business interruption could materially and adversely affect our business, financial condition and results of operations.

We experience competition from manufacturers of traditional braces and expect aggressive competition from these and other companies that may introduce new technologies in the future.

Currently, our Invisalign product competes directly against products manufactured and distributed by Ormco Orthodontics, a division of Sybron Dental Specialties (a Danaher Corporation subsidiary), and traditional braces manufactured by 3M Company and Dentsply International. These manufacturers have substantially greater financial resources and manufacturing and marketing experience than we do and may, in the future, attempt to develop an orthodontic system similar to ours or combine technologies that make our product economically unattractive. Large consumer product companies may also enter the orthodontic supply market. Furthermore, we may face competition in the future from new companies that may introduce new technologies. We may be unable to compete with these competitors and one or more of these competitors may render our technology obsolete or economically unattractive. If we are unable to compete effectively with existing products or respond effectively to any products developed by new or existing competitors, our business could be harmed. Increased competition has resulted in the past and may in the future result in volume discounting and price reductions, reduced gross margins, reduced profitability and loss of market share, any of which could have a material adverse effect on our revenues, volume growth, net profit (losses) and stock price. We cannot assure you that we will be able to compete successfully against our current or future competitors or that competitive pressures will not have a material adverse effect on our business, results of operations and financial condition.

Our information technology systems are critical to our business. System integration and implementation issues and system security risks could disrupt our operations, which could have a material adverse impact on our business and operating results.

We rely on the efficient and uninterrupted operation of complex information technology systems. All information technology systems are vulnerable to damage or interruption from a variety of sources. As our business has grown in size and complexity, the growth has placed, and will continue to place, significant demands on our information technology systems. To effectively manage this growth, we will need to continually upgrade and enhance our information systems. In addition, experienced computer programmers and hackers may be able to penetrate our network security and misappropriate our confidential information or that of third parties, create system disruptions or cause shutdowns. Furthermore, sophisticated hardware and operating system software and applications that we either internally develop or procure from third parties may contain defects in design and manufacture, including “bugs” and other problems that can unexpectedly interfere with the operation of the system. The costs to eliminate or alleviate security problems, viruses and bugs could be significant, and the efforts to address these problems could result in interruptions that may have a material adverse impact on our operations, revenues and operating results.

We are currently focused on adding more functionality into our business enterprise systems to more efficiently integrate these systems with our other system applications, such as customer facing and manufacturing tools, and intend to continue this effort for the foreseeable future. System upgrades and enhancements require significant expenditures and allocation of valuable employee resources. Delays in integration or disruptions to our business from implementation of these new or upgraded systems could have a material adverse impact on our financial condition and operating results. Furthermore, we continuously upgrade our customer facing software applications, specifically ClinCheck and VIP. Software applications frequently contain errors or defects, especially when they are first introduced or when new versions are released. The discovery of a defect or error in a new upgraded version or the failure of our primary information systems may result in the following consequences, among others: loss of revenue or delay in market acceptance, damage to our reputation or increased service costs, any of which could have a material adverse effect on our business, financial condition or results of operations.

Our success depends in part on our proprietary technology, and if we are unable to successfully enforce our intellectual property rights, our competitive position may be harmed. Litigating claims of this type is costly and could distract our management and cause a decline in our results of operations and stock price.

Our success will depend in part on our ability to maintain existing intellectual property and to obtain and maintain further intellectual property protection for our products, both in the U.S. and in other countries. Our inability to do so could harm our competitive position. As of September 30, 2009, we had 127 issued U.S. patents, 164 pending U.S. patent applications, and 57 issued foreign patents, and 117 pending foreign patent applications.

We intend to rely on our portfolio of issued and pending patent applications in the U.S. and in other countries to protect a large part of our intellectual property and our competitive position. However, our currently pending or future patent filings may not result in the issuance of patents. Additionally, any patents issued to us may be challenged, invalidated, held unenforceable, circumvented, or may not be sufficiently broad to prevent third parties from producing competing products similar in design to our products. During fiscal 2005 and 2006, requests were filed with the United States Patent and Trademark Office (“USPTO”) by a San Francisco, California law firm, acting on behalf of an unnamed party and in some instances acting on behalf of OrthoClear, requesting re-examination of a number of our patents. In addition, any protection afforded by foreign patents may be more limited than that provided under U.S. patents and intellectual property laws. We also rely on protection of our copyrights, trade secrets, know-how and proprietary information. We generally enter into confidentiality agreements with our employees, consultants and our collaborative partners upon commencement of a relationship with us. However, these agreements may not provide meaningful protection against the unauthorized use or disclosure of our trade secrets or other confidential information, and adequate remedies may not exist if unauthorized use or disclosure were to occur. Our inability to maintain the proprietary nature of our technology through patents, copyrights or trade secrets would impair our competitive advantages and could have a material adverse effect on our operating results, financial condition and future growth prospects. In particular, a failure to protect our proprietary rights might allow competitors to copy our technology, which could adversely affect our pricing and market share. In addition, in an effort to protect our intellectual property we have in the past been and may in the future be involved in litigation. The potential effects on our business operations resulting from litigation that we may participate in the future, whether or not ultimately determined in our favor or settled by us, are costly and divert the efforts and attention of our management and technical personnel from normal business operations. Any of these results from our litigation could adversely affect our results of operations and stock price.

We are currently a party to various other legal proceedings and claims. Litigation is subject to inherent uncertainties and unfavorable rulings could occur. An unfavorable ruling could include monetary damages or, in cases where injunctive relief is sought, an injunction prohibiting us from selling our products. Any of these results from our litigation could adversely affect our results of operations and stock price. *See Part II, Item 1 of this Quarterly Report on Form 10-Q for a summary of our material pending legal proceedings.*

While we believe we currently have adequate internal control over financial reporting, we are required to assess our internal control over financial reporting on an annual basis and any future adverse results from such assessment could result in a loss of investor confidence in our financial reports and have an adverse effect on our stock price.

Pursuant to the Sarbanes-Oxley Act of 2002 and the rules and regulations promulgated by the SEC, we are required to furnish in our Form 10-K an Annual Report by our management regarding the effectiveness of our internal control over financial reporting. The report includes, among other things, an assessment of the effectiveness of our internal control over financial reporting as of the end of our fiscal year, including a statement as to whether or not our internal control over financial reporting is effective. This assessment must include disclosure of any material weaknesses in our internal control over financial reporting identified by management. While we currently believe our internal control over financial reporting is effective, the effectiveness of our internal controls to future periods is subject to the risk that our controls may become inadequate because of changes in conditions, and, as a result, the degree of compliance of our internal control over financial reporting with the policies or procedures may deteriorate. If we are unable to assert that our internal control over financial reporting is effective in any future period (or if our auditors are unable to express an opinion on the effectiveness of our internal controls or conclude that our internal controls are ineffective), we could lose investor confidence in the accuracy and completeness of our financial reports, which could have an adverse effect on our stock price.

If we lose our key personnel or are unable to attract and retain key personnel, we may be unable to pursue business opportunities or develop our products.

We are highly dependent on the key employees in our clinical engineering, technology development, sales and marketing personnel and management teams. The loss of the services provided by those individuals may significantly delay or prevent the achievement of our product development and other business objectives and could harm our business. Our future success will also depend on our ability to identify, recruit, train and retain additional qualified personnel, including orthodontists. Few orthodontists are accustomed to working in a manufacturing environment since they are generally trained to work in private practices, universities and other research institutions. Thus, we may be unable to attract and retain personnel with the advanced qualifications necessary for the further development of our business. Furthermore, we may not be successful in retaining our key personnel or their services. If we are unable to attract and retain key personnel, our business could be materially harmed.

If we infringe the patents or proprietary rights of other parties or are subject to a patent infringement claim, our ability to grow our business may be severely limited.

Extensive litigation over patents and other intellectual property rights is common in the medical device industry. We have been sued for infringement of third party's patents in the past and we may be the subject of patent or other litigation in the future. From time to time, we have received and may in the future receive letters from third parties drawing our attention to their patent rights. While we do not believe that we infringe upon any valid and enforceable rights that have been brought to our attention, there may be other more pertinent rights of which we are presently unaware. The defense and prosecution of intellectual property suits, interference proceedings and related legal and administrative proceedings could result in substantial expense to us and significant diversion of effort by our technical and management personnel. An adverse determination of any litigation or interference proceeding to which we may become a party could subject us to significant liabilities. An adverse determination of this nature could also put our patents at risk of being invalidated or interpreted narrowly or require us to seek licenses from third parties. Licenses may not be available on commercially reasonable terms or at all, in which event, our business would be materially adversely affected.

We maintain single supply relationships for certain of our key machines and materials technologies, and our business and operating results could be harmed if supply is restricted or ends or the price of raw materials used in our manufacturing process increases.

We are highly dependent on manufacturers of specialized scanning equipment, rapid prototyping machines, resin and other advanced materials. We maintain single supply relationships for many of these machines and materials technologies. In particular, our scanning and stereolithography equipment are provided by a single supplier. We are also committed to purchasing all of our resin and polymer, the primary raw materials used in our manufacturing process, from a single source. In addition, technology changes by our vendors could disrupt access to required manufacturing capacity or require expensive, time consuming development efforts to adapt and integrate new equipment or processes. Our growth may exceed the capacity of one or more of these manufacturers to produce the needed equipment and materials in sufficient quantities to support our growth. In the event of technology changes, delivery delays, or shortages of or increases in price for these items, our business and growth prospects may be harmed.

We rely on our direct sales force to sell our products, and any failure to maintain our direct sales force could harm our business.

Our ability to sell our products and generate revenues depends upon our direct sales force within our North American and international markets. As of September 30, 2009, our North American sales organization consisted of 165 people, of which 135 were direct sales representatives and 30 were sales administration and regional sales management. Internationally, we had 44 people engaged in sales and sales support as of September 30, 2009. We do not have any long-term employment contracts with the members of our direct sales force. The loss of the services provided by these key personnel may harm our business. If we are unable to retain our direct sales force personnel or replace them with individuals of equivalent technical expertise and qualifications, or if we are unable to successfully instill such technical expertise or if we fail to establish strong relationships with our customers within a relatively short period of time, our revenues and our ability to maintain market share could be materially harmed. In addition, due to our large and fragmented customer base, we may not be able to provide all of our customers with product support immediately upon the launch of a new product. As a result, adoption of new products by our customers may be slower than anticipated and our ability to grow market share and increase our revenues may be harmed.

Complying with regulations enforced by the FDA and other regulatory authorities is an expensive and time-consuming process, and any failure to comply could result in substantial penalties.

Our products are medical devices and are subject to extensive regulation in the U.S. and internationally. FDA regulations are wide ranging and govern, among other things:

- product design, development, manufacturing and testing;
- product labeling;
- product storage;
- pre-market clearance or approval;
- advertising and promotion; and
- product sales and distribution.

Our failure to comply with applicable regulatory requirements could result in enforcement action by the FDA or state agencies, which may include any of the following sanctions:

- warning letters, fines, injunctions, consent decrees and civil penalties;
- repair, replacement, refunds, recall or seizure of our products;
- operating restrictions or partial suspension or total shutdown of production;
- refusing our requests for 510(k) clearance or pre-market approval of new products, new intended uses, or modifications to existing products;
- withdrawing clearance or pre-market approvals that have already been granted; and
- criminal prosecution.

If any of these events were to occur, they could harm our business. We must comply with facility registration and product listing requirements of the FDA and adhere to applicable Quality System regulations. The FDA enforces its Quality System regulations through periodic unannounced inspections. Our failure to take satisfactory corrective action in response to an adverse inspection or the failure to comply with applicable manufacturing regulations could result in enforcement action, and we may be required to find alternative manufacturers, which could be a long and costly process.

Before we can sell a new medical device in the U.S., or market a new use of or claim for an existing product we must obtain FDA clearance or approval, unless an exemption applies. Obtaining regulatory clearances or approvals can be a lengthy and time-consuming process. Even though the devices we market have obtained the necessary clearances from the FDA, we may be unable to maintain such clearances in the future. Furthermore, we may be unable to obtain the necessary clearances for new devices that we intend to market in the future. Our inability to maintain or obtain regulatory clearances or approvals could materially harm our business.

If the security of our customer and patient information is compromised, patient care could suffer, and we could be liable for related damages, and our reputation could be impaired.

We retain confidential customer and patient information in our processing centers. Therefore, it is critical that our facilities and infrastructure remain secure and that our facilities and infrastructure are perceived by the marketplace and our customers to be secure. Despite the implementation of security measures, our infrastructure may be vulnerable to physical break-ins, computer viruses, programming errors, attacks by third parties or similar disruptive problems. If we fail to meet our clients' expectations regarding the security of healthcare information, we could be liable for damages and our reputation could be impaired. In addition, patient care could suffer, and we could be liable if our systems fail to deliver correct information in a timely manner. Our insurance may not protect us from this risk.

If compliance with healthcare regulations becomes costly and difficult for our customers or for us, we may not be able to grow our business.

Participants in the healthcare industry are subject to extensive and frequently changing regulations under numerous laws administered by governmental entities at the federal, state and local levels, some of which are, and others of which may be, applicable to our business. Furthermore, our healthcare provider customers are also subject to a wide variety of laws and regulations that could affect the nature and scope of their relationships with us.

The healthcare market itself is highly regulated and subject to changing political, economic and regulatory influences. Regulations implemented pursuant to the Health Insurance Portability and Accountability Act (HIPAA), including regulations affecting the security and privacy of patient healthcare information held by healthcare providers and their business associates may require us to make significant and unplanned enhancements of software applications or services, result in delays or cancellations of orders, or result in the revocation of endorsement of our products and services by healthcare participants. The effect of HIPAA and newly enforced regulations on our business is difficult to predict, and there can be no assurance that we will adequately address the business risks created by HIPAA and its implementation or that we will be able to take advantage of any resulting business opportunities.

Extensive and changing government regulation of the healthcare industry may be expensive to comply with and exposes us to the risk of substantial government penalties.

In addition to medical device laws and regulations, numerous state and federal healthcare-related laws regulate our business, covering areas such as:

- storage, transmission and disclosure of medical information and healthcare records;
- prohibitions against the offer, payment or receipt of remuneration to induce referrals to entities providing healthcare services or goods or to induce the order, purchase or recommendation of our products; and
- the marketing and advertising of our products.

Complying with these laws and regulations could be expensive and time-consuming, and could increase our operating costs or reduce or eliminate certain of our sales and marketing activities or our revenues.

We face risks related to our international sales, including the need to obtain necessary foreign regulatory clearance or approvals.

We currently sell our products in Europe, Asia Pacific, Latin America and Japan and may expand into other countries from time to time. We do not know whether orthodontists, GPs and consumers outside our North American market will adopt Invisalign in sufficient numbers or as rapidly as we anticipate. In addition, sales of our products outside the U.S. are subject to foreign regulatory requirements that vary widely from country to country. The time required to obtain clearances or approvals required by other countries may be longer than that required for FDA clearance or approval, and requirements for such approvals may differ from FDA requirements. We may be unable to obtain regulatory approvals in one or more of the other countries in which we do business or in which we may do business in the future. We may also incur significant costs in attempting to obtain and maintain foreign regulatory approvals. If we experience delays in receipt of approvals to market our products outside of the U.S., or if we fail to receive these approvals, we may be unable to market our products or enhancements in international markets in a timely manner, if at all.

Our business exposes us to potential product liability claims, and we may incur substantial expenses if we are subject to product liability claims or litigation.

Medical devices involve an inherent risk of product liability claims and associated adverse publicity. We may be held liable if any product we develop or any product that uses or incorporates any of our technologies causes injury or is otherwise found unsuitable. Although we intend to continue to maintain product liability insurance, adequate insurance may not be available on acceptable terms, if at all, and may not provide adequate coverage against potential liabilities. A product liability claim, regardless of its merit or eventual outcome, could result in significant legal defense costs. These costs would have the effect of increasing our expenses and diverting management's attention away from the operation of our business, and could harm our business.

Historically, the market price for our common stock has been volatile.

The market price of our common stock could be subject to wide price fluctuations in response to various factors, many of which are beyond our control. The factors include:

- quarterly variations in our results of operations and liquidity;
- changes in recommendations by the investment community or in their estimates of our revenues or operating results;
- speculation in the press or investment community concerning our business and results of operations;
- strategic actions by our competitors, such as product announcements or acquisitions;
- announcements of technological innovations or new products by us, our customers or competitors; and
- general economic market conditions.

In addition, the stock market in general, and the market for technology and medical device companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated to or disproportionate to the operating performance of those companies. These broad market and industry factors may seriously harm the market price of our common stock, regardless of our operating performance. Historically, class action litigation is often brought against an issuing company following periods of volatility in the market price of a company's securities. Recently, a securities class action suit was filed against us on behalf of all persons or entities who purchased our common stock between January 30, 2007 and October 24, 2007. While we believe the lawsuit is without merit and intend to vigorously defend ourselves, we could incur substantial legal fees, and our management's attention and resources may be diverted from operating our business in order to respond to the litigation.

Future sales of significant amounts of our common stock may depress our stock price.

A large percentage of our outstanding common stock is currently owned by a small number of significant stockholders. These stockholders have sold in the past, and may sell in the future, large amounts of common stock over relatively short periods of time. Sales of substantial amounts of our common stock in the public market by our existing stockholders may adversely affect the market price of our common stock. Such sales could create public perception of difficulties or problems with our business and may depress our stock price.

Changes in, or interpretations of, accounting rules and regulations, could result in unfavorable accounting charges.

We prepare our consolidated financial statements in conformity with accounting principles generally accepted in the United States of America. These principles are subject to interpretation by the SEC and various bodies formed to interpret and create appropriate accounting policies. A change in these policies can have a significant effect on our reported results and may even retroactively affect previously reported transactions. Our accounting policies that recently have been or may be affected by changes in the accounting rules are as follows:

- revenue recognition;
- accounting for share-based payments; and
- accounting for income taxes.

If we fail to manage our exposure to global financial and securities market risk successfully, our operating results and financial statements could be materially impacted.

The primary objective of most of our investment activities is to preserve principal. To achieve this objective, a majority of our marketable investments are investment grade, liquid, short-term fixed-income securities and money market instruments denominated in U.S. dollars. If the carrying value of our investments exceeds the fair value, and the decline in fair value is deemed to be other-than-temporary, we will be required to write down the value of our investments, which could materially harm our results of operations and financial condition. Moreover, the performance of certain securities in our investment portfolio correlates with the credit condition of the U.S. financial sector. With the current unstable credit environment, we might incur significant realized, unrealized or impairment losses associated with these investments.

We have adopted a shareholders rights' plan to limit the possibility that we are acquired, which may mean that a transaction that shareholders are in favor of or are benefited by may be prevented.

Our board of directors has the authority to issue up to 5,000,000 shares of preferred stock and to determine the rights, preferences, privileges and restrictions of such shares without any further vote or action by our shareholders. To date, our board of directors has designated 200,000 shares as Series A participating preferred stock in connection with our shareholder rights' plan. The issuance of preferred stock under certain circumstances could have the effect of delaying or preventing an acquisition of the company or otherwise adversely affecting the rights of the holders of our stock. The shareholder rights' plan may have the effect of rendering more difficult or discouraging an acquisition of our company which is deemed undesirable by our board of directors. The shareholder rights' plan may cause substantial dilution to a person or group attempting to acquire us on terms or in a manner not approved by our board of directors, except pursuant to an offer conditioned on the negation, purchase or redemption of the rights issued under the shareholder rights' plan.

Our effective tax rate may vary significantly from period to period.

Various internal and external factors may have favorable or unfavorable effects on our future effective tax rate. These factors include, but are not limited to, changes in tax laws, regulations and/or rates, changing interpretations of existing tax laws or regulations, the future levels of tax benefits of stock option deductions relating to incentive stock options and employee stock purchase plans and changes in overall levels of pretax earnings. In June 2009, the Costa Rica Ministry of Foreign Trade, an agency of the Government of Costa Rica, granted a twelve year extension of the tax incentives which were previously granted in 2002. Under these incentives, all of the income we earn in Costa Rica during these twelve year incentive periods is subject to reduced rates of Costa Rica income tax. The incentive tax rates will expire in various years beginning in 2017. The Costa Rica corporate income tax rate that would apply, absent the incentives, is 30% for 2009. As a result of these incentives, income taxes decreased by \$1.3 million in 2008. In order to receive the benefit of the incentives, we must hire specified numbers of employees and maintain minimum levels of fixed asset investment in Costa Rica. If we do not fulfill these conditions for any reason, our incentive could lapse and our income in Costa Rica would be subject to taxation at higher rates, which could have a negative impact on our operating results.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

On August 16, 2009, we entered into a Settlement Agreement with Ormco, pursuant to which we agreed, among other things, to issue to Danaher Corporation ("Danaher"), an affiliate of Ormco, 7,586,489 fully paid and nonassessable shares of our common stock.

In connection with the Settlement Agreement, we issued 5,561,489 of such shares of our common stock to Danaher on August 16, 2009 in accordance with a Stock Purchase Agreement. In accordance with the terms of the Stock Purchase Agreement, immediately following the expiration of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, we issued to Danaher 2,025,000 fully paid and nonassessable shares of our common stock on September 22, 2009. Additional information regarding the Stock Purchase Agreement the transactions related thereto, and the settlement was previously disclosed by Align in its Current Report on Form 8-K filed with the Securities and Exchange Commission on August 17, 2009.

The shares may not be resold except pursuant to an effective registration statement under the Securities Act of 1933, as amended (the "Securities Act") or an available exemption from registration under the Securities Act and applicable state securities laws.

A copy of the Settlement Agreement and the Stock Purchase Agreement are filed as an exhibit to this quarterly report on Form 10-Q.

The sale and issuance of the securities issued pursuant to the Stock Purchase Agreement was deemed to be exempt from registration under the Securities Act in reliance upon Section 4(2) of the Securities Act, or Rule 506 of Regulation D promulgated thereunder. Danaher represented its intentions to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the securities. The sales of the securities were made without general solicitation or advertising. Danaher was an accredited investor and had adequate access, through its relationship with us, to information about us.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

Not applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

(a) Exhibits:

| Exhibit Number | Description | Filing | Date | Exhibit Number | Filed herewith |
|---------------------------|--|---------------|-------------|---------------------------|-----------------------|
| 10.1† | Settlement Agreement dated as if August 16, 2009 between Align Technology, Inc. andOrmco Corporation. | | | | * |
| 10.2 | Stock Purchase Agreement dated as of the 16 th day of August by and between Align Technology, Inc. and DanaHER Corporation. | | | | * |
| 10.3† | Joint Development, Marketing and Sales Agreement entered in as of August 16, 2009 by and between Align Technology, Inc. and Ormco Corporation. | | | | * |
| 31.1 | Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. | | | | * |
| 31.2 | Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. | | | | * |
| 32.1 | Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. | | | | * |

† Portions of the exhibit have been omitted pursuant to a request for confidential treatment. The confidential portions have been filed with the SEC.

SIGNATURES

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 undersigned thereunto duly authorized.

Date: November 5, 2009

ALIGN TECHNOLOGY, INC.

By: /s/ THOMAS M. PRESCOTT

Thomas M. Prescott

President and Chief Executive Officer

By: /s/ KENNETH B. AROLA

Kenneth B. Arola

Chief Financial Officer and Vice President, Finance

EXHIBIT INDEX

| <u>Exhibit Number</u> | <u>Description</u> | <u>Filing</u> | <u>Date</u> | <u>Exhibit Number</u> | <u>Filed herewith</u> |
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† Portions of the exhibit have been omitted pursuant to a request for confidential treatment. The confidential portions have been filed with the SEC.

CONFIDENTIAL TREATMENT REQUESTED BY ALIGN TECHNOLOGY, INC.

SETTLEMENT AGREEMENT

dated as of August 16, 2009

between

ALIGN TECHNOLOGY, INC.,

and

ORMCO CORPORATION

[*] Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been filed separately with the Securities and Exchange Commission.

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LIST OF EXHIBITS

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|------------|--------------------------|
| Exhibit A: | Stock Purchase Agreement |
| Exhibit B: | Consent Judgment |

[*] Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been filed separately with the Securities and Exchange Commission.

SETTLEMENT AGREEMENT, dated as of August 16, 2009 (this “*Agreement*”), between Align Technology, Inc., a Delaware corporation (the “*Company*”), and Ormco Corporation, a Delaware Corporation (“*Ormco*”) (Ormco and the Company are the “*Parties*” and each individually a “*Party*”).

RECITALS:

- A. The Settlement. The Company and Ormco intend to settle, upon the terms and conditions set forth in this Agreement, the litigation involving Ormco Corporation, as Plaintiff and Counterdefendant, and the Company as Defendant and Counterclaimant, that is pending in the U.S. District Court for the Central District of California, Western Division, Case No. SACV 03-16 CAS (ANx) (such litigation, the “*Litigation*”), which Litigation involves, among other things, Ormco’s U.S. Patent Number 6,616,444 patent (such patent, the “*Patent*”).
- B. The Collaboration. Simultaneous with this Settlement Agreement, the Company and Ormco are entering into the Joint Development, Marketing and Sales Agreement (the “*Collaboration Agreement*”), under which Ormco and Company would jointly develop and market an orthodontic product offering that will involve the combination of removable aligners and orthodontic brackets with arch wires (the “*Collaboration*”).
- C. The Investment. In consideration for settling the Litigation, the Company is also issuing to an affiliate of Ormco, Danaher Corporation (the “*Investor*”), 7,586,489 shares of Common Stock, par value \$0.0001 per share, of the Company (“*Common Stock*”) (such amount, the “*Securities*”) on the terms and conditions set forth in the Stock Purchase Agreement attached hereto as Exhibit A (the “*Stock Purchase Agreement*”); provided, however, that the Company shall (upon the Investor’s election) pay the Investor the Make Whole HSR Cash Payment (as defined in the Stock Purchase Agreement) in lieu of issuing 2,025,000 Securities (the “*Second Closing Securities*”) in the event that the Second Closing Securities are not issued to the Investor due to the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act, as amended (the “*HSR Act*”), failing to terminate or expire by September 30, 2009 (the “*HSR Clearance Condition*” and such date as it may be extended by the Purchaser through February 28, 2010 until the Second Closing Securities are issued, the “*HSR Outside Date*”).
- D. The Cash Payment. In consideration for settling the Litigation, the Company is also paying Ormco \$13,148,866 in cash (the “*Base Company Cash Payment*”).
- E. Transaction Documents. The term “*Transaction Documents*” refers collectively to this Agreement and the Stock Purchase Agreement and any exhibits hereto and thereto.

NOW, THEREFORE, in consideration of the premises, and of the mutual promises, representations, warranties, covenants and agreements set forth herein, the adequacy and sufficiency of all of which are hereby acknowledged, the Parties agree as follows:

[*] Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been filed separately with the Securities and Exchange Commission.

ARTICLE I

Settlement

1.1 Settlement Payments and Consideration. In settlement of the Litigation:

(a) the Company is issuing to the Investor 7,586,489 Securities, as follows: 5,561,489 Securities on the business day following the execution of this Agreement (and the Company has issued instructions to its transfer agent to do so); and the Second Closing Securities at the Second Closing, in each case in accordance with the Stock Purchase Agreement; provided, however, that if the Second Closing Securities are not issued to the Investor by the HSR Outside Date because the HSR Clearance Condition is not fulfilled by that date, then (upon the Investor's election), in lieu of issuing to the Investor the Second Closing Securities, the Company shall pay to the Investor the Make Whole HSR Cash Payment on the second business day immediately following Purchaser's election after the HSR Outside Date by wire transfer of immediately available United States funds to a bank account designated by the Investor (such Make Whole HSR Cash Payment to be paid to the Purchaser at Purchaser's election on March 1, 2010 if the Second Closing Securities have not been issued to the Investor by February 28, 2010, for any reason); and

(b) the Company will pay to Ormco on the first business day immediately following the execution of this Agreement the Base Company Cash Payment by wire transfer of immediately available United States funds to a bank account previously designated by Ormco.

1.2 Undertakings Concerning the Litigation. Upon execution of this Agreement and the Stock Purchase Agreement, the Company and Ormco shall promptly sign the Consent Judgment attached hereto as Exhibit B and submit it to the Court.

1.3 Acknowledgment. The Parties have agreed, without admitting any liability of any kind beyond the Company and its affiliates acknowledging and accepting in every respect the findings, verdicts, judgments, rulings and orders in the Litigation, including but not limited to the judgment entered by the Court in the Consent Judgment (all of which the Company and its affiliates hereby so acknowledge and accept), to enter into this Agreement pursuant to which each and every claim and/or cause of action, known or unknown, that was or could have been asserted by the Parties in the Litigation with respect to the Patent will be forever and finally released.

1.4 Ormco Release and Covenant not to Assert. Upon execution of this Agreement and the Stock Purchase Agreement by the Parties, Investor, Ormco and their affiliates hereby fully, finally and forever settle and release the Company and its affiliates from any and all past and future claims for infringement, including any and all alleged past damages, based on the Company's or its affiliates' activities from September 9, 2003 through expiration of the '444 patent. This shall finally settle and resolve all claims asserted against the Company and its affiliates from any and all claims, demands, damages or liability of any nature whatsoever, known or unknown, which Investor, Ormco or their affiliates have or may have which arise out

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of, concern or relate in any way to the '444 patent. Investor, Ormco and their affiliates further hereby expressly waive any and all rights under Section 1542 of the California Civil Code, which states:

A GENERAL RELEASE DOES NOT EXTEND TO CLAIMS WHICH THE CREDITOR DOES NOT KNOW OR SUSPECT TO EXIST IN HIS OR HER FAVOR AT THE TIME OF EXECUTING THE RELEASE, WHICH IF KNOWN BY HIM OR HER MUST HAVE MATERIALLY AFFECTED HIS OR HER SETTLEMENT WITH THE DEBTOR.

Ormco expressly agrees and understands that this Agreement shall apply to all unknown, unsuspected and unanticipated claims, injuries and damages as well as those that are now disclosed, in each case, solely with respect to the Patent.

Ormco and its current affiliates hereby covenant that, with respect to the Company's current products and processes (including any enhancements), they will not, anywhere in the world, initiate or cause to be initiated against the Company or any current affiliates of the Company any claim of infringement of any claim in any patent owned or controlled by Ormco or any of its current affiliates and existing as of the effective date of this Agreement, or that issues from any patent application having a filing date, or claiming priority to any patent application having a filing date with the applicable government authority, no later than the effective date of this Agreement, solely with respect to any activities relating to removable dental aligners and/or processes for making removable dental aligners, including attachments, buttons and similar auxiliaries for use in connection with the removable dental aligners (and for the avoidance of doubt not to include any activities relating to non-removable appliances) .

1.5 Company Release and Covenant not to Assert . Upon execution of this Agreement and the Stock Purchase Agreement , the Company and its affiliates hereby fully, finally and forever settle and release Ormco and it affiliates from any and all past and future claims that Claims 37, 38, 39, 40, and 69 of the Patent are not infringed by the Company, that Claims 37, 38, 39, 40, 45 and 69 of the Patent are invalid, and that the Patent is unenforceable and waive any right to appeal from or contest in any way, in or before any court, arbitrator or other tribunal in any jurisdiction, any of the findings, judgments, rulings or orders made by the Court in the Litigation, including but not limited to the judgment entered by the Court in the Consent Judgment. The Company further agrees to not assist others in challenging the enforceability of the Patent, defending against a claim of infringement with respect to one or more claims of the Patent, challenging the validity of Claims 37, 38, 39, 40, 45 or 69 of the '444 patent and subjecting the Patent to any re-examination proceeding in the United States Patent and Trademark Office and to cease and withdraw any such challenges previously made or other assistance previously provided.

The Company and its affiliates further hereby expressly waive any and all rights under Section 1542 of the California Civil Code, which states:

A GENERAL RELEASE DOES NOT EXTEND TO CLAIMS WHICH THE CREDITOR DOES NOT KNOW OR SUSPECT TO EXIST IN HIS OR HER FAVOR AT THE TIME OF EXECUTING THE RELEASE, WHICH IF KNOWN

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BY HIM OR HER MUST HAVE MATERIALLY AFFECTED HIS OR HER SETTLEMENT WITH THE DEBTOR.

The Company expressly agrees and understands that this Agreement shall apply to all unknown, unsuspected and unanticipated claims, injuries and damages as well as those that are now disclosed, in each case, solely with respect to the Patent.

The Company and its current affiliates hereby covenant that they will not, anywhere in the world, initiate or cause to be initiated against Ormco or any current affiliates of Ormco any claim of infringement of any patent owned or controlled by the Company or any of its current affiliates and existing as of the effective date of this Agreement, or that issues from any patent application having a filing date, or claiming priority to any patent application having a filing date, with the applicable government authority no later than the effective date of this Agreement, for any activities relating to those products currently being manufactured and/or sold by Ormco or any of its current affiliates including any enhancements to those products; provided, however, that any removable aligner products are created without using a computer or other digital means to create the physical model of the teeth on which the aligners are formed.

The Company shall withdraw from prosecution the claims contained in the Preliminary Amendment filed by the Company on [*] with the United States Patent and Trademark Office (“USPTO”) for U.S. Patent Application No. [*] and shall not, at anytime in the future, re-submit for prosecution any claims that are not patentably distinct from those claims. Further the Company supports and will not contest Ormco’s claim of priority in inventing the subject matter being claimed by Ormco in those claims in U.S. Patent Application No. [*] that are recited in a filing submitted by Ormco to the USPTO on [*] (the “[*] claims”) and will cooperate with Ormco in any proceeding in which a third party alleges that Ormco was not [*] claims based upon the Company’s withdrawn [*].

The Company shall withdraw from prosecution the claims contained in the Preliminary Amendment filed by the Company on [*] with the United States Patent and Trademark Office (“USPTO”) for U.S. Patent Application No. [*] and shall not, at anytime in the future, re-submit for prosecution any claims that are not patentably distinct from those claims. Further the Company supports and will not contest Ormco’s claim of priority in inventing the subject matter being claimed by Ormco in those claims in U.S. Patent Application No. [*] that are recited in a filing submitted by Ormco to the USPTO on [*] (the “[*] claims”) and will cooperate with Ormco in any proceeding in which a third party alleges that Ormco was not [*] claims based upon the Company’s withdrawn [*].

1.6 Announcement of Settlement and Public Disclosures. Immediately following the execution and delivery of this Agreement, Ormco and the Company shall issue separate press releases announcing the execution of this Agreement, which press releases shall be subject to the prior review and approval of the each Party. Subject to each Party’s disclosure obligations imposed by law or regulation or stock exchange rule or trading market listing requirement, Ormco and the Company will cooperate with each other in the development and distribution of all news releases and other public information disclosures with respect to this Agreement and any of the transactions contemplated by this Agreement or the other Transaction Documents and the Collaboration Agreement, and no Party will make any such news release or

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public disclosure without first consulting with the other Parties and receiving their consent (which shall not be unreasonably withheld, conditioned or delayed), and each of Ormco and the Company shall coordinate with the other Parties with respect to any such news release or public disclosure and use reasonable best efforts to obtain confidential treatment with respect to any commercially-sensitive information required by law or regulation or stock exchange rule or trading market listing requirement to be disclosed. The Investor and the Company agree to keep strictly confidential and not to disclose to any person other than their representatives the terms of this Agreement, and all such other commercially-sensitive information designated by a Party as such and to cooperate in seeking confidential treatment for any such information or other documentation required by law or regulation to be filed with the Securities and Exchange Commission or other governmental entity.

1.7 Cooperation; Filings; Other Actions. Each of Investor and the Company shall cooperate and consult with the other and use reasonable best efforts to implement the Settlement and the transactions contemplated by this Agreement and the other Transaction Documents and the Collaboration Agreement, to prepare and file all necessary documentation, to effect all necessary applications, notices, petitions, filings and other documents, and to obtain all necessary permits, consents, orders, approvals and authorizations of, or any exemption by, all third parties and governmental entities, and expiration or termination of any applicable waiting periods, necessary or advisable to implement the Settlement and consummate the transactions contemplated by this Agreement and the other Transaction Documents and the Collaboration Agreement, and to perform their covenants contemplated by this Agreement and the other Transaction Documents and the Collaboration Agreement. Each of the Investor and the Company agrees to keep the other Parties apprised of the status of matters relating to completion of the transactions contemplated hereby.

1.8 Representations and Warranties of the Parties. Each of the Parties acknowledges, agrees, represents and warrants to the other Parties that:

(a) It has not heretofore assigned or transferred, or purported to assign or transfer, to any person or entity any claim or cause of action with respect to the Litigation or the '444 patent and each Party further covenants not to make any such assignment or transfer;

(b) There are no liens or claims of lien, or assignments in law or equity or otherwise, of or against any claim or cause of action with respect to the Litigation;

(c) It has been represented by legal counsel in the negotiation and joint preparation of this Agreement, has received advice from legal counsel in connection with this Agreement and is fully aware of this Agreement's provisions and legal effect; and

(d) It enters into this Agreement freely, without coercion, and based on its own judgment and not in reliance upon any representations or promises made by any other Party, apart from those set forth in this Agreement.

(e) It has the corporate power and authority to enter into or issue this Agreement and the other Transaction Documents and the Collaboration Agreement and to carry out its obligations hereunder and thereunder.

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(f) The execution, delivery and performance of this Agreement and the other Transaction Documents and the Collaboration Agreement by such Party, the implementation of the Settlement and the consummation of the transactions contemplated hereby and thereby have been duly authorized by such Party.

(g) This Agreement and the other Transaction Documents and the Collaboration Agreement have been duly and validly executed and delivered by such Party, and, assuming due authorization, execution and delivery of the same by the other Parties, constitute valid and binding obligations of such Party enforceable against it by the other Parties in accordance with their respective terms.

1.9 Expenses. Each Party shall bear its own fees and costs incurred in connection with the Litigation or this Agreement.

ARTICLE II

Miscellaneous

2.1 Amendment. No amendment or waiver of this Agreement will be effective with respect to any Party unless made in writing and signed by an officer of a duly authorized representative of such Party.

2.2 Waivers. No failure or delay by any Party in exercising any right, power or privilege hereunder shall operate as a waiver thereof nor shall any single or partial exercise thereof preclude any other or further exercise thereof or the exercise of any other right, power or privilege. The conditions to each Party's obligation to consummate the transactions contemplated hereby are for the sole benefit of such Party and may be waived by such Party in whole or in part to the extent permitted by applicable law. No waiver of any Party to this Agreement will be effective unless it is in a writing signed by a duly authorized officer of the waiving Party that makes express reference to the provision or provisions subject to such waiver.

2.3 Counterparts and Facsimile. For the convenience of the Parties hereto, this Agreement may be executed in any number of separate counterparts, each such counterpart being deemed to be an original instrument, and all such counterparts will together constitute the same agreement. Executed signature pages to this Agreement may be delivered by facsimile and such facsimiles will be deemed as sufficient as if actual signature pages had been delivered.

2.4 Governing Law and Forum. This Agreement will be governed by and construed in accordance with the laws of the State of Delaware applicable to contracts made and to be performed entirely within such State. The Parties hereby irrevocably and unconditionally consent to submit to the exclusive jurisdiction of the U.S. District Court for the Central District of California, Western Division for any actions, suits or proceedings arising out of or relating to this Agreement and the transactions contemplated hereby.

2.5 **WAIVER OF JURY TRIAL**. **EACH OF THE PARTIES HERETO HEREBY IRREVOCABLY WAIVES ANY AND ALL RIGHT TO TRIAL BY JURY IN ANY LEGAL PROCEEDING ARISING OUT OF OR RELATED TO THIS AGREEMENT OR THE TRANSACTIONS CONTEMPLATED HEREBY, EXCEPT**

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WITH RESPECT TO ENFORCING ANY PATENTS TO THE EXTENT THIS AGREEMENT IS BREACHED OR NO LONGER IN EFFECT.

2.6 Notices. Any notice, request, instruction or other document to be given hereunder by any Party to the other will be in writing and will be deemed to have been duly given (a) on the date of delivery if delivered personally or by telecopy or facsimile, upon confirmation of receipt, (b) on the first business day following the date of dispatch if delivered by a recognized next-day courier service, or (c) on the third business day following the date of mailing if delivered by registered or certified mail, return receipt requested, postage prepaid. All notices hereunder shall be delivered as set forth below, or pursuant to such other instructions as may be designated in writing by the Party to receive such notice.

- (a) All correspondence to the Company shall be addressed as follows:

Align Technology, Inc.
881 Martin Avenue
Santa Clara, CA 95050
Attention: Roger E. George
Vice President, General Affairs and General Counsel
Telecopy: 408-470-1010

with copies to (which copies alone shall not constitute notice):

Wilson Sonsini Goodrich & Rosati
650 Page Mill Road
Palo Alto, CA 94304
Attention: Chris F. Fennell
Telecopy: 650-493-6811

- (b) All correspondence to Ormco shall be addressed as follows:

In care of Danaher Corporation
2099 Pennsylvania Avenue, NW
Washington, DC 20006
Attention: Jonathan P. Graham
Senior Vice President and General Counsel
Telecopy: 202-828-0860

with copies to (which copies alone shall not constitute notice):

Wachtell, Lipton, Rosen & Katz
51 West 52nd Street
New York, NY 10019
Attention: Trevor S. Norwitz
Telecopy: 212-403-2333

[*] Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been filed separately with the Securities and Exchange Commission.

2.7 Entire Agreement. This Agreement, together with the other Transaction Documents and the Collaboration Agreement and the non-disclosure letter entered into among Ormco, the Investor and the Company on August 9, 2009, represents the entire agreement between the Parties concerning the subject matter hereof and supersedes all prior written or oral negotiations, representations and agreements with respect thereto. No Party is relying on any statement or representation other than as explicitly stated in this Agreement or the other Transaction Documents or the Collaboration Agreement.

2.8 Assignment. This Agreement shall be binding upon and inure to the benefit of the Parties and their respective successors and permitted assigns. This Agreement shall not be assignable except by operation of law or by mutual written consent of the Parties. Any assignment in derogation of this provision shall be null and void. The Transaction Documents and the Collaboration Agreement shall be assignable in accordance with the terms set forth therein.

2.9 Other Definitions. Wherever required by the context of this Agreement, the singular shall include the plural and vice versa, and the masculine gender shall include the feminine and neuter genders and vice versa, and references to any agreement, document or instrument shall be deemed to refer to such agreement, document or instrument as amended, supplemented or modified from time to time. All article, section, paragraph or clause references not attributed to a particular document shall be references to such parts of this Agreement, and all exhibit, annex and schedule references not attributed to a particular document shall be references to such exhibits, annexes and schedules to this Agreement. When used herein:

- (1) the terms “*herein*,” “*hereof*” and “*hereunder*” and other words of similar import refer to this Agreement as a whole and not to any particular section, paragraph or subdivision;
- (2) the word “*or*” is not exclusive; and
- (3) the words “*including*,” “*includes*,” “*included*” and “*include*” are deemed to be followed by the words “*without limitation*”.

2.10 Captions. The article, section, paragraph and clause captions herein are for convenience of reference only, do not constitute part of this Agreement and will not be deemed to limit or otherwise affect any of the provisions hereof.

2.11 Severability. If any provision of this Agreement or the application thereof to any person (including, the officers and directors of the Investor and the Company) or circumstance is determined by a court of competent jurisdiction to be invalid, void or unenforceable, the remaining provisions hereof, or the application of such provision to persons or circumstances other than those as to which it has been held invalid or unenforceable, will remain in full force and effect and shall in no way be affected, impaired or invalidated thereby, so long as the economic or legal substance of the transactions contemplated hereby is not affected in any manner materially adverse to any Party. Upon such determination, the Parties shall negotiate in good faith in an effort to agree upon a suitable and equitable substitute provision to effect the original intent of the Parties.

[*] Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been filed separately with the Securities and Exchange Commission.

2.12 No Third Party Beneficiaries. Nothing contained in this Agreement, expressed or implied, is intended to or shall confer upon any person other than the Parties hereto, any benefit right or remedies.

2.13 Time of Essence. Time is of the essence in the performance of each and every term of this Agreement.

2.14 Specific Performance. The Parties agree that irreparable damage would occur in the event that any of the provisions of this Agreement were not performed in accordance with their specific terms. It is accordingly agreed that the Parties shall be entitled to specific performance of the terms hereof (without requirement to post a bond), this being in addition to any other remedies to which they are entitled at law or equity.

* * *

[*] Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been filed separately with the Securities and Exchange Commission.

IN WITNESS WHEREOF , this Agreement has been duly executed and delivered by the duly authorized officers of the Parties hereto as of the date first herein above written.

ALIGN TECHNOLOGY, INC.

By: /s/ Thomas M. Prescott
Name: Thomas M. Prescott
Title: President & CEO

ORMCO CORPORATION

By: /s/ Donald L. Tuttle
Name: Donald L. Tuttle
Title: President

[*Signature Page to Settlement Agreement*]

[*] Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been filed separately with the Securities and Exchange Commission.

EXHIBIT A-STOCK PURCHASE AGREEMENT

Incorporated by reference to Exhibit 10.2 of the registrant's Quarterly Report on Form 10-Q filed on November 5, 2009.

[*] Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been filed separately with the Securities and Exchange Commission.

EXHIBIT B – CONSENT JUDGMENT

THOMAS P. LAMBERT (SBN 050952)
tpl @ msk.com
KARIN G. PAGNANELLI (SBN 174763)
kgp @ msk.com
MITCHELL SILBERBERG & KNUPP LLP
11377 West Olympic Boulevard
Los Angeles, CA 90064-1683
Telephone: (310) 312-2000
Facsimile: (310) 312-3100

CHRISTOPHER B. MEAD *pro hac vice*
LONDON & MEAD
1225 19th Street NW, Suite 320
Washington, DC 20036
Telephone: (202) 331-3334
Facsimile: (202) 785-4280

DAVID L. DEBRUIN *pro hac vice*
RICHARD MARSCHALL *pro hac vice*
CHARLES J. CRUEGER *pro hac vice*
JOSEPH T. MIOTKE *pro hac vice*
MICHAEL BEST & FRIEDRICH LLP
100 East Wisconsin Avenue
Suite 3300
Milwaukee, WI 53202-4108
Telephone: (414) 271-6560
Facsimile: (414) 277-0656

Attorneys for Plaintiff
ORMCO CORPORATION

DANIEL J. FURNISS (SBN 73531)
djfurniss @ townsend.com
ANNE M. ROGASKI (SBN 184754)
amrogaski @ townsend.com
TOWNSEND TOWNSEND AND CREW LLP
379 Lytton Avenue
Palo Alto, CA 94301
Telephone: (650) 326-2400
Facsimile: (650) 326-2422

Attorneys for Defendant
ALIGN TECHNOLOGY, INC.

NITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

ORMCO CORPORATION,
Plaintiff,
v.
ALIGN TECHNOLOGY, INC.,
Defendant.
AND RELATED COUNTERCLAIMS

CASE NO. SACV 03-16 CAS (ANx)
The Honorable Christina A. Snyder
CONSENT JUDGMENT
CTRM.: 5

[*] Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission.
Omitted portions have been filed separately with the Securities and Exchange Commission.

This Consent Judgment is entered into between and among Ormco Corporation, (“Ormco”), and Align Technology, Inc. (“Align”) (collectively, the “Parties”), through their respective counsel of record.

This action comes before the Court on the pleadings and proceedings of record and it has been represented to the Court that, pursuant to a Settlement Agreement, Ormco and Align have agreed to a settlement of all issues remaining for trial or otherwise the subject of pending motions and Align has waived any right to appeal any of the findings, judgments, rulings or orders entered by the Court in this action.

WHEREFORE, with the consent of Ormco and Align, through their undersigned attorneys, it is hereby finally ORDERED, ADJUDGED and DECREED as follows:

1. This Court has personal jurisdiction over the Parties and the subject matter of this action, including the enforcement of the Settlement Agreement entered among the Parties.
2. Claims 37, 38, 39, 40 and 69 of Ormco’s U.S. Patent No. 6,616,444 are infringed by Align.
3. Claims 37, 38, 39, 40, 45 and 69 of Ormco’s U.S. Patent No. 6,616,444 are not invalid.
4. Ormco’s U.S. Patent No. 6,616,444 are not unenforceable.

[*] Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been filed separately with the Securities and Exchange Commission.

5. Pursuant to the terms and conditions of the Settlement Agreement entered between Ormco and Align, the issues of damages, willfulness and attorneys' fees as they relate to Ormco's allegations of infringement of its patents have been fully settled and all remaining allegations that were made or could have been made by Ormco in Case No. SACV 03-16 CAS (ANx) are hereby dismissed with prejudice.

6. Ormco's pending Motion for a Permanent Injunction is hereby denied as moot.

7. All defenses and counterclaims that were made or could have been made by Align in Case No. SACV 03-16 CAS (ANx) are hereby dismissed with prejudice.

8. Except as set forth in the Parties' Settlement Agreement, each party shall bear its own costs and attorneys' fees.

SO Ordered:

DATED: _____

The Honorable Christina A. Snyder
United States District Judge

[*] Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been filed separately with the Securities and Exchange Commission.

Stipulated to by:

Dated: August , 2009

MICHAEL BEST & FRIEDRICH LLP

By: _____

David L. De Bruin
Richard H. Marschall
Charles J. Crueger
Joseph T. Miotke
-and-
Christopher B. Mead
-and-
Thomas P. Lambert
Karin G. Pagnanelli

Attorneys for Plaintiff
ORMCO CORPORATION

Dated: August , 2009

TOWNSEND AND TOWNSEND AND CREW LLP

By: _____

Anne M. Rogaski
Daniel J. Furniss
Jon V. Swenson
Heidi J. Kim

Attorneys for Defendant
ALIGN TECHNOLOGY

[*] Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission.
Omitted portions have been filed separately with the Securities and Exchange Commission

STOCK PURCHASE AGREEMENT

This STOCK PURCHASE AGREEMENT (this “Agreement”) is dated as of the 16th day of August, 2009 by and between Align Technology, Inc., a Delaware corporation with its principal office located at 881 Martin Avenue, Santa Clara, CA 95050 (the “Company”), and Danaher Corporation, a Delaware corporation with its principal office located at 2099 Pennsylvania Avenue, NW, Washington, DC 20006 (the “Purchaser”).

WHEREAS, the Company and Ormco Corporation (“Ormco”) have entered into the Settlement Agreement dated as of even date herewith (the “Settlement Agreement”);

WHEREAS, pursuant to Section 1.1(a) of the Settlement Agreement, the Company desires to issue and sell to the Purchaser 7,586,489 fully paid, and nonassessable shares (the “Shares”) of the authorized but unissued shares of common stock, \$0.0001 par value per share, of the Company (the “Common Stock”) on the terms and subject to the conditions set forth in this Agreement;

WHEREAS, in light of the HSR Clearance Condition (all capitalized terms used herein but not defined herein have the meaning given to them in the Settlement Agreement), the Company and the Purchaser desire to issue the Shares in two closings, with 5,561,489 fully paid and non-assessable shares of Common Stock (the “Initial Shares”) issued to the Purchaser simultaneously with the execution and delivery of this Agreement at the First Closing and the balance of the Shares, 2,025,000 fully paid and non-assessable shares of Common Stock (the “Second Closing Shares”) issued to the Purchaser at the Second Closing; *provided, however*, that if the HSR Clearance Condition is not met by the HSR Outside Date, the Company shall (at the election of the Purchaser delivered to the Company in writing) pay the Purchaser an amount equal to the number of Second Closing Shares multiplied by the average of the closing prices of the Common Stock of the Company for the last 10 trading days prior to the Purchaser’s election (the “Make-Whole HSR Cash Payment”) on the first business day following the HSR Outside Date; and

WHEREAS, the Company and the Purchaser desire, in connection with the consummation of the several transactions contemplated by the Settlement Agreement, to make certain covenants and agreements with one another pursuant to this Agreement.

NOW THEREFORE, in consideration of the mutual agreements, representations, warranties and covenants herein contained, the parties hereto agree as follows:

1. Definitions. As used in this Agreement, the following terms shall have the following respective meanings:

1.1 “Affiliate” of a party means any corporation or other business entity controlled by, controlling or under common control with such party. For purposes of this definition, “*control*” (including, with correlative meanings, the terms “*controlled by*” and “*under common control with*”) when used with respect to any person, means the possession, directly or

indirectly, of the power to cause the direction of management and/or policies of such person, whether through the ownership of voting securities by contract or otherwise, including without limitation the direct or indirect beneficial ownership of fifty percent (50%) or more of the voting or income interest in such corporation or other business entity.

1.2 “Change in Control” means any of the following: (i) a merger, consolidation, statutory share exchange or other business combination or transaction involving the Company where the existing stockholders of the Company immediately prior to the effective date of such merger, consolidation or other business combination or transaction own less than 50% of the total voting securities of the surviving corporation following such merger, consolidation or other business combination or transaction in equivalent proportions to their interests prior to such effective date; (ii) any person or 13D Group becomes a beneficial owner, directly or indirectly, of 50% or more of the aggregate number of the voting securities of the Company or of properties or assets constituting 50% or more of the consolidated assets of the Company and its subsidiaries; (iii) in any case not covered by (ii), the Company issues securities representing 50% or more of its total voting power, including by way of a merger or other business combination with the Company or any of its subsidiaries; or (iii) a sale of all or substantially all the assets of the Company.

1.3 “Effective Date” means the date that the Registration Statement is first declared effective by the SEC.

1.4 “Exchange Act” means the Securities Exchange Act of 1934, as amended, and all of the rules and regulations promulgated thereunder.

1.5 “Holder” means the Purchaser and any other holder of Registrable Securities to whom the registration rights conferred by this Agreement have been transferred in compliance with Section 9.11 hereof.

1.6 “Losses” means any and all losses, claims, damages, liabilities, settlement costs and expenses, including, without limitation, reasonable attorneys’ fees.

1.7 “Proceeding” means an action, claim, suit, investigation or proceeding (including, without limitation, a partial proceeding, such as a deposition), whether commenced or threatened in writing.

1.8 “Prospectus” means the prospectus included in the Registration Statement (including, without limitation, a prospectus that includes any information previously omitted from a prospectus filed as part of an effective registration statement in reliance upon Rule 430A, 430B or Rule 430C promulgated under the Securities Act), as amended or supplemented by any prospectus supplement, with respect to the terms of the offering of any portion of the Registrable Securities covered by the Registration Statement, and all other amendments and supplements to the Prospectus including post-effective amendments, and all material incorporated by reference or deemed to be incorporated by reference in such Prospectus.

1.9 “Purchaser Controlled Corporation” shall mean a corporation of which the Purchaser owns not less than 50% of the outstanding voting power entitled to vote in the election of directors of such corporation.

1.10 “Registrable Securities” means the Shares, together with any securities issued or issuable upon any stock split, dividend or other distribution, recapitalization or similar event with respect to the foregoing.

1.11 “Registration Statement” means each registration statement required to be filed under Section 7, including (in each case) the Prospectus, amendments and supplements to such registration statement or Prospectus, including pre- and post-effective amendments, all exhibits thereto, and all material incorporated by reference or deemed to be incorporated by reference in such registration statement.

1.12 “SEC” means the Securities and Exchange Commission.

1.13 “Second Closing Date” means the date of the Second Closing.

1.14 “Securities Act” means the Securities Act of 1933, as amended, and all of the rules and regulations promulgated thereunder.

1.15 “Trading Market” means The Nasdaq Global Select Market or any other national securities exchange, market or trading or quotation facility on which the Common Stock is then listed or quoted.

1.16 “13D Group” means any group of persons formed for the purpose of acquiring, holding, voting or disposing of voting securities which would be required under Section 13(d) of the Exchange Act, and the rules and regulations promulgated thereunder, to file a statement on Schedule 13D pursuant to Rule 13d-1(a) or a Schedule 13G pursuant to Rule 13d-1(c) with the SEC as a “person” within the meaning of Section 13(d)(3) of the Exchange Act if such group beneficially owned voting securities of the Company representing more than 5% of any class of voting securities then outstanding.

2. Purchase and Sale of Shares.

2.1 Purchase and Sale. Subject to and upon the terms and conditions set forth in this Agreement, the Company agrees to issue and sell the Shares to the Purchaser at the Closings. The Shares are being issued to the Purchaser in consideration of Purchaser’s obligations under the Settlement Agreement and the transactions contemplated thereby. Therefore, no payment of cash or other form of consideration is owing by the Purchaser at the Closings (as defined below).

2.2 Closing. The closings of the transactions contemplated under this Agreement (the “Closings”) shall take place at the offices of Wilson Sonsini Goodrich & Rosati, 650 Page Mill Road, Palo Alto, California 94304-1050. The first closing (the “First Closing”) shall take place simultaneously with the execution and delivery of this Agreement. The second closing (the “Second Closing”) shall take place on the second business day after all of the conditions precedent set forth in Section 5 have been satisfied in full or at such other location, date and time as may be agreed upon between the Purchaser and the Company. At the First Closing, the Company shall deliver to the Purchaser a single stock certificate, registered in the name of the Purchaser, representing the Initial Shares. At the Second Closing, the Company shall deliver to the Purchaser a single stock certificate, registered in the name of the Purchaser, representing the Second Closing Shares; *provided, however*, that if the HSR Clearance Condition is not met by

the HSR Outside Date, the Company shall (at the election of the Purchaser delivered to the Company in writing) pay to the Purchaser the Make-Whole HSR Cash Payment on the first business day immediately following such date. Wilson Sonsini Goodrich & Rosati shall hold any such stock certificates in escrow for Purchaser until delivered to Purchaser or one of Purchaser's designees.

2.3 Second Closing Adjustments. In the event that, at or prior to the Second Closing, (i) the number of shares of Common Stock or securities convertible or exchangeable into or exercisable for shares of Common Stock issued and outstanding is changed as a result of any reclassification, stock split (including reverse split), stock dividend or distribution (including any dividend or distribution of securities convertible or exchangeable into or exercisable for shares of Common Stock), merger, tender or exchange offer or other similar transaction, or (ii) the Company fixes a record date that is at or prior to the Second Closing Date for the payment of any non-stock dividend or distribution on the Common Stock, then at the Purchaser's option, which may be exercised in the Purchaser's sole discretion, the number of shares of Common Stock to be issued to the Purchaser at the Second Closing under this Agreement shall be equitably adjusted and/or the shares of Common Stock to be issued to the Purchaser at the Second Closing under this Agreement shall be equitably substituted with shares of other stock or securities or property (including cash), in each case, to provide the Purchaser with substantially the same economic benefit from this Agreement as the Purchaser had prior to the applicable transaction. Notwithstanding anything in this Agreement to the contrary, in no event shall the Purchaser be required to make any payment by virtue of the foregoing.

3. Representations and Warranties of the Company. Except as set forth in the Company's Form 10-K for the fiscal year ended December 31, 2008 subsequent quarterly reports on Form 10-Q and subsequent current reports on Form 8-K, each as publicly filed and available prior to the date hereof (excluding any risk factor disclosures contained in such documents under the heading "Risk Factors" and any disclosure of risks, uncertainties or contingencies included in any "forward-looking statements" disclaimer or other statements that are non-specific or are predictive or forward-looking in nature) (such Form 10-K, Form 10-Qs and Form 8-Ks, the "Current SEC Reports") and in the Schedules attached hereto, the Company hereby represents and warrants to the Purchaser as follows:

3.1 Organization and Qualification. The Company is an entity duly organized, validly existing and in good standing under the laws of the jurisdiction of its incorporation or organization (as applicable), with the requisite corporate authority to own and use its properties and assets and to carry on its business as currently conducted. The Company is not in violation of any of the provisions of its certificate of incorporation, bylaws or other organizational or charter documents. The Company is duly qualified to do business and is in good standing as a foreign corporation or other entity in each jurisdiction in which the nature of the business conducted or property owned by it makes such qualification necessary, except where the failure to be so qualified or in good standing, as the case may be, could not, individually or in the aggregate, (i) materially and adversely affect the legality, validity or enforceability of any Transaction Document, (ii) have or result in a material adverse effect on the results of operations, assets, liabilities, business or financial condition of the Company and its subsidiaries, taken as a whole on a consolidated basis, or (iii) materially and adversely impair the Company's ability to

perform fully on a timely basis its obligations under any of the Transaction Documents (any of (i), (ii) or (iii), a “ Material Adverse Effect ”).

3.2 Capitalization . As of August 12, 2009, the authorized capital stock of the Company consists of (i) 200,000,000 shares of Common Stock, of which 66,678,118 shares are outstanding and (ii) 5,000,000 shares of preferred stock, of which no shares are outstanding. As of August 12, 2009, except with respect to the 8,755,192 shares of Common Stock subject to outstanding options or awards made under the Company’s 2005 Incentive Plan, 2001 Equity Incentive Plan and 1997 Equity Incentive Plan, 3,714,487 shares of which will be, as of January 31, 2010, subject to vested awards or vested options with exercise prices below \$14.00 per share, in each case based upon the terms and conditions of such options or awards as they existed on August 12, 2009, there are no existing options, warrants, calls, preemptive (or similar) rights, subscriptions or other rights, agreements, arrangements or commitments of any character obligating the Company to issue, transfer or sell, or cause to be issued, transferred or sold, any shares of the capital stock of the Company or other equity interests in the Company or any securities convertible into or exchangeable for such shares of capital stock or other equity interests, and there are no outstanding contractual obligations of the Company to repurchase, redeem or otherwise acquire any shares of its capital stock or other equity interests. Between August 12, 2009 and the date hereof, the Company has not issued any equity securities except through employee or director stock option exercises in the ordinary course.

3.3 Authorization; Enforcement . The Company has the requisite corporate authority to enter into and to consummate the transactions contemplated by this Agreement, the Settlement Agreement and the Joint Development, Marketing and Sales Agreement dated as of the date hereof between the Company and Ormco (the “ Collaboration Agreement ” and together with the Agreement and the Settlement Agreement, the “ Transaction Documents ”) and otherwise to carry out its obligations hereunder and thereunder. The execution and delivery of the Transaction Documents by the Company and the consummation by it of the transactions contemplated hereby and thereby have been duly authorized by all necessary corporate action on the part of the Company and no further consent or action is required by the Company, its Board of Directors or its stockholders. Each of the Transaction Documents is duly executed by the Company and is, or when delivered in accordance with the terms hereof and thereof, will constitute, the valid and binding obligation of the Company enforceable against the Company in accordance with its terms, except as may be limited by (i) applicable bankruptcy, insolvency, reorganization or other laws of general application relating to or affecting the enforcement of creditors rights generally, and (ii) the effect of rules of law governing the availability of specific performance and other equitable remedies.

3.4 No Conflicts . The execution, delivery and performance of the Transaction Documents by the Company and the consummation by the Company of the transactions contemplated hereby and thereby do not, and will not, (i) conflict with or violate any provision of the Company’s certificate of incorporation, bylaws or other organizational or charter documents, (ii) conflict with, or constitute a material default (or an event that with notice or lapse of time or both would become a default) under, or give to others any rights of termination, amendment, acceleration or cancellation (with or without notice, lapse of time or both) of, any material credit facility or debt instrument to which the Company is a party, or (iii) result in a material violation

of any agreement or instrument, permit, franchise, license, judgment, order, statute, law, ordinance, rule or regulations, applicable to the Company or its properties or assets.

3.5 Valid Issuance of the Shares. The Shares are duly authorized and, when issued in accordance with this Agreement, will be duly and validly issued, fully paid and nonassessable, free and clear of all liens and shall not be subject to preemptive or similar rights of stockholders.

3.6 SEC Reports; Financial Statements.

(a) Since January 1, 2008, the Company has filed on a timely basis all reports required to be filed by it under the Exchange Act, including pursuant to Section 13(a) or 15(d) thereof. Such reports required to be filed by the Company under the Exchange Act, including pursuant to Section 13(a) or 15(d) thereof, together with any materials filed or furnished by the Company under the Exchange Act, whether or not any such reports were required being collectively referred to herein as the “SEC Reports”. As of their respective dates, the SEC Reports filed by the Company complied in all material respects with the requirements of the Securities Act and the Exchange Act and the rules and regulations of the SEC promulgated thereunder, and none of the SEC Reports, when filed by the Company, contained any untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading. The financial statements of the Company included in the SEC Reports comply in all material respects with applicable accounting requirements and the rules and regulations of the SEC with respect thereto as in effect at the time of filing. Such financial statements have been prepared in accordance with United States generally accepted accounting principles applied on a consistent basis during the periods involved (“GAAP”), except as may be otherwise specified in such financial statements, the notes thereto and except that unaudited financial statements may not contain all footnotes required by GAAP or may be condensed or summary statements, and fairly present in all material respects the consolidated financial position of the Company and its consolidated subsidiaries as of and for the dates thereof and the results of operations and cash flows for the periods then ended, subject, in the case of unaudited statements, to normal, year-end audit adjustments. All material agreements to which the Company or any subsidiary is a party or to which the property or assets of the Company or any subsidiary are subject are included as part of or identified in the SEC Reports, to the extent such agreements are required to be included or identified pursuant to the rules and regulations of the SEC.

(b) Since January 1, 2009, except as disclosed in Schedule 3.6(b) hereto, (i) there has been no event, occurrence or development that, individually or in the aggregate, has had or that would result in a Material Adverse Effect on the Company, (ii) the Company has not incurred any material liabilities other than (A) trade payables and accrued expenses incurred in the ordinary course of business consistent with past practice and (B) liabilities not required to be reflected in the Company’s financial statements pursuant to GAAP or required to be disclosed in filings made with the SEC, (iii) the Company has not altered its method of accounting or changed its auditors, (iv) the Company has not declared or made any dividend or distribution of cash or other property to its stockholders, in their capacities as such, or purchased, redeemed or made any agreements to purchase or redeem any shares of its capital stock (except for

repurchases by the Company of shares of capital stock held by employees, officers, directors, or consultants pursuant to an option to repurchase such shares upon the termination of employment or services), and (v) the Company has not issued any equity securities to any officer, director or Affiliate, except pursuant to current or previously existing Company stock-based plans.

3.7 Brokers or Finders. The Company has not incurred, and shall not incur, directly or indirectly, any liability for any brokerage or finders' fees or agents commissions or any similar charges in connection with this Agreement or any transaction contemplated hereby.

3.8 The Nasdaq Global Select Market. The Company's Common Stock is listed on The Nasdaq Global Select Market, and there are no proceedings to revoke or suspend such listing.

3.9 Absence of Litigation. Except as disclosed in the Company's Current SEC Reports, there is no proceeding, or, to the Company's knowledge, inquiry or investigation, before or by any court, public board, government agency, self-regulatory organization or body pending or, to the knowledge of the Company, threatened against or affecting the Company that could, individually or in the aggregate, have or reasonably be expected to result in a Material Adverse Effect.

4. Representations and Warranties of the Purchaser. The Purchaser represents and warrants to the Company as follows:

4.1 Organization; Authority. The Purchaser is an entity duly organized, validly existing and in good standing under the laws of the jurisdiction of its organization with the requisite corporate, partnership or other power and authority to enter into and to consummate the transactions contemplated by the Transaction Documents and otherwise to carry out its obligations hereunder and thereunder. The purchase by the Purchaser of the Shares hereunder has been duly authorized by all necessary corporate, partnership or other action on the part of the Purchaser. Each of the Transaction Documents has been duly executed and delivered by the Purchaser and constitutes the valid and binding obligation of the Purchaser, enforceable against it in accordance with its terms, except as may be limited by (i) applicable bankruptcy, insolvency, reorganization or other laws of general application relating to or affecting the enforcement of creditors rights generally, and (ii) the effect of rules of law governing the availability of specific performance and other equitable remedies.

4.2 No Public Sale or Distribution; Investment Intent. The Purchaser is acquiring the Shares for its own account and not with a view towards, or for resale in connection with, the public sale or distribution thereof, except pursuant to sales registered under the Securities Act or under an exemption from such registration and in compliance with applicable federal and state securities laws, and the Purchaser does not have a present arrangement to effect any distribution of the Shares to or through any person or entity; *provided, however*, that by making the representations herein, the Purchaser does not agree to hold any of the Shares for any minimum or other specific term and reserves the right to dispose of the Shares at any time in accordance with or pursuant to a registration statement or an exemption under the Securities Act.

4.3 Investor Status; Etc. At the time the Purchaser was offered the Shares, it was, and at the date hereof it is, an “accredited investor” as defined in Rule 501(a) under the Securities Act. The Purchaser has such knowledge, sophistication and experience in business and financial matters so as to be capable of evaluating the merits and risks of the prospective investment in the Shares, and has so evaluated the merits and risks of such investment. The Purchaser is able to bear the economic risk of an investment in the Shares and, at the present time, is able to afford a complete loss of such investment.

4.4 Shares Not Registered. The Purchaser understands that the Shares have not been registered under the Securities Act, by reason of their issuance by the Company in a transaction exempt from the registration requirements of the Securities Act, and that the Shares must continue to be held by the Purchaser unless a subsequent disposition thereof is registered under the Securities Act or is exempt from such registration. The Purchaser understands that the exemptions from registration afforded by Rule 144 (the provisions of which are known to it) promulgated under the Securities Act depend on the satisfaction of various conditions, and that, if applicable, Rule 144 may afford the basis for sales only in limited amounts.

4.5 No Conflict. The execution and delivery of the Transaction Documents by the Purchaser and the consummation of the transactions contemplated hereby and thereby will not conflict with or result in any violation of or default by the Purchaser (with or without notice or lapse of time, or both) under, or give rise to a right of termination, cancellation or acceleration of any obligation or to a loss of a material benefit under (i) any provision of the organizational documents of the Purchaser or (ii) any agreement or instrument, permit, franchise, license, judgment, order, statute, law, ordinance, rule or regulations, applicable to the Purchaser or its respective properties or assets.

4.6 Brokers. The Purchaser has not retained, utilized or been represented by any broker or finder in connection with the transactions contemplated by this Agreement.

4.7 No Ownership. Immediately prior to the issuance of the Shares hereunder, except as set forth on Schedule 4.7 hereof, neither the Purchaser nor any of its Affiliates beneficially owned any voting securities of the Company.

5. Conditions Precedent.

5.1 Conditions to the Obligation of the Purchaser to Consummate the Second Closing. The obligation of the Purchaser to consummate the Second Closing and to purchase and pay for the Second Closing Shares being purchased by it pursuant to this Agreement is subject to the satisfaction of the following conditions precedent:

(a) The representations and warranties contained herein of the Company shall be true and correct on and as of the Second Closing Date in all material respects with the same force and effect as though made on and as of the Second Closing Date.

(b) The Company shall have performed in all material respects all obligations and conditions herein required to be performed or observed by the Company on or prior to the Second Closing Date.

(c) No proceeding challenging this Agreement or the transactions contemplated hereby, or seeking to prohibit, alter, prevent or materially delay the Second Closing, shall have been instituted before any court, arbitrator or governmental body, agency or official and shall be pending.

(d) The issuance of the Second Closing Shares to the Purchaser shall not be prohibited by any law or governmental order or regulation. All necessary consents, approvals, licenses, permits, orders and authorizations of, or registrations, declarations and filings with, any governmental or administrative agency or of any other person with respect to any of the transactions contemplated hereby shall have been duly obtained or made and shall be in full force and effect.

(e) All instruments and corporate proceedings in connection with the transactions specifically contemplated by this Agreement to be consummated at the Second Closing shall be reasonably satisfactory in form and substance to the Purchaser, and the Purchaser shall have received copies (executed or certified, as may be appropriate) of all documents which the Purchaser may have reasonably requested in connection with such transactions.

(f) Any waiting periods (and any extensions thereof) applicable to the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended (the “HSR Act”) shall have been terminated or expired.

5.2 Conditions to the Obligation of the Company to Consummate the Second Closing. The obligation of the Company to consummate the Second Closing and to issue and sell to the Purchaser the Second Closing Shares to be purchased by it at the Second Closing is subject to the satisfaction of the following conditions precedent:

(a) The representations and warranties contained herein of the Purchaser shall be true and correct on and as of the Second Closing Date in all material respects with the same force and effect as though made on and as of the Second Closing Date.

(b) The Purchaser shall have performed in all material respects all obligations and conditions herein required to be performed or observed by the Purchaser on or prior to the Second Closing Date.

(c) No proceeding challenging this Agreement or the transactions contemplated hereby, or seeking to prohibit, alter, prevent or materially delay the Second Closing, shall have been instituted before any court, arbitrator or governmental body, agency or official and shall be pending.

(d) The sale of the Second Closing Shares by the Company shall not be prohibited by any law or governmental order or regulation. All necessary consents, approvals, licenses, permits, orders and authorizations of, or registrations, declarations and filings with, any governmental or administrative agency or of any other person with respect to any of the transactions contemplated hereby shall have been duly obtained or made and shall be in full force and effect.

(e) All instruments and corporate proceedings in connection with the transactions contemplated by this Agreement to be consummated at the Second Closing shall be reasonably satisfactory in form and substance to the Company, and the Company shall have received counterpart originals, or certified or other copies of all documents, including without limitation records of corporate or other proceedings, which it may have reasonably requested in connection therewith.

(f) Any waiting periods (and any extensions thereof) applicable to the HSR Act shall have been terminated or expired.

6. Other Agreements of the Parties .

6.1 Securities Law Transfer Restrictions . The Purchaser shall not sell, assign, pledge, transfer or otherwise dispose or encumber any of the Shares being purchased by it hereunder, except (i) pursuant to an effective registration statement under the Securities Act or (ii) pursuant to an available exemption from registration under the Securities Act and applicable state securities laws. Any transfer or purported transfer of the Shares in violation of this Section 6.1 shall be voidable by the Company. The Company shall not register any transfer of the Shares in violation of this Section 6.1. The Company may, and may instruct any transfer agent for the Company, to place such stop transfer orders as may be required on the transfer books of the Company in order to ensure compliance with the provisions of this Section 6.1.

6.2 Legends . Until all of the Shares can be sold pursuant to Rule 144 promulgated under the Securities Act, each certificate requesting any of the Shares shall be endorsed with the legends set forth below, and the Purchaser covenants that, except to the extent such restrictions are waived in writing by the Company, it shall not transfer the shares represented by any such certificate without complying with the restrictions on transfer described in this Agreement and the legends endorsed on such certificate (such legends to be removed by the Company from any such certificate at the request of Purchaser at such time that all of the Shares can be sold pursuant to Rule 144 promulgated under the Securities Act):

“THE SHARES REPRESENTED BY THIS CERTIFICATE HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933 AND MAY NOT BE OFFERED, SOLD, ASSIGNED, PLEDGED TRANSFERRED OR OTHERWISE DISPOSED OF IN THE ABSENCE OF AN EFFECTIVE REGISTRATION STATEMENT UNDER SAID ACT OR PURSUANT TO AN AVAILABLE EXEMPTION FROM REGISTRATION UNDER SAID ACT.”

“THE SHARES REPRESENTED BY THIS CERTIFICATE ARE SUBJECT TO CERTAIN RESTRICTIONS ON TRANSFERABILITY AND RESALE AND CERTAIN OTHER RESTRICTIONS, ALL AS SET FORTH IN A CERTAIN DEFINITIVE AGREEMENT BETWEEN THE COMPANY AND THE ORIGINAL HOLDER OF THESE SHARES, A COPY OF WHICH MAY BE OBTAINED AT THE PRINCIPAL OFFICE OF THE COMPANY.”

6.3 Other Transfer Restrictions.

(a) In addition to the restrictions set forth in Section 6.1, until the date that is twelve (12) months after the date hereof, the Purchaser shall not, directly or indirectly, sell, transfer, pledge, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase or otherwise dispose of, any Shares to any competitor of the Company (or any Affiliate thereof) or any activist investor (or any Affiliate thereof).

(b) No transferee of the Shares sold, transferred or otherwise disposed of by the Purchaser as permitted by this Section 6.3 shall be bound (other than a Purchaser Controlled Corporation) by the terms of this Agreement, nor shall such transferee (other than a Purchaser Controlled Corporation) be entitled, in any manner whatsoever, to any rights afforded Purchaser under this Agreement.

(c) Any attempted sale, transfer or other disposition by Purchaser or a Purchaser Controlled Corporation which is not in compliance with this Section 6.3 shall be null and void.

6.4 Standstill. (a) For a period commencing with the date of this Agreement and ending on the earliest to occur of (i) the termination of the period of exclusivity pursuant to its terms set forth in the Collaboration Agreement, (ii) the eighteenth month anniversary of the date hereof or (iii) a Standstill Termination Event (as defined below) (such period, the “Standstill Period”), none of the Purchaser, any Affiliate of the Purchaser or any of their directors, officers, employees, agents or advisors (“Representatives”) shall, for or on behalf of the Purchaser, without the prior written consent of the Company:

(a) acquire, offer to acquire, or agree to acquire, directly or indirectly, by purchase or otherwise, any voting securities such that, upon such acquisition, Purchaser would beneficially own in excess of the Contemplated Percentage, or direct or indirect rights to acquire any voting securities of the Company or any subsidiary thereof such that, upon such acquisition, Purchaser would beneficially own in excess of the Contemplated Percentage (for the purposes of this Agreement, the “Contemplated Percentage” shall mean the percentage of outstanding voting securities of the Company determined by dividing (i) the sum of the (x) number of outstanding shares of Common Stock of the Company beneficially owned by the Purchaser as of the date hereof, plus (y) the Shares, by (ii) the total number of outstanding voting securities of the Company as of the date hereof, plus the Shares; provided, however, if a party or 13D Group acquires more shares of outstanding Common Stock of the Company than the Contemplated Percentage, the Contemplated Percentage will be increased to equal the percentage of outstanding Common Stock held by such party or 13D Group, but in no event shall the Contemplated Percentage exceed 14.9%);

(b) make, or in any way participate, directly or indirectly, in any “solicitation” of “proxies” to vote (as such terms are used in the rules of the SEC), seek to advise or influence any person or entity with respect to the voting of any voting securities of the Company;

(c) deposit any Shares in a voting trust or, except as otherwise provided or contemplated herein, subject any Shares to any arrangement or agreement with any third party with respect to the voting of such Shares;

(d) make any public announcement with respect to, or submit a proposal for, or offer of (with or without conditions) any extraordinary transaction involving the Company or any of its securities or assets;

(e) form, join or in any way participate in a 13D Group, partnership, limited partnership, syndicate or other group or otherwise act in concert with any third person for the purpose of acquiring, holding, voting or disposing of securities of the Company; *provided, however*, that by agreeing to this clause (e), the Purchaser does not agree to hold any of the Shares for any minimum or other specific term and reserves the right to dispose of the Shares at any time in accordance with or pursuant to a registration statement or an exemption under the Securities Act and Sections 6.1 and 6.3 of this Agreement;

(f) otherwise act or seek to control the management, Board of Directors or policies of the Company;

(g) take any action that would reasonably be expected to require the Company to make a public announcement regarding the possibility of any of the events described in clauses (a) through (f) above; or

(h) request the Company, directly or indirectly, to amend or waive any provision of this Section 6.4;

provided, however, that nothing in this Agreement shall prevent or limit in any way the Purchaser or its Affiliates from:

(i) subject to Sections 6.1, 6.3 and 6.5 of this Agreement, voting (including the granting or withholding of any consent) or disposing of any voting securities then beneficially owned by the Purchaser or its Affiliates in any manner;

(ii) making confidential proposals to the Board of Directors with respect to transactions involving the Company, any of the Company's subsidiaries or any properties, assets or businesses of the Company or any of the Company's subsidiaries;

(iii) making any offer or entering into any agreement with respect to, or otherwise consummating, any transaction involving the Company or Company securities, assets or properties in the ordinary course of business or pursuant to the terms of the Collaboration Agreement or any subsequent definitive agreement with the Company; or

(iv) acquiring or offering to acquire, directly or indirectly, any company or business unit thereof that beneficially owns Company securities so long as such securities are not a material portion of the assets of such company or business unit.

Notwithstanding the foregoing, the restrictions on Purchaser and its Representatives in the above provisions of this Section 6.4 shall automatically and immediately terminate upon the occurrence of a Standstill Termination Event.

For purposes of this Agreement, a “Standstill Termination Event” means:

- Control;
 - (i) the Company enters into any agreement or agreement in principle with respect to any Change in
- securities of the Company;
 - (ii) any person or 13D Group shall have become the beneficial owner of 20% or more of any class of
- other shareholder rights plan to facilitate any Change in Control or any acquisition of securities by any person or 13D Group, unless with respect to a modification in connection with an acquisition of securities which would result in a person or 13D Group becoming the beneficial owner of less than 20% of any class of securities of the Company, contemporaneously with such modification the Company takes such action as may be necessary to permit Purchaser to acquire the same beneficial ownership in the aggregate as such person or 13D Group and the Company agrees to amend the definition of “Contemplated Percentage” to permit such acquisition;
- securities of the Company;
 - (iv) a tender or exchange offer that if consummated would constitute a Change in Control is made for
- exchange offer that if consummated would constitute a Change in Control;
 - (v) any person or 13D Group publicly proposes, or announces an intention to commence a tender or
- the person or 13D Group would, if successful, elect or acquire the ability to elect or to have elected a majority of the Board of Directors; or
 - (vi) any person or 13D Group commences (or publicly proposes to commence) a proxy solicitation by which
- any proceeding under any bankruptcy, reorganization, insolvency, dissolution or liquidation law of any jurisdiction or any such petition is filed or any such proceeding is commenced against the Company or any of its subsidiaries and either (A) the Company or such subsidiary by any act indicates its approval thereof, consent thereto or acquiescence therein or (B) such petition, application or proceeding is not dismissed within 60 days.
- (vii) the Company or any of its subsidiaries makes an assignment for the benefit of creditors or commences

6.5 Purchaser’s Voting Obligations. During the Standstill Period, on all matters submitted to the vote, written consent or approval of the stockholders of the Company, the Purchaser shall take all such action as may be required so that the Shares then beneficially owned by the Purchaser are voted for or cast in favor of : (i) nominees to the Board of Directors of the Company in accordance with recommendations of the Board of Directors of the Company, (ii) increases in the authorized capital stock of the Company and amendments to, or adoptions of, employee stock option plans and employee stock purchase plans, in each case which are approved by the Company’s Board of Directors, and (iii) all other ordinary course, non-extraordinary

matters approved by the Company's Board of Directors where such matters are submitted to a vote, action by written consent or other approval of the stockholders of the Company.

6.6 Pre-emptive Rights.

(a) Sale of New Securities. At any time that the Company makes any public or nonpublic offering or sale of any equity securities, options or debt that is convertible or exchangeable into equity or that includes an equity component (such as, an "equity" kicker) (including any hybrid security) (any such security other than that issued (i) pursuant to the granting or exercise of stock options or other stock incentives pursuant to the Company's stock incentive plans approved by the Board of Directors or the issuance of stock pursuant to the Company's employee stock purchase plan approved by the Board of Directors or similar plan, (ii) in connection with acquisitions by the Company to stockholders of acquired companies, or (iii) to banks, equipment lessors or other financial institutions pursuant to commercial leasing or debt financing transactions, in connection with sponsored research, collaboration, technology license, development, OEM, marketing or other similar agreements or strategic partnerships, or to suppliers or third party service providers in connection with the provision of goods or services, a "New Security") the Purchaser shall be afforded the opportunity to acquire from the Company for the same price (net of any underwriting discounts or sales commissions) and on the same terms (except that, to the extent permitted by law and the Certificate of Incorporation and bylaws of the Company, the Purchaser may elect to receive such securities in nonvoting form, convertible into voting securities) as such securities are proposed to be offered to others, up to the amount of New Securities required to enable Purchaser to maintain the Contemplated Percentage interest in the Company.

(b) Notice. In the event the Company proposes to offer or sell New Securities, it shall give the Purchaser written notice of its intention, describing the price (or range of prices), anticipated amount of securities, timing and other terms upon which the Company proposes to offer the same (including, in the case of a registered public offering and to the extent possible, a copy of the prospectus included in the registration statement filed with respect to such offering), no later than ten business days, as the case may be, after the initial filing of a registration statement with the SEC with respect to an underwritten public offering, after the commencement of marketing with respect to a Rule 144A offering or after the Company proposes to pursue any other offering). The Purchaser shall have ten business days from the date of receipt of such a notice to notify the Company in writing that it intends to exercise its rights provided in this Section 6.6 and as to the amount of New Securities the Purchaser desires to purchase, up to the maximum amount calculated pursuant to Section 6.6(a). Such notice shall constitute a binding indication of interest of the Purchaser to purchase the amount of New Securities so specified at the price and other terms set forth in the Company's notice to it. The failure of the Purchaser to respond within such ten business day period shall be deemed to be a waiver of the Purchaser's rights under this Section 6.6 only with respect to the offering described in the applicable notice.

(c) Purchase Mechanism. If the Purchaser exercises its rights provided in this Section 6.6, the closing of the purchase of the New Securities with respect to which such right has been exercised shall take place within 15 calendar days after the giving of notice of such exercise, which period of time shall be extended for a maximum of 90 days in order to comply

with applicable laws and regulations (including receipt of any applicable regulatory or stockholder approvals). Each of the Company and the Purchaser agrees to use its commercially reasonable efforts to secure any regulatory or stockholder approvals or other consents, and to comply with any law or regulation necessary in connection with the offer, sale and purchase of, such New Securities.

(d) Failure of Purchase. In the event the Purchaser fails to exercise its rights provided in this Section 6.6 within said ten-business day period or, if so exercised, the Purchaser is unable to consummate such purchase within the time period specified in Section 6.6 (c) above because of its failure to obtain any required regulatory or stockholder consent or approval, the Company shall thereafter be entitled (during the period of 60 days following the conclusion of the applicable period) to sell or enter into an agreement to sell the New Securities not elected to be purchased pursuant to this Section 6.6 or which the Purchaser is unable to purchase because of such failure to obtain any such consent or approval, at a price and upon terms, taken together in the aggregate, no more favorable to the purchasers of such securities than were specified in the Company's notice to the Purchaser. Notwithstanding the foregoing, if such sale is subject to the receipt of any regulatory or stockholder approval or consent or the expiration of any waiting period, the time period during which such sale may be consummated shall be extended until the expiration of five business days after all such approvals or consents have been obtained or waiting periods expired, but in no event shall such time period exceed 120 days from the date of the applicable agreement with respect to such sale. In the event the Company has not sold the New Securities within said 60-day period (as such period may be extended in the manner described above for a period not to exceed 120 days from the date of said agreement), the Company shall not thereafter offer, issue or sell such New Securities without first offering such securities to the Purchaser in the manner provided above.

(e) Non-Cash Consideration. In the case of the offering of New Securities for consideration in whole or in part other than cash, including securities acquired in exchange therefor (other than securities by their terms so exchangeable), the consideration other than cash shall be deemed to be the fair value thereof as determined by the Board of Directors in good faith; *provided, however*, that such fair value as determined by the Board of Directors shall not exceed the aggregate market price of the securities being offered as of the date the Board of Directors authorizes the offering of such securities.

(f) Cooperation. The Company and the Purchaser shall cooperate in good faith to facilitate the exercise of the Purchaser's rights under this Section 6.6, including to secure any required approvals or consents.

6.7 Listing of Common Stock. As soon as reasonably practicable, the Company will apply for additional listing of the Shares on The Nasdaq Global Select Market.

6.8 Form D; Blue Sky Filings. The Company agrees to timely file a Form D with respect to the Shares as required under Regulation D and to provide a copy thereof, promptly upon request of the Purchaser. The Company shall take such action as the Company shall reasonably determine is necessary in order to obtain an exemption for, or to qualify the Shares for, sale to the Purchaser at the Closings under applicable securities or "Blue Sky" laws of the

states of the United States, and shall provide evidence of such actions promptly upon request of the Purchaser.

6.9 Taking of Necessary Action. Each of the Company and the Purchaser shall use its commercially reasonable efforts promptly to take or cause to be taken all action and promptly to do or cause to be done all things necessary, proper, or advisable under applicable laws and regulations to consummate and make effective the transactions contemplated by this Agreement. Without limiting the foregoing, the Company and the Purchaser will use its commercially reasonable efforts to make all filings (including without limitation, under the HSR Act as applicable) and obtain all consents of governmental entities which may be necessary or, in the reasonable opinion of the Purchaser or the Company, as the case may be, advisable for the consummation of the transactions contemplated by this Agreement. The Purchaser shall (i) file, or have caused to be filed, all necessary filings required to be made by the Purchaser under the HSR Act in connection with the transactions contemplated by this Agreement as soon as reasonably practicable following the date hereof, and (ii) use all commercially reasonable efforts to have such filings made within seven (7) trading days of the date hereof.

7. Registration Rights.

7.1 Registration Statement.

(a) As soon as commercially practicable (but in any event within ninety (90) days) following receipt of a written request from the Purchaser, the Company shall prepare and file with the SEC a shelf Registration Statement covering the resale of all Registrable Securities for an offering to be made on a continuous basis pursuant to Rule 415. The Registration Statement shall be on Form S-3 (except if the Company is not then eligible to register for resale the Registrable Securities on Form S-3, in which case such registration shall be on another appropriate form in accordance with the Securities Act and the Exchange Act).

(b) The Company shall use its commercially reasonable efforts to cause the shelf Registration Statement to be declared effective by the SEC as promptly as possible after the filing thereof, and shall use its commercially reasonable efforts to keep the Registration Statement continuously effective under the Securities Act until the earlier of the date that all Shares covered by such Registration Statement have been sold or can be sold publicly under Rule 144 (the “Effectiveness Period”). Notwithstanding the foregoing, if the SEC, by written or oral comment or otherwise, limits the Company’s ability to request effectiveness, or prohibits the effectiveness of, a Registration Statement with respect to any or all the Registrable Securities pursuant to Rule 415, it shall not be a breach or default by the Company under this Agreement and shall not be deemed a failure by the Company to use commercially reasonable efforts.

(c) The Company shall notify the Purchaser in writing promptly (and in any event within two trading days) after receiving notification from the SEC that the Registration Statement has been declared effective.

(d) Notwithstanding anything in this Agreement to the contrary, at any time after the initial Registration Statement is filed and declared effective pursuant to this Agreement, the Company may, by written notice to the Purchaser, suspend sales under a

Registration Statement after the Effective Date thereof and/or require that the Purchaser immediately cease the sale of shares of Common Stock pursuant thereto and/or defer the filing of any subsequent Registration Statement if the Board of Directors determines in good faith, by appropriate resolutions, that, as a result of material undisclosed information or events with respect to the Company, it would be detrimental to the Company (other than as relating solely to the price of the Common Stock) to maintain a Registration Statement at such time. Upon receipt of such notice, the Purchaser shall immediately discontinue any sales of Registrable Securities pursuant to such registration until the Purchaser is advised in writing by the Company that the current Prospectus or amended Prospectus, as applicable, may be used. The total number of days that any such suspension may be in effect in any 180 day period shall not exceed 90 days. Immediately after the end of any suspension period under this Section 7.1(d), the Company shall take all necessary actions (including filing any required supplemental prospectus) to restore the effectiveness of the applicable Registration Statement and the ability of the Purchaser to publicly resell its Registrable Securities pursuant to such effective Registration Statement.

(e) The Company shall not be obligated to effect any such registration pursuant to this Section 7:

(i) Prior to one (1) year anniversary of the date hereof;

(ii) In any particular jurisdiction in which the Company would be required to execute a general consent to service of process in effecting such registration, qualification, or compliance, unless the Company is already subject to service in such jurisdiction and except as may be required by the Securities Act;

(iii) Subject to Section 7.1(f) with respect to Piggyback Registration Rights, during the period starting with the date sixty (60) days prior to the Company's good faith estimate of the date of filing of, and ending on a date one hundred eighty (180) days after the effective date of, a Company-initiated registration; *provided* that the Company is actively employing in good faith commercially reasonable efforts to cause such registration statement to become effective; or

(iv) If (i) in the good faith judgment of the Board of Directors of the Company, the filing of a Registration Statement covering the Registrable Securities would be detrimental to the Company and the Board of Directors of the Company concludes, as a result, that it is in the best interests of the Company to defer the filing of such Registration Statement at such time, and (ii) the Company shall furnish to the Purchaser a certificate signed by the President of the Company stating that in the good faith judgment of the Board of Directors of the Company, it would be detrimental to the Company for such Registration Statement to be filed in the near future and that it is, therefore, in the best interests of the Company to defer the filing of such Registration Statement, then (in addition to the limitations set forth above) the Company shall have the right to defer such filing for a period of not more than one hundred eighty (180) days after receipt of the request of the Purchaser, and, provided further, that the Company shall not defer its obligation in this manner more than once in any twelve-month period.

(f) Piggyback Registration Rights. Whenever the Company proposes to register any of its equity securities other than a registration statement under Section 7.1(a) or a

Special Registration (as defined below) and the registration form to be filed may be used for the registration or qualification for distribution of Registrable Securities, the Company will give prompt written notice to the Purchaser and all other Holders of its intention to effect such a registration (but in no event less than ten days prior to the anticipated filing date) and (subject to the next paragraph below) will include in such registration all Registrable Securities with respect to which the Company has received written requests for inclusion therein within ten business days after the date of the Company's notice (a "Piggyback Registration"). Any such person that has made such a written request may withdraw its Registrable Securities from such Piggyback Registration by giving written notice to the Company and the managing underwriter, if any, on or before the fifth business day prior to the planned effective date of such Piggyback Registration. The Company may terminate or withdraw any registration under this Section 7.1(f) prior to the effectiveness of such registration, whether or not the Purchaser or any other Holders have elected to include Registrable Securities in such registration. "Special Registration" means the registration of (i) equity securities and/or options or other rights in respect thereof solely registered on Form S-4 or Form S-8 (or successor form) or (ii) shares of equity securities and/or options or other rights in respect thereof to be offered to directors, members of management, employees, consultants, customers, lenders or vendors of the Company or Company subsidiaries or in connection with dividend reinvestment plans.

If (x) the Company grants "piggyback" registration rights to one or more third parties to include their securities in an underwritten offering under the Registration Statement or (y) a Piggyback Registration relates to an underwritten primary offering on behalf of the Company, and in either case the managing underwriters advise the Company that in their reasonable opinion the number of securities requested to be included in such offering exceeds the number which can be sold without adversely affecting the marketability of such offering (including an adverse effect on the per share offering price), the Company will include in such registration or prospectus only such number of securities that in the reasonable opinion of such underwriters can be sold without adversely affecting the marketability of the offering (including an adverse effect on the per share offering price), which securities will be so included in the following order of priority: (i) first, in the case of a Piggyback Registration, the securities the Company proposes to sell, (ii) second, Registrable Securities of the Purchaser and all other Holders who have requested registration of Registrable Securities, *pro rata* on the basis of the aggregate number of such securities or shares owned by each such person and (iii) third, any other securities of the Company that have been requested to be so included, subject to the terms of this Agreement.

7.2 Registration Procedures. In connection with the Company's registration obligations hereunder, the Company shall:

(a) (i) Subject to Section 7.1(d), prepare and file with the SEC such amendments, including post-effective amendments, to each Registration Statement and the Prospectus used in connection therewith as may be necessary to keep the Registration Statement continuously effective, as to the applicable Registrable Securities for the Effectiveness Period and prepare and file with the SEC such additional Registration Statements in order to register for resale under the Securities Act all of the Registrable Securities; (ii) cause the related Prospectus to be amended or supplemented by any required Prospectus supplement, and as so supplemented or amended to be filed pursuant to Rule 424; (iii) respond as promptly as reasonably possible, and in any event within 15 trading days (except to the extent that the Company reasonably

requires additional time to respond to accounting or Rule 415 comments), to any comments received from the SEC with respect to the Registration Statement or any amendment thereto; and (iv) comply in all material respects with the provisions of the Securities Act and the Exchange Act with respect to the disposition of all Registrable Securities covered by the Registration Statement during the applicable period in accordance with the intended methods of disposition by the Purchaser thereof set forth in the Registration Statement as so amended or in such Prospectus as so supplemented.

(b) Notify the Purchaser as promptly as reasonably practicable (and in any event within one business day) of any of the following events: (i) the SEC notifies the Company whether there will be a “review” of any Registration Statement; (ii) the SEC comments in writing on any Registration Statement; (iii) any Registration Statement or any post-effective amendment is declared effective; (iv) the SEC or any other federal or state governmental authority requests any amendment or supplement to any Registration Statement or Prospectus or requests additional information related thereto; (v) the SEC issues any stop order suspending the effectiveness of any Registration Statement or initiates any proceedings for that purpose; (vi) the Company receives notice of any suspension of the qualification or exemption from qualification of any Registrable Securities for sale in any jurisdiction, or the initiation or threat of any proceeding for such purpose; or (vii) the financial statements included in any Registration Statement become ineligible for inclusion therein or any Registration Statement or Prospectus or other document contains any untrue statement of a material fact or omits to state any material fact required to be stated therein or necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading.

(c) Use its commercially reasonable efforts to avoid the issuance of or, if issued, obtain the withdrawal of (i) any order suspending the effectiveness of any Registration Statement, or (ii) any suspension of the qualification (or exemption from qualification) of any of the Registrable Securities for sale in any jurisdiction, as soon as possible.

(d) Promptly deliver to the Purchaser, without charge, as many copies of the Prospectus or Prospectuses (including each form of prospectus) and each amendment or supplement thereto as the Purchaser may reasonably request.

(e) (i) In the time and manner required by each Trading Market, prepare and file with such Trading Market an additional shares listing application covering all of the Registrable Securities; (ii) take all steps necessary to cause such Shares to be approved for listing on each Trading Market as soon as possible thereafter; and (iii) during the Effectiveness Period, maintain the listing of such Shares on such Trading Market.

(f) Comply in all material respects with all rules and regulations of the SEC applicable to the registration of the Shares.

7.3 Registration Expenses. The Company shall pay all fees and expenses incident to the performance of or compliance with Section 7 of this Agreement by the Company, including without limitation (a) all registration and filing fees and expenses, including without limitation those related to filings with the SEC, any Trading Market, and in connection with applicable state securities or blue sky laws, (b) printing expenses (including without limitation

expenses of printing certificates for Registrable Securities), (c) messenger, telephone and delivery expenses, (d) fees and disbursements of counsel for the Company, (e) fees and expenses of all other persons retained by the Company in connection with the consummation of the transactions contemplated by this Agreement, and (f) all listing fees to be paid by the Company to the Trading Market.

7.4 Indemnification

(a) Indemnification by the Company. The Company shall, notwithstanding any termination of this Agreement, indemnify and hold harmless the Purchaser, and the affiliates, officers, directors, partners, members, agents and employees of the Purchaser, to the fullest extent permitted by applicable law, from and against any and all Losses, as incurred, arising out of or relating to any untrue or alleged untrue statement of a material fact contained in the Registration Statement, any Prospectus or any form of Company prospectus or in any amendment or supplement thereto or in any Company preliminary prospectus, or arising out of or relating to any omission or alleged omission of a material fact required to be stated therein or necessary to make the statements therein (in the case of any Prospectus or form of prospectus or supplement thereto, in the light of the circumstances under which they were made) not misleading, except to the extent, but only to the extent, that (A) such untrue statements, alleged untrue statements, omissions or alleged omissions are based solely upon information regarding the Purchaser furnished in writing to the Company by the Purchaser for use therein, or to the extent that such information relates to the Purchaser or the Purchaser's proposed method of distribution of Registrable Securities and was reviewed and expressly approved by the Purchaser expressly for use in the Registration Statement, or (B) with respect to any prospectus, if the untrue statement or omission of material fact contained in such prospectus was corrected on a timely basis in the prospectus, as then amended or supplemented, if such corrected prospectus was timely made available by the Company to the Purchaser, and the Purchaser was advised in writing not to use the incorrect prospectus prior to the use giving rise to Losses.

(b) Indemnification by the Purchaser. The Purchaser shall indemnify and hold harmless the Company and the officers, directors, partners, members, agents and employees of the Company, to the fullest extent permitted by applicable law, from and against all Losses arising solely out of any untrue statement of a material fact contained in the Registration Statement, any Prospectus, or any form of prospectus, or in any amendment or supplement thereto, or arising out of or relating to any omission of a material fact required to be stated therein or necessary to make the statements therein (in the case of any Prospectus or form of prospectus or supplement thereto, in the light of the circumstances under which they were made) not misleading, but only to the extent that such untrue statement or omission is contained in any information so furnished by the Purchaser in writing to the Company specifically for inclusion in such Registration Statement or such Prospectus or to the extent that (i) such untrue statements or omissions are based solely upon information regarding the Purchaser furnished to the Company by the Purchaser in writing expressly for use therein, or (ii) to the extent that such information relates to Purchaser or Purchaser's proposed method of distribution of Registrable Securities and was reviewed and expressly approved by the Purchaser expressly for use in the Registration Statement, such Prospectus or such form of Prospectus or in any amendment or supplement thereto. In no event shall the liability of the Purchaser hereunder be greater in amount than the dollar amount of the net proceeds (after discounts and commissions but before expenses)

received by the Purchaser upon the sale of the Registrable Securities giving rise to such indemnification obligation.

(c) Conduct of Indemnification Proceedings. If any Proceeding shall be brought or asserted against any person entitled to indemnity hereunder (an “Indemnified Party”), such Indemnified Party shall promptly notify the person from whom indemnity is sought (the “Indemnifying Party”) in writing, and the Indemnifying Party shall assume the defense thereof, including the employment of counsel reasonably satisfactory to the Indemnified Party and the payment of all fees and expenses incurred in connection with defense thereof; *provided*, that the failure of any Indemnified Party to give such notice shall not relieve the Indemnifying Party of its obligations or liabilities pursuant to this Agreement, except (and only) to the extent that it shall be finally determined by a court of competent jurisdiction (which determination is not subject to appeal or further review) that such failure shall have proximately and materially adversely prejudiced the Indemnifying Party.

An Indemnified Party shall have the right to employ one separate counsel in any such Proceeding and to participate in the defense thereof, but the fees and expenses of such one separate counsel shall be at the expense of such Indemnified Party or Parties unless: (i) the Indemnifying Party has agreed in writing to pay such fees and expenses; or (ii) the Indemnifying Party shall have failed promptly to assume the defense of such Proceeding and to employ counsel reasonably satisfactory to such Indemnified Party in any such Proceeding; or (iii) the named parties to any such Proceeding (including any impleaded parties) include both such Indemnified Party and the Indemnifying Party, and such Indemnified Party shall have been advised by counsel that a conflict of interest is likely to exist if the same counsel were to represent such Indemnified Party and the Indemnifying Party (in which case, if such Indemnified Party notifies the Indemnifying Party in writing that it elects to employ separate counsel at the expense of the Indemnifying Party, the Indemnifying Party shall not have the right to assume the defense thereof and the reasonable fees and expenses of separate counsel shall be at the expense of the Indemnifying Party). It being understood, however, that the Indemnifying Party shall not, in connection with any one such Proceeding (including separate Proceedings that have been or will be consolidated before a single judge) be liable for the fees and expenses of more than one separate firm of attorneys at any time for all Indemnified Parties, which firm shall be appointed by a majority of the Indemnified Parties. The Indemnifying Party shall not be liable for any settlement of any such Proceeding effected without its written consent, which consent shall not be unreasonably withheld. No Indemnifying Party shall, without the prior written consent of the Indemnified Party, effect any settlement of any pending Proceeding in respect of which any Indemnified Party is a party, unless such settlement includes an unconditional release of such Indemnified Party from all liability on claims that are the subject matter of such Proceeding.

(d) Contribution. If a claim for indemnification under Section 7.4(a) or (b) is unavailable to an Indemnified Party (by reason of public policy or otherwise), then each Indemnifying Party, in lieu of indemnifying such Indemnified Party, shall contribute to the amount paid or payable by such Indemnified Party as a result of such Losses, in such proportion as is appropriate to reflect the relative fault of the Indemnifying Party and Indemnified Party in connection with the actions, statements or omissions that resulted in such Losses as well as any other relevant equitable considerations. The relative fault of such Indemnifying Party and

Indemnified Party shall be determined by reference to, among other things, whether any action in question, including any untrue or alleged untrue statement of a material fact or omission or alleged omission of a material fact, has been taken or made by, or relates to information supplied by, such Indemnifying Party or Indemnified Party, and the parties' relative intent, knowledge, access to information and opportunity to correct or prevent such action, statement or omission. The amount paid or payable by a party as a result of any Losses shall be deemed to include, subject to the limitations set forth in Section 7.4(c), any reasonable attorneys' or other reasonable fees or expenses incurred by such party in connection with any Proceeding to the extent such party would have been indemnified for such fees or expenses if the indemnification provided for in this Section was available to such party in accordance with its terms.

The parties hereto agree that it would not be just and equitable if contribution pursuant to this Section 7.4(d) were determined by pro rata allocation or by any other method of allocation that does not take into account the equitable considerations referred to in the immediately preceding paragraph. Notwithstanding the provisions of this Section 7.4(d), the Purchaser shall not be required to contribute, in the aggregate, any amount in excess of the amount by which the proceeds actually received by the Purchaser from the sale of the Registrable Securities subject to the Proceeding exceeds the amount of any damages that the Purchaser has otherwise been required to pay by reason of such untrue or alleged untrue statement or omission or alleged omission. No person guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Securities Act) shall be entitled to contribution from any person who was not guilty of such fraudulent misrepresentation.

The indemnity and contribution agreements contained in this Section 7.4(d) are in addition to any liability that the Indemnifying Parties may have to the Indemnified Parties.

7.5 Rule 144; Rule 144A Reporting . With a view to making available to the Purchaser and Holders the benefits of certain rules and regulations of the SEC which may permit the sale of the Registrable Securities to the public without registration, the Company agrees to use its commercially reasonable efforts to:

(a) make and keep public information available, as those terms are understood and defined in Rule 144(c)(1) or any similar or analogous rule promulgated under the Securities Act, at all times after the effective date of this Agreement;

(b) file with the SEC, in a timely manner, all reports and other documents required of the Company under the Exchange Act, and if at any time the Company is not required to file such reports, make available, upon the request of any Holder, such information necessary to permit sales pursuant to Rule 144A (including the information required by Rule 144A(d)(4) and the Securities Act); and

(c) so long as the Purchaser or a Holder owns any Registrable Securities, furnish to the Purchaser or such Holder forthwith upon request: a written statement by the Company as to its compliance with the reporting requirements of Rule 144 under the Securities Act, and of the Exchange Act; a copy of the most recent annual or quarterly report of the Company; and such other reports and documents as the Purchaser or Holder may reasonably

request in availing itself of any rule or regulation of the SEC allowing it to sell any such securities without registration; and

(d) to take such further action as any Holder may reasonably request, all to the extent required from time to time to enable such Holder to sell Registrable Securities without registration under the Securities Act.

7.6 Dispositions. The Purchaser agrees that it will comply with the prospectus delivery requirements of the Securities Act as applicable to it in connection with sales of Registrable Securities pursuant to the Registration Statement and shall sell its Registrable Securities in accordance with the Plan of Distribution set forth in the Prospectus. The Purchaser further agrees that, upon receipt of a notice from the Company of the occurrence of any event of the kind described in Sections 7.2(b)(iv), (v), (vi) or (vii), the Purchaser will discontinue disposition of such Registrable Securities under the Registration Statement until the Purchaser is advised in writing by the Company that the use of the Prospectus, or amended Prospectus, as applicable, may be used. The Company may provide appropriate stop orders to enforce the provisions of this paragraph.

8. Termination; Liabilities Consequent Thereon. This Agreement may be terminated and the transactions contemplated hereunder abandoned at any time prior to the Second Closing by mutual agreement of the Company and the Purchaser. Any termination pursuant to this Section 8 shall be without liability on the part of any party, unless such termination is the result of a material breach of this Agreement by a party to this Agreement in which case such breaching party shall remain liable for such breach notwithstanding any termination of this Agreement; provided, however, that if at the time of termination both the Second Closing Shares remain unissued and the Make-Whole HSR Cash Payment remains unpaid, then the Company shall pay the Make-Whole HSR Cash Payment to the Investor on the first business day immediately following the termination.

9. Miscellaneous Provisions.

9.1 Public Statements or Releases. None of the parties to this Agreement shall make, issue, or release any announcement, whether to the public generally, or to any of its suppliers or customers, with respect to this Agreement or the transactions provided for herein, or make any statement or acknowledgment of the existence of, or reveal the status of, this Agreement or the transactions provided for herein, without the prior consent of the other parties, which shall not be unreasonably withheld or delayed, provided, that nothing in this Section 9.1 shall prevent any of the parties hereto from making such public announcements as it may consider necessary in order to satisfy its legal obligations, but to the extent not inconsistent with such obligations, it shall provide the other parties with an opportunity to review and comment on any proposed public announcement before it is made.

9.2 Further Assurances. Each party agrees to cooperate fully with the other party and to execute such further instruments, documents and agreements and to give such further written assurances, as may be reasonably requested by the other party to better evidence and reflect the transactions described herein and contemplated hereby, and to carry into effect the intents and purposes of this Agreement.

9.3 Rights Cumulative. Each and all of the various rights, powers and remedies of the parties shall be considered to be cumulative with and in addition to any other rights, powers and remedies which such parties may have at law or in equity in the event of the breach of any of the terms of this Agreement. The exercise of any right, power or remedy shall neither constitute the exclusive election thereof nor the waiver of any other right, power or remedy available to such party.

9.4 Pronouns. All pronouns or any variation thereof shall be deemed to refer to the masculine, feminine or neuter, singular or plural, as the identity of the person, persons, entity or entities may require.

9.5 Notices.

(a) Any notices, reports or other correspondence (hereinafter collectively referred to as “correspondence”) required or permitted to be given hereunder shall be sent by postage prepaid first class mail, courier or telecopy or delivered by hand to the party to whom such correspondence is required or permitted to be given hereunder. Any notice or other communication delivered by hand or mailed shall be deemed to have been delivered on the date on which such notice or communication is delivered by hand, or in the case of certified mail deposited with the appropriate postal authorities on the date when such notice or communication is actually received, and in any other case shall be deemed to have been delivered on the date on which such notice or communication is actually received.

(b) All correspondence to the Company shall be addressed as follows:

Align Technology, Inc.
881 Martin Avenue
Santa Clara , CA 95050
Attention : President and Chief Executive Officer
Facsimile: 408-470-1010

with a copy to:

Wilson Sonsini Goodrich & Rosati
650 Page Mill Road
Palo Alto, CA 94304
Attention: Chris F. Fennell
Facsimile : 650-493-6811

(c) All correspondence to the Purchaser shall be addressed as follows:

Danaher Corporation
2099 Pennsylvania Avenue, NW
Washington, DC 20006
Attention: General Counsel
Facsimile: 202-419-7676

with a copy to:

Wachtell, Lipton, Rosen & Katz
51 West 52nd Street
New York, NY 10019
Attention: Trevor S. Norwitz
Facsimile : 212-403-2333

9.6 Captions. The captions and paragraph headings of this Agreement are solely for the convenience of reference and shall not affect its interpretation.

9.7 Severability. Should any part or provision of this Agreement be held unenforceable or in conflict with the applicable laws or regulations of any jurisdiction, the invalid or unenforceable part or provisions shall be replaced with a provision which accomplishes, to the extent possible, the original business purpose of such part or provision in a valid and enforceable manner, and the remainder of this Agreement shall remain binding upon the parties hereto.

9.8 Governing Law; Injunctive Relief.

(a) This Agreement shall be governed by and construed in accordance with the internal and substantive laws of Delaware and without regard to any conflicts of laws concepts which would apply the substantive law of some other jurisdiction.

(b) Each of the parties hereto acknowledges and agrees that damages will not be an adequate remedy for any material breach or violation of this Agreement if such material breach or violation would cause immediate and irreparable harm (an “Irreparable Breach”). Accordingly, in the event of a threatened or ongoing Irreparable Breach, each party hereto shall be entitled to seek, in any state or federal court in the State of Delaware, equitable relief of a kind appropriate in light of the nature of the ongoing or threatened Irreparable Breach, which relief may include, without limitation, specific performance or injunctive relief. Such remedies shall not be the parties’ exclusive remedies, but shall be in addition to all other remedies provided in this Agreement.

9.9 Amendments. No provision of this agreement may be waived, changed or modified, or the discharge thereof acknowledged orally, but only by an agreement in writing signed by the party against which the enforcement of any waiver, change, modification or discharge is sought.

9.10 Expenses. Each party will bear its own costs and expenses in connection with this Agreement.

9.11 Assignment. This Agreement shall be binding upon and inure to the benefit of the parties and their successors and permitted assigns. Except as otherwise set forth in this Agreement, the Company may not assign this Agreement or any rights or obligations hereunder without the prior written consent of the Purchaser, except in connection with a Change in Control of the Company. The Purchaser may designate one of its subsidiaries to hold the Shares and may assign its rights under this Agreement to any person to whom the Purchaser assigns or transfers any Shares, provided (i) such transferor agrees in writing with the transferee or assignee to assign such rights, and a copy of such agreement is furnished to the Company after

such assignment, (ii) the Company is furnished with written notice of the name and address of such transferee or assignee, (iii) such transferee agrees in writing to be bound, with respect to the transferred Shares, by the provisions hereof that apply to the Purchaser and (iv) such transfer shall have been made in accordance with the applicable requirements of this Agreement and with all laws applicable thereto.

9.12 Survival. The respective representations and warranties given by the parties hereto, and the other covenants and agreements contained herein, shall survive the Second Closing Date and the consummation of the transactions contemplated herein for a period of two years, without regard to any investigation made by any party.

9.13 Entire Agreement. This Agreement and the other Transaction Documents constitute the entire agreement between the parties hereto respecting the subject matter hereof and supersedes all prior agreements, negotiations, understandings, representations and statements respecting the subject matter hereof, whether written or oral.

IN WITNESS WHEREOF, the parties hereto have executed this Agreement under seal as of the day and year first above written.

Company

ALIGN TECHNOLOGY, INC.

By: /s/ Thomas M. Prescott

Name: Thomas M. Prescott

Title: President and Chief Executive Officer

Purchaser

DANAHER CORPORATION

By: /s/ Robert S. Lutz

Name: Robert S. Lutz

Title: VP - Chief Accounting Officer

Schedule 3.6(b)

Any matter disclosed in this Schedule 3.6(b) shall not be deemed an admission or representation as to the materiality of the item so disclosed. No disclosure in this Schedule 3.6(b) relating to any possible breach or violation of any agreement, law or regulation shall be construed as an admission or indication that any such breach or violation exists or has actually occurred, and nothing in this Schedule 3.6(b) constitutes an admission of any liability or obligation of Align Technology, Inc. (the "Company") to any third party or shall confer upon or give to any third party any remedy, claim, liability, reimbursement, cause of action or other right.

This Schedule 3.6(b) and the information and disclosures contained in this Schedule 3.6(b) shall provide an exception to or otherwise qualify the representations, warranties and covenants of Company contained in the Stock Purchase Agreement dated August 16, 2009 between the Company and Danaher Corporation specifically referred to in such disclosure and such other representations, warranties and covenants, to the extent such disclosure shall reasonably appear to be applicable to such other representations, warranties and covenants.

On August 11, 2009, a purported class action complaint was filed in the United States District Court for the Northern District of California by Charles Wozniak against the Company and its president and chief executive officer. The complaint alleges that, during a purported class period of January 30, 2007 through October 24, 2007, the defendants made false and misleading statements concerning the Company's business, operations and financial prospects in violation of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and SEC Rule 10b-5 promulgated thereunder. The plaintiff in the action seeks damages of an unspecified amount.

Schedule 4.7

As of the date of this Agreement, Purchaser owns 850,643 shares of Purchaser Common Stock.

CONFIDENTIAL TREATMENT REQUESTED BY ALIGN TECHNOLOGY, INC.

**JOINT DEVELOPMENT, MARKETING
AND SALES AGREEMENT**

This Joint Development, Marketing and Sales Agreement (the “Agreement”) is made and entered into as of the “Effective Date” (defined below) by and between Align Technology, Inc., a Delaware Corporation, having a place of business at 881 Martin Avenue, Santa Clara, California 95050 (“Align”), and Ormco Corporation, a Delaware corporation, with offices at 1717 West Collins Avenue, Orange, California 92867, (“Ormco”, each a “Party”, together the “Parties”).

WHEREAS, Ormco is engaged in the manufacture, distribution, sale and marketing of orthodontic products including, among other things, a customized fixed bracket and wire system and method of placing customized appliances on the teeth of patients;

WHEREAS, Align is also engaged in the manufacture, distribution, sale and marketing of an orthodontic product, namely a removable aligner;

WHEREAS, the Parties desire to enter into a business relationship related to the development, marketing and sale of a solution for treating malocclusions consisting of the use of both Ormco fixed customized brackets and wires and Align’s removable aligners; and

WHEREAS, the Parties acknowledge that they must share know-how, sales resources and information in order to create and market a new joint solution that would be marketed to dental professionals worldwide and the Parties desire to set forth the terms on which the Parties shall collaborate in the design, development, production, marketing and sale of an initial joint solution product and future joint solutions that the Parties determine to make;

NOW THEREFORE, in consideration of the foregoing, and of the mutual covenants and promises as set forth herein, the receipt and sufficiency of which are hereby acknowledged, the Parties hereof agree as follows:

1. Definitions.

As used herein, the following words or phrases have the following meanings:

1.1 “13D Group” means any group of persons formed for the purpose of acquiring, holding, voting or disposing of voting securities which would be required under Section 13(d) of the Exchange Act, and the rules and regulations promulgated thereunder, to file a statement on Schedule 13D pursuant to Rule 13d-1(a) or a Schedule 13G pursuant to Rule 13d-1(c) with the SEC as a “person” within the meaning of Section 13(d)(3) of the Exchange Act if such group beneficially owned voting securities of the Company representing more than 5% of any class of voting securities then outstanding.

1.2 “Affiliates” shall mean any corporation, company or other legal entity which controls, is controlled by, or is under common control with, a Party directly or

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indirectly through one or more intermediaries, but any such corporation, company or legal entity shall be deemed to be an Affiliate only as long as such control exists. For purposes of this definition, “control” means direct or indirect ownership of more than fifty percent (50%) of (i) the voting power of the shares or other securities of the corporation or company for election of directors (or other managing authority) or (ii) interest in the net assets or profit of a legal entity which is not a corporation or company.

1.3 “Align Intellectual Property” means any and all Intellectual Property owned or controlled by Align or its Affiliates as of the Effective Date or written, invented, developed or otherwise created thereafter solely by or on behalf of Align or its Affiliates, or separately acquired by Align or its Affiliates, and expressly excludes anyOrmco Intellectual Property.

1.4 “Align Products” shall mean the systems and products provided to a dental professional by Align to enable that dental professional to provide its patients a set of removable aligners designed to move the teeth of an orthodontic patient to a final occlusion determined by the patient’s treating dental professional.

1.5 “Change in Control” means any of the following: (i) a merger, consolidation, statutory share exchange or other business combination or transaction involving a Party where the existing stockholders of the Party immediately prior to the effective date of such merger, consolidation or other business combination or transaction own less than 50% of the total voting securities of the surviving corporation following such merger, consolidation or other business combination or transaction in equivalent proportions to their interests prior to such effective date; (ii) any person or 13D Group becomes a beneficial owner, directly or indirectly, of 50% or more of the aggregate number of the voting securities of the Party or of properties or assets constituting 50% or more of the consolidated assets of the Party and its subsidiaries; (iii) in any case not covered by (ii), the Party issues securities representing 50% or more of its total voting power, including by way of a merger or other business combination with the Party or any of its subsidiaries; or (iii) a sale of all or substantially all the assets of the Party; provided, however, that a Change in Control shall not be deemed to occur if a Party that is a wholly-owned subsidiary as of the date hereof continues to be controlled by the same ultimate parent entity.

1.6 “Effective Date” means August 16, 2009.

1.7 “Hereof,” “herein,” and “hereunder” when used in this Agreement shall refer to the Agreement as a whole, unless the context otherwise requires.

1.8 “Hybrid Solution(s)” shall mean the use of the Ormco Product and Align Product in combination to treat malocclusions including the set-up, the design, and manufacturing of one or more customized fixed appliances, arch wires, and removable aligners designed for use on the teeth of an orthodontic patient.

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1.9 “Intellectual Property” means any or all of the following and all rights in, arising out of, or associated therewith: (A) all United States and foreign patents and utility models and applications therefor and all reissues, divisions, re-examinations, renewals, extensions, provisionals, continuations and continuations-in-part thereof and equivalent or similar rights anywhere in the world in inventions and discoveries including without limitation invention disclosures (“Patents”); (B) all trade secrets and other rights in know-how and confidential or proprietary information (including Proprietary Information) (“Trade Secrets”); (C) all copyrights, copyright registrations and applications therefor and all other rights corresponding thereto throughout the world (“Copyrights”); (D) trademarks, service marks, trade dress, company names, brand names, logos, and fictitious names, together with any and all worldwide vested and/or inchoate rights in and to any or all of the foregoing (“Trademarks”); (E) utility models and/or any other form of protection of various forms of intellectual and/or industrial property recognized anywhere in the world including any and all rights of domestic and/or foreign priority; and (F) any similar, corresponding or equivalent rights to any of the foregoing anywhere in the world, including the right to sue and recover damages for infringements including, without limitation, any past infringements.

1.10 “Joint Development Intellectual Property” means any and all Intellectual Property written, invented, developed or otherwise created by Align and Ormco jointly in the course of the Project during the Term of this Agreement. Whether Intellectual Property written, invented, developed or otherwise created in the course of the Project during the Term of this Agreement is “jointly” written, invented, developed or otherwise created shall be determined in accordance with the applicable sections of United States Code Title 35 — Patents, or, with respect to original works of authorship or rights in semiconductor topology applicable sections of United States Code Title 17 — Copyrights, regardless of whether the Intellectual Property is patentable, copyrightable, or eligible for mask work right protection. Joint Development Intellectual Property shall not include any Align Intellectual Property or Ormco Intellectual Property.

1.11 “Ormco Intellectual Property” means any and all Intellectual Property owned by Ormco or its Affiliates as of the Effective Date or invented, developed or otherwise created thereafter solely by or on behalf of Ormco or its Affiliates, or separately acquired by Ormco or its Affiliates, and expressly excludes any Align Intellectual Property.

1.12 “Ormco Products” shall mean the systems and products provided to a dental professional by Ormco that enables the dental professional to provide a patient fixed orthodontic appliances, arch wires, and placement jigs that have been created for use on that particular individual orthodontic patient.

1.13 “Project” means the design, development, implementation, testing, modification and/or improvement of the Hybrid Solution, whether products, hardware, software, electronic, mechanical or otherwise.

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1.14 “Proprietary Information” means information, data, know-how, trade secrets or experience whether patentable or not including, without limitation, all design or manufacturing techniques, operating instructions, machinery designs, raw materials or products specifications, drawings, blue prints, all computer programs, source code, algorithms, software routines, microcode and other similar data and any other technical and commercial information relating to the research, design, development, manufacture, assembly, use or sale of orthodontic appliances.

1.15 “Regulatory Authorities” shall mean the United States Food and Drug Administration (“FDA”) and all other governmental or regulatory authorities existing anywhere in the world having jurisdiction over the marketing, manufacture and/or commercial sale of the Hybrid Solution or any component thereof.

1.16 “Specifications” means those performance and other specifications for the operation, form and other material characteristics of a Hybrid Solution (or portion thereof) as determined by the Parties in accordance with this Agreement.

1.17 “Term” means the period from the Effective Date through the Termination Date.

1.18 “Termination Date” means any date upon which this Agreement shall terminate in accordance with the terms hereof.

2. Steering Committee.

2.1 The Parties will organize the Steering Committee promptly after the Effective Date of this Agreement. The initial membership of the Steering Committee shall be composed of the President of Ormco, the Vice President of Marketing and Product Development for Ormco, a member of Ormco’s Product Management Group, a member of Align’s Sales Management Group, the Vice President of Operations of Align and the Vice President of Research and Development, and ITG of Align. The Parties may, from time to time, change or replace their representative on the Steering Committee with another person having a similar level of responsibility as the person being replaced. The Steering Committee shall convene on such schedule (but not less frequently than monthly) and employ such procedures as it shall determine from time to time in good faith, and, except as otherwise specifically required by this Agreement, shall act by unanimous consent.

2.2 The Steering Committee will provide general oversight and coordination of the Parties’ collaboration for the Project, and will be responsible for overseeing the creation of development and marketing plans and schedules for the Project, monitoring the Parties’ progress on the development and marketing of the Hybrid Solutions, and determining the content and frequency of reports to be generated by the parties. The Steering Committee may develop and unanimously agree upon work plans to address all such activities as it determines, and make amendments thereto, including with respect those terms relating to the commercialization and marketing of the Hybrid Solution.

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Each Party will conduct its respective activities designated in each such agreed upon work plan in the manner and on the schedule specified therein.

2.3 **Contacts.** The Steering Committee will designate employees at both Ormco and Align who will serve as (i) the technical persons responsible for facilitating communications between Align and Ormco regarding the design, development, and testing of the Hybrid Solutions and all enhancements to it; (ii) persons with authority to review and approve on behalf of such Party usage of the Product Tradename (as per Section 10), (iii) the persons responsible for the development and implementation of all advertising and marketing initiatives for the Hybrid Solutions, (iv) persons responsible for coordinating all sales and customer service activities with respect to the Hybrid Solution, and (v) persons responsible for coordinating all manufacturing and shipping operations related to the Hybrid Solution. Each party may request the Steering Committee to change its respective contacts at any time by providing the Committee with a written notice requesting the change and explaining the reason for the request.

2.4 The Parties will resolve deadlock among the Steering Committee through the Executive Review procedure described in Section 13.7 below.

2.5 **Executive Sponsors.** Each Party shall appoint a member of its senior management as an executive sponsor for the Project (“Executive Sponsor”). Executive Sponsors will be responsible for monitoring the Parties’ relationship, conducting periodic briefings for each other and their management teams, and providing a defined means of communication with other senior executives. Each Party may change its Executive Sponsor at any time by written notice to the other Party.

3. Joint Development.

3.1 **Development of the Product.** Subject to the terms and conditions of this Agreement, Align and Ormco shall cooperate with and assist each other in the joint design and development of the Hybrid Solution. The development of the Hybrid Solution shall seek to include the functionalities described in Exhibit A attached hereto and such other Specifications to which the Parties agree.

3.2 Any work plan created to develop the Hybrid Solution must be unanimously approved by the Steering Committee. As applicable, each work plan shall include, among other things:

- (1) The Specifications for the Hybrid Solution;
- (2) Delivery and acceptance guidelines for deliverables and product or process identified in the mutually agreed upon plan, including all Hybrid Solutions prior to any commercial launch of the same;

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- (3) Allocation of responsibility for the actions required for development, implementation, marketing and support of the of the Hybrid Solutions;
- (4) Establishment of the Parties' respective corresponding personnel, and other resource commitments to the development of the Hybrid Solutions; and
- (5) Establishment of a schedule for carrying out the development and marketing activities for such Hybrid Solutions.

The Parties presently anticipate completing the development of Hybrid Solution 1.0 (as described in Exhibit A hereto) [*], subject to applicable regulatory compliance.

3.3 **Enhancements to the Product.** No less often than quarterly, the Steering Committee shall, during the course of its regularly scheduled monthly meetings, review (and modify as applicable) the Hybrid Solution development road map and associated work plan. Ormco and Align each acknowledge that from time to time it may be advantageous to develop enhancements to the Hybrid Solutions that incorporate enhancements to the Parties' respective product offerings that are components of the Hybrid Solution. The Parties shall work together to agree on the timing, extent or nature of such enhancements and/or revisions, or on the sharing of expense with respect to such enhancements and/or revisions.

3.4 **Costs of Performance.** Except as otherwise specifically provided in this Agreement, each Party will bear the costs and expenses of performing its obligations hereunder.

3.5 **Taxes.** Neither Party shall be obligated to pay any taxes of the other or any other expenses for which the other Party is liable to pay under applicable law based upon or in connection with the transactions contemplated by this Agreement.

4. Costs of Manufacture. Ormco shall bear all the costs and expenses, including taxes, related to the manufacture and shipping of the Ormco Product and Align shall bear all the costs and expenses, including taxes, related to the manufacture and shipping of the Align Product.

5. No License Fee. No license fee shall be due by either Align or Ormco with respect to Align Product or Ormco Product as incorporated into the Hybrid Solutions as marketed and sold in accordance with this Agreement. This Section 5 shall not apply to any product that is sold by either Align or Ormco independent of the Hybrid Solution even though the product being sold may be used for the same purpose as the component supplied by that Party to the Hybrid Solution.

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6. Marketing and Sales.

6.1 Terms and Conditions of Sales. The members of the Steering Committee shall research and analyze applicable data in order to determine negotiate and to reach agreement on the following matters as soon and as rapidly as practicable following the Effective Date within a timeframe as established by the Steering Committee but no later than [*]: (i) the initial list prices for the Hybrid Solution [*], (ii) the discounts that will be available to the various sales channels, (iii) the other terms and conditions of the sales of the Hybrid Solution to third party dental professionals (it being understood that any software provided to customer shall be subject to software end user licenses and not subject to sale), and (iv) the terms and conditions under which the Parties will act as the distributor of the Hybrid Solution. Align and Ormco shall cooperate in the future to establish different list prices and discounts as needed to address cost changes or market conditions. All other terms and conditions of sales of the Hybrid Solution that are not addressed in the mutually agreed-to terms shall be set by the Party selling the Hybrid Solution to the applicable end user.

6.2 Changes in Pricing. The list price for the Hybrid Solution will be reviewed by the Steering Committee on an annual basis, or sooner upon the request of a Party hereto.

6.3 Marketing Assistance/Assignment of Sales Personnel. Align and Ormco shall, each at its own expense, cooperate in marketing and selling the Hybrid Solution. For each sales lead generated by or becoming known to a Party hereto, each Party shall, for a preliminary time period to be agreed upon by the Steering Committee, when requested by the Party identifying the lead, use its reasonable efforts to provide a sales representative to assist in pursuing such leads with a view toward generating a sale of the Hybrid Solution.

6.4 Marketing Plan. The Parties will jointly develop as soon as practicable a comprehensive marketing plan and a milestone based program plan for the worldwide introduction of the Hybrid Solution, which introduction shall consider, among other things, Ormco's and Align's respective manufacturing capacities. There shall be overall joint cooperation and review of all proposed promotional and marketing initiatives with respect to the Hybrid Solution. Periodic conferences shall be held among the Align and Ormco marketing personnel designated by the Steering Committee to review the progress of the advertising and marketing initiatives implemented pursuant to this Agreement and to discuss and review in advance any new advertising and marketing strategies with respect to the Hybrid Solution. The Parties shall make a good faith effort to agree on any necessary changes to the advertising and marketing strategies developed under this Agreement.

6.5 Sales Efforts.

6.5.1 Within [*] days following the Effective Date, the Steering Committee shall use commercially reasonable efforts to establish mutually

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agreed upon sales targets with respect to the Hybrid Solution. Thereafter, on a quarterly basis the Steering Committee shall review and revise such sales targets. Each Party shall annually establish sales goals for its sales representatives for the sale of the Hybrid Solution consistent with achieving such sales targets.

6.5.2 Each Party shall, at its own expense, use its commercially reasonable efforts to introduce, market, promote and take orders for the Hybrid Solution worldwide, actively seek qualified customers for the Hybrid Solution, make regular sales calls to qualified dental professionals all in an effort to meet and exceed such mutually agreed upon sales targets. The Steering Committee may, from time to time in its discretion, develop sales procedures for such matters as contact management and enhancement and coordinated selling activities with respect to the Hybrid Solution.

6.5.3 The Parties shall each, at its own cost and expense, provide its sales professionals with sufficient training, resources and materials to directly promote and sell the Hybrid Solution to dental professionals.

6.5.4 The Parties shall cooperate, each at its own expense, to develop training materials and programs with respect to the Hybrid Solutions for use with potential purchasers of the Hybrid Solution, and following such development shall at its own expense, make such training available to those potential purchasers.

6.6 Non-Competition.

6.6.1 During the Term (and during the Non-Renewal Transition Period solely with respect to restricting the activities of the Electing Party and such party's Affiliates, successors or assigns), neither Ormco nor Align (nor any of their Affiliates, successors or assigns) shall, directly or indirectly, for itself or on behalf of or in conjunction with any Affiliate, other person, firm, company, partnership, corporation, business, group, association or other entity (a "Person"), engage in (or facilitate or provide any cooperation (including any Intellectual Property) to any other such Person), whether as facilitator, participant, owner, partner, or joint venturer, independent contractor, consultant, advisor, sales representative, or in any managerial capacity, in any business developing or selling a [*].

6.6.2 Ormco reserves all rights, for its sole benefit and profit to sell, make, have made, import, have imported, use, distributed, offer, or offer to sell (i) removable aligners to dental professionals; provided, however, it does not market the removable aligners for use in combination with the Ormco Product to treat an orthodontic patient and (ii) fixed orthodontic

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appliances as a stand-alone solution. Align reserves all rights, for its sole benefit and profit to sell, make, have made, import, have imported, use, distributed, offer, or offer to sell (i) fixed orthodontic appliances to dental professionals; provided, however, it does not market the fixed orthodontic appliances for use in combination with the Align Product to treat an orthodontic patient and (ii) removable aligners as a stand-alone solution. The Parties acknowledge and agree that no license to Intellectual Property is granted to the other Party pursuant to this Section 6.6.2.

6.7 **Certifications.** The Parties shall agree upon any requirements that must be met for a dental professional to purchase the Hybrid Solution which requirement may include the requirement for the dental professional to possess certain qualifications or obtain a certification from Ormco or Align, including without limitation, receiving appropriate training from Align with respect to the Align Product features included in the Hybrid Solution. The requirements shall be intended to increase the likelihood that the dental professional's experience with the Hybrid Solution is positive.

6.8 **No Marketing Fees.** It is contemplated that the Parties will share equally in the effort to advertise, promote and market the Hybrid Solution, with each Party bearing the cost of their advertising, promotional and marketing efforts (both costs incurred internally and paid to third parties). As a result, unless otherwise expressly agreed upon by the parties in a separate writing, or determined by the Steering Committee, neither Party will be required to pay to the other a fee for any advertising, promotion or marketing services performed by the other Party.

6.9 **Order Flow and Fulfillment.** Each Party will only sell the Hybrid Solutions to those dental professionals that (i) have received and are current in the training and certification contemplated herein, and (ii) are credit worthy as determined by mutually agreed upon criteria, and in absence of such mutually agreed upon criteria, as determined, in its reasonable discretion, by the Party selling the Hybrid Solution. With respect to Hybrid Solution Version 1.0, orders for such Hybrid Solution, whether generated by Align or Ormco, shall be submitted to Ormco for fulfillment. Ormco shall process orders for shipment in accordance with commercially reasonable standards. Ormco shall submit invoices to purchasers for products shipped and shall be responsible for collection of such invoices. Thereafter, for other Hybrid Solutions versions, the Parties shall mutually agree upon an order and fulfillment process, with each of the Parties using commercially reasonable efforts to timely manufacture, supply and deliver their respective Products for use in the Hybrid Solution.

6.10 **Reporting and Revenue Accounting.**

6.10.1 Each Party shall provide to the other Party written reports fifteen (15) days following the end of each month (provided that for those months in which a Party's fiscal quarter ends the report shall be, if practicable, provided to that Party 24 hours prior to the end of its fiscal quarter) that describe for those Hybrid Solutions sold by the reporting Party during the

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month: the identity of the purchasers of the Hybrid Solution, the products sold, quantities purchased, prices charged and any discounts applied.

6.10.2 [*] of the revenue generated from the sales of the Hybrid Solutions shall be considered the revenue of Ormco and [*] the revenue of Align for all accounting and other purposes. The Steering Committee shall determine the means to be used to calculate the revenue associated with the sale of the Hybrid Solution after taking into account such items as any applicable sales and use taxes a Party is required to pay, the gross invoice price of a Hybrid Solution as packed for shipment and the following items to the extent included in the gross invoice price: (i) sales or turnover taxes on sales invoices; (ii) transportation charges and insurance charges on shipments to customers; and (iii) trade or quantity discounts (but not cash discounts allowed to customers or agents' commissions); the handling of credits allowed for Hybrid Solution Products returned or not accepted by the customer; and such other factors as the Steering Committee deems appropriate.

6.10.3 The report described in Section 6.10.1 shall be accompanied by a check in the amount of [*] of any payments received during the month being reported for those Hybrid Solutions sold by the Parties (or if otherwise instructed by a Party, shall be made by wire transfer to an account designated by that Party in writing from time to time). With respect to revenue received in a currency other than U.S. Dollars, unless otherwise agreed upon by the Parties in writing, all such revenues shall be paid in the currency in which they were invoiced.

During the Term of the Agreement and for 3 years thereafter, Ormco and Align shall keep accurate records of its compliance with the payment terms of this Agreement. Each Party shall have the right, effective upon thirty (30) days prior written notice, during normal business hours, no more often than once per calendar year (unless a prior audit reveals a discrepancy), to have audited the relevant books and records relating to the other Party's compliance with such payment terms. If a Party elects to perform such audit through its own representatives, then the audited Party may, within thirty (30) days of receipt of the audit result, dispute the results, in which case the auditing Party may elect, at its sole discretion, to have the audit performed by an independent third-party auditor. The exercise by a Party of any right to audit or the acceptance by a Party of any report shall be without prejudice to any of the auditing Party's rights or remedies. If it is determined that the audited Party underreported and thus underpaid or has misrepresented any payment payable to the other Party by at least ten percent (10%) for the audited period, then the audited Party shall, in addition to making immediate payment of the payments due based on the actual and true items, pay all reasonable out-of-pocket costs

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and expenses paid by the auditing Party to the independent auditor.

7. Compliance with Laws and Business Practices. Any exports, sales, transfers, or any other disposition of Ormco Products and Align Products, to the extent incorporated in the Hybrid Solution, are subject to the laws and regulations of the United States. Specifically, contracts and orders placed for the Hybrid Solution may require advance U.S. Government Export approval or licensing, and, therefore all such contracts and orders are subject to the receipt of any necessary approvals and licenses. The Parties shall solicit orders, and each Party shall process and ship orders, in accordance with all applicable laws and regulations.

8. Regulatory Approval. For each country, territory, or other geographic subdivision into which the Parties agree to sell the Hybrid Solution (the “Selling Territory”) (i) Ormco shall be responsible for obtaining from, and maintaining with, any Regulatory Authority having jurisdiction in the Selling Territory over an Ormco Product the regulatory approval needed to import, manufacture and sell the Ormco Product in the Selling Territory and Ormco shall own all such regulatory approvals and (ii) Align shall be responsible for obtaining from, and maintaining with, any Regulatory Authority having jurisdiction in the Selling Territory over an Align Product the regulatory approval needed to import, manufacture and sell the Align Product in the Selling Territory and Align shall own all such regulatory approvals. Each Party shall bear the cost of obtaining the regulatory approvals for which it is responsible. The responsibility and cost of obtaining any regulatory approvals needed from a Regulatory Authority in a Selling Territory to import, manufacture and sell the Hybrid Solution or any component thereof that are in addition to those needed for the Align and Ormco Product, shall be equally shared by the Parties. The Parties shall jointly own those regulatory approvals.

9. Customer Support. Each Party shall establish and maintain support facilities sufficient to provide support for the Hybrid Solutions it provides to its customers; *provided however*, that Ormco shall provide mutually agreed upon back-up support to Align with respect to the Ormco Product portion of the Hybrid Solution and Align shall provide mutually agreed upon back-up support to Ormco with respect to the Align Product portion of the Hybrid Solution. The Parties shall maintain the availability of support services for a period of at least three years after the termination of this Agreement. The term “support,” for purposes of this Section 9, means resolving questions relating to, among other things, product delivery, product use, and clinical support.

10. Intellectual Property Rights.

10.1 Tradenames/Trademarks.

10.1.1 The Hybrid Solution shall be branded with one or more Trademarks that are acceptable to both Align and Ormco (the “Product Tradename”). The Product Tradename shall be used by the Parties only

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for purposes of marketing and selling the Hybrid Solution pursuant to this Agreement. Notwithstanding the foregoing, this Agreement does not impose any restrictions with respect to Align's use of the "Invisalign" Trademark on Align Products for any and all purposes and Ormco's use of the "Insignia" Trademark on Ormco Product for any and all purposes. Each Party's use of the Product Tradename shall comply with any mutually agreed upon Trademark usage guidelines. Each use by one Party of the Product Tradename shall, when appropriate to protect the Product Tradename, be accompanied by the appropriate trademark symbol (either "™" or "®"). If either Party's use of the Product Tradename, does not comply with the then-current Trademark usage policies agreed upon by the Parties, such Party will promptly remedy such deficiencies upon receipt of written notice of such deficiencies from the other Party.

10.1.2 Nothing herein is intended to nor shall operate to grant to a Party any other right, title or interest in the other Party's Trademarks. All goodwill resulting from the use of a Party's Trademark will inure solely to the Party owning such Trademark. Neither Party will, at any time during or after this Agreement, register, attempt to register, claim any interest in, contest the use of, or otherwise adversely affect the validity of any of each other's Trademark (including, without limitation, any act or assistance to any act, which may infringe or lead to the infringement of any such marks).

10.1.3 Align shall have no interest in any of Trademarks of Ormco; without limiting the generality of the foregoing clause of this sentence, Align shall have no rights with respect to the Trademark "Insignia" and related Trademarks. Ormco shall have no interest in any of the Trademarks of Align; without limiting the generality of the foregoing clause of this sentence, Ormco shall have no rights with respect to the Trademark "Invisalign" and related Trademarks.

10.2 Project Licenses.

10.2.1 Subject to the terms and conditions contained herein, during the Term of this Agreement and any three-year transition period as described in Section 12.4.3, Align hereby grants to Ormco a nontransferable, non-sublicensable, non-exclusive license to use the Align Intellectual Property (excluding Trademarks) solely to the extent as is required to fulfill its obligations under this Agreement to develop, manufacture, market the Hybrid Solution (and with respect to any three-year transition period, solely to the extent required to continue to develop, manufacture, market, promote, offer to sell and sell the Hybrid Solution during the transition period).

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10.2.2 Subject to the terms and conditions contained herein, during the Term of this Agreement and any three-year transition period as described in Section 12.4.3, Ormco hereby grants to Align a nontransferable, non-sublicensable, non-exclusive license to use the Ormco Intellectual Property (excluding Trademarks) solely to the extent as is required to fulfill its obligations under this Agreement to develop, manufacture, and market the Hybrid Solution (and with respect to any three-year transition period, solely to the extent required to continue to develop, manufacture, market, promote, offer to sell and sell the Hybrid Solution during the transition period).

10.2.3 Neither Party shall be entitled to use the Intellectual Property of the other Party to develop, manufacture or market a product that is not sold or otherwise transferred as a part of the sale of a Hybrid Solution as permitted under this Agreement. Each Party hereto acknowledges that the other has expended considerable time, effort and funds in developing and generating the Intellectual Property owned by it, and has and will continue to have a substantial proprietary interest and valuable trade secret therein.

10.2.4 Except as expressly provided under this Agreement, neither Party shall (nor shall they allow any third party to): (i) decompile, disassemble, reverse engineer or attempt to reconstruct, identify or discover, by any means whatever, any source code, underlying ideas, underlying user interface techniques or algorithms of any software provided by a Party hereto in object code format or disclose any of the foregoing (except to the extent that such restriction is impermissible under applicable law); (ii) modify, incorporate into or with other software or documentation, or create a derivative work of any part of the other Party's Intellectual Property; or (iii) attempt to copy, access, or distribute, or circumvent any use restrictions in, any software constituting the other Party's Intellectual Property.

10.3 Ownership of Intellectual Property.

10.3.1 Align Intellectual Property. Subject to the provisions of Section 10.2, nothing in this Agreement grants to Ormco any right, title or interest in and to any Align Intellectual Property. Except for the express licenses to Align Intellectual Property granted hereunder, Align reserves all rights, not expressly granted hereunder, in the Align Intellectual Property.

10.3.2 Ormco Intellectual Property. Subject to the provisions of Section 10.2, nothing in this Agreement grants to Align any right, title or interest in and any Ormco Intellectual Property. Except for the express licenses to Ormco Intellectual Property granted hereunder, Align reserves all rights, not expressly granted hereunder, in the Ormco Intellectual Property.

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10.3.3 Joint Development Intellectual Property. Joint Development Intellectual Property shall be owned jointly by Ormco and Align, with each of Ormco and Align (and their respective successors and assigns) holding an undivided one-half (1/2) unrestricted interest in such Joint Development Intellectual Property, with no duty of accounting. For the avoidance of doubt, any new Intellectual Property conceived of and developed solely by one party shall be owned solely by that party.

10.3.4 Notwithstanding anything to the contrary in this Agreement, in the event a Party translates into another language (“Translating Party”) any portion of the other Party’s Intellectual Property (“Material Owner”), the Translating Party acknowledges and agrees that ownership for such translated materials (“Translated Materials”) shall belong to the Material Owner, and accordingly, the Translating Party hereby irrevocably transfer, assigns and conveys (and agrees to transfer, assign and convey) all of the Translating Party’s right, title and interest in such Translated Materials (including copyrights therein) to the Material Owner.

10.4 Protection of Intellectual Property.

10.4.1 Each of the Parties shall make prompt, full and complete disclosure to the other of all Joint Development Intellectual Property it believes may be copyrightable, patentable or of commercial value.

10.4.2 With respect to all Joint Development Intellectual Property believed by either Party to be copyrightable, patentable or of commercial value, the Parties shall decide jointly whether and where to apply for copyright, patent or other appropriate forms of Intellectual Property registration and protection. To the extent the Parties agree to register and protect Joint Development Intellectual Property in a particular jurisdiction, the Parties shall do so at their joint expense using counsel as mutually agreed.

10.4.3 In the event the Parties elect not to jointly pursue protection of any Joint Development Intellectual Property, either Party (the “Protection Electing Party”) may seek such protection in its own name and at its sole expense using counsel of its choice. As to Joint Development Intellectual Property with respect to which the Protection Electing Party elects to seek protection, the non-electing party shall assign its intellectual property rights in and to such Joint Development Intellectual Property to the Protection Electing Party and the Protection Electing Party shall grant to the non-electing party a perpetual, non-revocable, worldwide, royalty free license to use the Joint Development Intellectual Property (for the avoidance of doubt, such license shall survive the termination of this

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Agreement).

10.4.4 All expenses of obtaining, renewing and or maintaining Intellectual Property protection or registration of a Party's Intellectual Property shall be borne by such Party, or, in the case of registration or protection sought jointly for the Joint Development Intellectual Property, by both Parties sharing equally in such expenses.

10.5 Enforcement of Intellectual Property Rights.

10.5.1 Align shall be solely responsible for enforcing any and all Align Intellectual Property in its sole discretion, and Ormco shall be solely responsible for enforcing any and all Ormco Intellectual Property in its sole discretion, whether or not such Align Intellectual Property or Ormco Intellectual Property is incorporated into the Hybrid Solution.

10.5.2 Each Party shall promptly to advise the other of suspected or known material infringements on any Joint Development Intellectual Property.

10.5.3 The Parties shall consult as to the appropriate action to be taken with respect to any material infringement of any Joint Development Intellectual Property. If the Parties agree to settle or jointly prosecute any claim for misappropriation and/or infringement of any Joint Development Intellectual Property, the Parties shall share equally in the costs and expenses, including attorney's fees, incurred in connection with such prosecution and shall share equally in any settlements or other recoveries thereon.

10.5.4 If one of the Parties hereto ("Abstaining Party") does not agree to be responsible for its full share of the costs and expenses of enforcing Joint Development Intellectual Property against a third party, then the other Party ("Acting Party") may sue in its own name and at its sole expense and, in such case, to the extent required under applicable law, the Abstaining Party shall agree to be joined as a plaintiff for standing purposes and to cooperate as reasonably requested in such action (subject to reimbursement for reasonable costs, expenses, and attorneys' fees attributable to such cooperation). In such event, any recovery shall inure to the Acting Party and not to the Abstaining Party, whether or not such Abstaining Party is compelled to joins as a plaintiff as provided herein.

10.6 Defense of Intellectual Property.

10.6.1 Align shall be solely responsible for defending any and all claims of third parties against Align Products for infringement or misappropriation, and Ormco shall be solely responsible for defending any and all claims of third parties against Ormco Products for infringement or misappropriation, whether or not the Align Product or Ormco Product at

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issue in any claim is incorporated into the Hybrid Solution.

10.6.2 Each Party shall promptly advise the other Party of claims of infringement brought, or threatened in a writing addressed to a Party, against any Ormco Product or Align Product used in the Hybrid Solution.

10.6.3 The Parties shall consult as to the appropriate action to be taken with respect to any third party claims asserting that the Hybrid Solution infringes or misappropriates a third party's Intellectual Property (a "Third Party Claim"). Any disputes regarding the appropriate action to be taken in response to the Third Party Claim shall be resolved in accordance with Section 13.7. The Parties shall, if they jointly elect to defend against the Third Party Claim, share equally in the costs and expenses, including attorney's fees, incurred in connection with such defense of the Hybrid Solution (subject to Ormco's responsibility for Ormco Products and Align's responsibility for Align Products). Each Party shall bear only such damages as are awarded against it.

10.7 Intellectual Property Marking. The Parties shall agree in writing to all Intellectual Property markings to be applied to the Hybrid Solution and Joint Development Intellectual Property, including Copyright and Patent notices. The Parties agree that all permitted distribution and marketing of the Hybrid Solution and Joint Development Intellectual Property (and copies thereof) shall include such mutually agreed upon markings.

10.8 Confidential Information.

10.8.1 Confidential Information. During the course of this Agreement, a Party ("Receiving Party") may be given access to information from the other Party ("Disclosing Party") that (i) relates to the other's past, present, and future research, development, business activities, products (including without limitation computer object and source code), services, and technical knowledge, and (ii) has been identified as confidential or reasonably deemed to be confidential information given the circumstances of disclosure (collectively, "Confidential Information"). Trade Secrets included in the Jointly Developed Intellectual Property shall be deemed the Confidential Information of both Parties under this Agreement. Notwithstanding, Confidential Information shall exclude information that the Receiving Party can demonstrate: (i) was independently developed by the Receiving Party without any use of the Disclosing Party's Confidential Information or by the Receiving Party's employees or other agents (or independent contractors hired by the Receiving Party) who have not been exposed to the Disclosing Party's Confidential Information; (ii) becomes known to the Receiving Party, without restriction, from a source (other than the Disclosing Party) that had a right to disclose it without breach of

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this Agreement; (iii) was in the public domain at the time it was disclosed or enters the public domain through no act or omission of the Receiving Party; or (iv) was rightfully known to the Receiving Party, without restriction, at the time of disclosure.

10.8.2 Confidentiality Obligation. The Receiving Party shall treat as confidential all of the Disclosing Party's Confidential Information and shall not use such Confidential Information except as may be expressly permitted under this Agreement. Without limiting the foregoing, the Receiving Party shall (i) not disclose or distribute the Disclosing Party's Confidential Information to a third party, and (ii) use at least the same degree of care which it uses to prevent the disclosure of its own confidential information of like importance, but in no event with less than reasonable care, to prevent the disclosure of the Disclosing Party's Confidential Information.

10.8.3 Agreement Terms. Each Party agrees that the terms and conditions, but not the existence, of this Agreement shall be treated as the other's Confidential Information and that no reference to the terms and conditions of this Agreement or to activities pertaining thereto may be made in any form of public or commercial advertising without the prior written consent of the other Party; provided, however, that each Party may disclose the terms and conditions of this Agreement: (i) as required by any court or other governmental body; (ii) as otherwise required by law; (iii) to legal counsel of the Parties; (iv) in connection with the requirements of an initial public offering or securities filing; (v) in confidence, to accountants, banks, and financing sources and their advisors; (vi) in confidence, in connection with the enforcement of this Agreement or rights under this Agreement; or (vii) in confidence, in connection with a merger or acquisition or proposed merger or acquisition, or the like.

10.8.4 Remedies. Unauthorized use by a Party of the other Party's Confidential Information will diminish the value of such information. Therefore, if a Receiving Party breaches any of its obligations with respect to confidentiality or use of the Disclosing Party's Confidential Information hereunder, the other Disclosing Party shall be entitled to seek equitable relief to protect its interest therein, including injunctive relief, as well as money damages.

10.8.5 Required Disclosure. In the event the Receiving Party must disclose the Disclosing Party's Confidential Information pursuant to the order or requirement of a court, administrative agency, or other governmental body, to the extent permitted under applicable law, the Receiving Party shall provide prompt notice thereof to the Disclosing Party and shall use its reasonable efforts to obtain a protective order or

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otherwise prevent public disclosure of such information.

11. Warranties and Limitation of Liability.

11.1 Warranty. Align hereby warrants to Ormco that under normal use and service, Align Products are free from defects in design and workmanship. Ormco hereby warrants to Align that under normal use and service, Ormco Products are free from defects in design and workmanship. Each Party warrants to the other that the products delivered by such Party for use in connection with the Hybrid Solution will be complete and in conformity with the products regularly supplied by each to purchasers and lessees of its other or similar products.

11.2 Product Warranty. The product forming a part of the Hybrid Solution shall be sold with a warranty to be agreed upon between the Parties hereto, essentially to the effect that the products will be free from defects in design, workmanship and material, for ninety (90) days following delivery (unless otherwise agreed upon by the Parties) and on such other terms and conditions as are to be agreed upon between the Parties. Subject to the limitations on warranty contained in this Agreement, Align shall assume all liability for breach of such warranty to the extent that a breach of warranty relates solely to Align Products incorporated into the Hybrid Solution. Subject to the limitations on warranty contained in this Agreement, Ormco shall assume all liability for breach of such warranty to the extent that such breach relates solely to Ormco Products incorporated into the Hybrid Solution. Align and Ormco shall jointly and equally assume all liability for breach of such warranty to the extent that a breach of warranty relates to matters that are not covered by either of the two preceding sentences.

11.3 Limitation on Warranty. EXCEPT AS OTHERWISE EXPRESSLY SET FORTH HEREIN AND EXCEPT FOR WARRANTY OF TITLE WITH RESPECT TO TANGIBLE ITEMS PROVIDED UNDER THIS AGREEMENT, NEITHER PARTY MAKES ANY OTHER WARRANTIES, EXPRESS OR IMPLIED TO THE OTHER WITH RESPECT TO ITS PRODUCTS. EXCEPT AS OTHERWISE EXPRESSLY SET FORTH HEREIN, THERE ARE NO WARRANTIES OR ANY AFFIRMATIONS OF FACT OR PROMISES BY EITHER PARTY HERETO AS TO MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, INFRINGEMENT OR OTHERWISE. THE EMPLOYEES OR AGENTS OF NEITHER PARTY HAVE ANY AUTHORITY TO MAKE ANY WARRANTY OR REPRESENTATION REGARDING THE MANNER OR BENEFITS OF USE OF ANY PRODUCT OTHER THAN THOSE EXPRESSLY SET FORTH IN THIS AGREEMENT.

11.4 Limitation of Liability. IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER FOR ANY INDIRECT, SPECIAL, INCIDENTAL, CONSEQUENTIAL, EXEMPLARY OR PUNITIVE DAMAGES, OR FOR LOSS OF PROFITS, REVENUE, OR DATA, WHETHER IN AN ACTION IN CONTRACT, TORT, STRICT LIABILITY OR OTHERWISE, EVEN IF ADVISED OF THE POSSIBILITY OF THOSE DAMAGES.

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11.5 Indemnity. Upon request of one Party (“Indemnified Party”), the other Party (“Indemnifying Party”) shall defend the Indemnified Party, its officers, directors, employees against, indemnify for and/or settle any third party claims, liabilities and losses, to the extent that such claims, liabilities and losses are alleged to arise out of the Indemnifying Party’s illegal or fraudulent acts related to the performance of this Agreement (except to the extent that such claims, liabilities and losses are attributable to the Indemnified Party’s own illegal or fraudulent acts). Such indemnification is expressly conditioned upon Indemnified Party promptly notifying the Indemnifying Party of such third party claims in writing. The Indemnified Party shall cooperate with the Indemnifying Party in all reasonable respects in connection with the defense of any such action and provide the Indemnifying Party the authority to assume and control the defense thereof, and if it so undertakes, it shall also undertake all other required steps or proceedings to settle or defend any such action, including the employment of counsel, and payment of all reasonably incurred expenses. The Indemnified Party shall have the right to employ separate counsel to provide input into the defense, at the Indemnified Party’s own cost. The Indemnified Party shall not settle any claim or action under this Section 11.5 without first obtaining Indemnifying Party’s written permission, which permission shall not be unreasonably withheld.

12. Term and Termination.

12.1 Term. This Agreement, unless earlier terminated in accordance with one or more provision of this Agreement, shall remain in effect during a period commencing with the Effective Date and ending on [*] (the “Initial Term”); provided, however, the Agreement shall continue to remain in full force and effect following the end of the Initial Term for two successive two (2) year terms (the “Renewal Terms”), unless six months prior to the end of the Initial Term or a Renewal Term one Party provides the other written notice of its desire to have the Agreement terminate at the end of the Term then in effect.

12.2 Conditions for Termination. This Agreement shall terminate upon any of the conditions contained in this Section 12.2.

12.2.1 This Agreement shall terminate upon the occurrence of a material breach of this Agreement by either Party hereto (a “Termination for Breach”), provided:

12.2.1.a The breaching Party (the “Breaching Party”) is given a written notice by the other Party hereto containing a claim of breach and setting forth the nature of the breach and circumstances giving rise to such a claim and the other Party (the “Non-Breaching Party”) does not elect to waive its right to terminate; and

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12.2.1.b The Party to whom the written notice is given fails to remedy such circumstances within sixty (60) days after receipt of the notice.

12.2.2 [*].

12.3 This Agreement shall terminate if any of the following events occur as to one Party hereto (the “ Affected Party ”) and the other Party (the “ Non-Affected Party ”) does not provide written notice within thirty (30) days after it becomes aware of such event that it intends to waive termination of this Agreement: (i) a Party makes an assignment for the benefit of its creditors, requests or permits a proposal, arrangement or reorganization under or, as an insolvent debtor, takes the benefit of any legislation now or hereafter in force for bankrupt or insolvent debtors; (ii) a receiver or other officer with like powers is appointed for a Party for a substantial part of its assets; (iii) a lienholder takes possession of a substantial and material part of a Party’s property; (iv) an order is made for the winding up, liquidation, revocation, or cancellation of incorporation of a Party; or (v) a Party ceases carrying on its business as a going concern (collectively, a “ 12.3 Termination ”).

12.4 Effects of Termination/Liability.

12.4.1 Except as set forth herein, neither Party shall be liable to the other for any claims, damages, costs, expenses or other charges incurred in connection with the entering into, performance, breach, termination, expiration or non-renewal of this Agreement including but not limited to, any damages based on injury to reputation or on any loss (or anticipated loss) of business, sales, profits, earnings or income, in any way related to expenditures, investments, costs, actions taken or commitments made or entered into in reliance of or in any way related to the performance of this Agreement, unless specifically provided for herein. This Section 12.4.1 shall not apply to any claims any Party may have against another Party relating to infringement of such Party’s Intellectual Property.

12.4.2 Notwithstanding the Termination Date of this Agreement, the provisions of Sections 10 (excluding 10.1 and 10.2), 11, 12.4 and 13 shall survive the Termination Date indefinitely, and the provisions of Section 6.10 shall survive until the third anniversary of the Termination Date. Without limiting the generality of the foregoing sentence, for three years after the Termination Date, each Party shall continue to use commercially reasonable efforts to supply to the other Party on reasonable commercial terms such number of the other Party’s Products as may be required for a Party to fulfill orders for the Hybrid Solution that were accepted prior to the Termination Date.

12.4.3 If only one Party elects to not renew any Term (the “ Electing ”

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Party”), then the other Party (the “Non-Electing Party”) shall have the right to continue to market, promote, offer to sell and sell the Hybrid Solution under the Product Tradename for a period of three calendar years following the Termination Date (in the case of such non-renewal, the “Non-Renewal Transition Period”). [*]. A three-year transition period shall also apply with respect to a Termination for Breach and, to the fullest extent possible given the circumstances of the Affected Party, to a 12.3 Termination. The Electing Party, [*], the Breaching Party, or the Affected Party, as applicable (the “Non-Transitioning Party”), shall be obligated to provide the Non-Electing Party, [*], the Non-Breaching Party, or the Non-Affected Party, as applicable (the “Transitioning Party”) when needed, with (and manufacture as needed) such number of the Non-Transitioning Party’s Products as are required by the Transitioning Party for orders accepted by the Transitioning Party for the Hybrid Solution during the three-year transition period. The amount to be charged by the Non-Transitioning Party for the Products it supplies to the Transitioning Party shall be negotiated by the Parties but shall in no event yield to the Non-Transitioning Party a gross profit per product with respect to such Products greater than 50% of the average gross profit per product for such Products over the 12 months preceding the Termination Date.

13. Miscellaneous Provisions.

13.1 Authority; No Conflict. This Agreement constitutes the legal, valid and binding obligation of both Parties. The Parties have the absolute and unrestricted right, power, and authority to execute and deliver this Agreement and to perform all obligations under this Agreement.

13.2 Assignment. Neither Party shall assign this Agreement or any interest therein or any of the rights provided herein; provided however, that a Party undergoing a Change in Control may assign this Agreement without consent in connection with such Change in Control of such Party [*] without the prior written consent of the other Party. Any assignment or transfer in contravention of this provision shall be null and void. This Agreement shall be binding upon and inure to the benefit of the parties hereto, and their respective permitted assigns and successors. Nothing in this Agreement shall be interpreted to grant any rights to or permit any party to grant any rights to any person or entity that is not a party hereto.

13.3 Confidentiality. Each Party shall ensure that it, its employees and third party agents having access to any Confidential Information or Proprietary Information of the other Party, will restrict and control the use, copying, modification, disclosure, transfer, protection and security of such items, in accordance with these provisions. Each Party shall protect the Confidential Information or Proprietary Information of the other Party with at least the same standard of care that it uses to protect its own like

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information.

13.4 Nonsolicitation. The Parties hereto shall not, at any time during the term this Agreement and for a period of one year thereafter, directly or indirectly, for itself or for any other person, firm, corporation, partnership, association or other entity, solicit the employment of any employee of the other Party, unless such employee or former employee has not been employed by the other Party, its subsidiaries or its predecessors in interest, for a period in excess of six months; provided, however, that the restrictions of this Section 13.3 shall not apply to any solicitation (or hiring or employment as a result of any solicitation) that consists of advertising in a newspaper or periodical of general circulation or through the Internet.

13.5 Publicity. Subject to each Party's disclosure obligations imposed by law or regulation or stock exchange rule or trading market listing requirement, the Parties will cooperate with each other in the development and distribution of all news releases and other public information disclosures with respect to this Agreement, and no Party will make any such news release or public disclosure without first consulting with the other Parties and receiving their consent (which shall not be unreasonably withheld, conditioned or delayed), and each of the Parties shall coordinate with the each other with respect to any such news release or public disclosure and use reasonable best efforts to obtain confidential treatment with respect to any commercially-sensitive information required by law or regulation or stock exchange rule or trading market listing requirement to be disclosed and to cooperate in seeking confidential treatment for any such information or other documentation required by law or regulation to be filed with the Securities and Exchange Commission or other governmental entity. .

13.6 Notices. All notices permitted or required hereunder shall be effective: upon receipt if delivered personally; on the third business after sending if sent via registered or certified U.S. mail, postage paid, return receipt requested; on the second business day after sending, charges prepaid for next day delivery, via a nationally recognized overnight delivery service (Federal Express, DHL and UPS are acceptable for these purposes); and upon acknowledgment of receipt by the Party to be charged with notice if sent via any other means. Notice shall be given to the following address or to such other address as to which a Party shall give notice:

| | |
|--------------|--|
| If to Align: | Align Technology, Inc. 881 Martin Avenue Santa Clara, California 95050 Attention: General Counsel |
|--------------|--|

| | |
|--------------|--|
| If to Ormco: | Ormco Corporation 1717 W. Collins Ave Orange, CA 92867 Attention: General Counsel |
|--------------|--|

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13.7 Dispute Resolution

13.7.1 Internal Review. In the event that a dispute, difference or question arises pertaining to any matters which are the subject of the Alliance (“Dispute”), and either Party so requests in writing, prior to the initiation of any formal legal action, the following dispute resolution shall apply:

13.7.2 The Steering Committee will use its good faith efforts to resolve the Dispute within ten (10) days. If the Steering Committee is unable to resolve the Dispute in such period, the Steering Committee will refer the Dispute to the Executive Sponsors as set forth in Section 13.7.3 below.

13.7.3 For all Disputes referred to the Executive Sponsors from the Steering Committee above, the Executive Sponsors shall use their good faith efforts to resolve the Dispute within twenty (20) days after such referral. If the Executive Sponsors are unable to resolve the Dispute in such period, the Executive Sponsors will refer the Dispute to the Chief Executive Officers of Ormco and Align as set forth in Section 13.7.4 below

13.7.4 For all Disputes referred to the Chief Executive Officers from the Executive Sponsors above, the Chief Executive Officers shall use their good faith efforts to resolve the Dispute within twenty (20) days after such referral.

13.7.5 In the event of a Dispute which cannot be resolved by the Chief Executive Officers, either Party may commence a non-binding mediation to resolve the Dispute by providing written notice to the other Party (a “Mediation Notice”) informing the other Party of the dispute and the issues to be resolved and containing a list of five (5) recommended individuals to serve as the mediator. Within ten (10) business days after the receipt of a Mediation Notice, the other Party shall respond by written notice to the Party initiating mediation, providing a list of five (5) recommended individuals to serve as the mediator and which adds additional issues to be resolved. The recommended mediators shall be individuals with experience in the healthcare industry and shall not be any employee, director, shareholder or agent of either Party or an affiliate of either Party, or otherwise involved (whether by contract or otherwise) in the affairs of either Party. If, within twenty (20) business days after receipt of the Mediation Notice, the Parties shall have been unable to agree upon an individual to serve as mediator, or to the extent the mediator selected by the Parties is unable to resolve the dispute, the dispute will be settled by final and binding arbitration conducted in the manner described in subsection 13.8 below. If, within twenty (20) business days after receipt of the Mediation Notice, the Parties shall have agreed upon an individual to serve as mediator, the mediator shall conduct a mediation in an effort to

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resolve the dispute, employing commercially reasonable procedures selected by the mediator in consultation with the Parties, completing such mediation no later than sixty (60) days after engagement.

13.8 Arbitration.

13.8.1 Any Dispute not timely resolved in accordance with Section 13.7 herein, shall be finally and exclusively resolved by arbitration in accordance with the then-prevailing prevailing JAMS Streamlined Arbitration Rules and Procedures, except as modified herein (the “Rules”). If the Dispute (including all claims and counterclaims) is for \$15 million or less, there shall be a single arbitrator. The parties shall have ten (10) days from commencement of the arbitration in accordance with the Rules to agree on a single arbitrator. Failing timely agreement, the arbitrator shall be selected by JAMS. If the Dispute (including all claims and counterclaims) is for more than \$15 million, there shall be three (3) neutral arbitrators of whom each of Buyer and Seller shall select one within twenty (20) days of the commencement of the arbitration. The two arbitrators so appointed shall select a third arbitrator to serve as chairperson within fourteen (14) days of the designation of the second of the two initial arbitrators. If any arbitrator is not timely appointed, at the request of any party such arbitrator shall be appointed by JAMS pursuant to the listing, striking and ranking procedure in the Rules. All arbitration pursuant to Section 13.8 shall be confidential and shall be treated as compromise and settlement negotiations, and no oral or documentary representations made by the parties during such arbitration shall be admissible for any purpose in any subsequent proceedings. The arbitral tribunal is not empowered to award damages in excess of compensatory damages, and each party hereby irrevocably waives any right to recover punitive, exemplary or similar damages with respect to any Dispute. Any arbitration proceedings, decision or award rendered hereunder and the validity, effect and interpretation of this arbitration agreement shall be governed by the Federal Arbitration Act, 9 U.S.C. §1 et seq. The award shall be final and binding upon the parties and shall be the sole and exclusive remedy between the parties regarding any claims, counterclaims, issues or accounting presented to the arbitral tribunal. Judgment upon any award may be entered in any court having jurisdiction.

13.8.2 Without seeking to expand the scope of Section 13.8.1 and for purpose of clarification only, the Parties acknowledge that the restrictions of Section 13.8.1 do not apply to any claim(s) by one Party against the other for infringement of one or more claims of a patent owned or controlled by either Party. Neither Party will be precluded from seeking provisional remedies in the courts including, but not limited to, temporary restraining orders and preliminary injunctions, to protect its rights and

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interests, but such relief will not be sought as a means to avoid or stay arbitration.

13.8.3 This Section 13.8 provides the sole recourse for the settlement of any dispute arising under or in connection with this Agreement.

13.8.4 Any arbitration action shall be brought only in the city or county in which the corporate headquarters of the defendant to such action is located.

13.9 Costs. Except as expressly provided herein, each Party shall bear their own costs in connection with this Agreement and the Project, including their own costs in preparing for and participating in the resolution of any dispute under this Agreement, and the costs of mediator(s) and arbitrator(s) shall be equally divided between the Parties.

13.10 Relationship of the Parties. The parties hereto agree that no fiduciary, agency, employment, partnership, joint venture or franchise relationship is created or shall be deemed to be created hereunder. The parties agree that in performing their responsibilities pursuant to this Agreement they are in the position of independent contractors. Neither Party shall have, and neither shall represent to have, any power, right or authority to bind the other or to assume or create any obligation or responsibility, express or implied, on behalf of the other Party or in the other Party's name, except as herein expressly permitted.

13.11 Events Excusing Performance. Neither Party shall be liable to the other Party for failure to perform any of the services required herein in the event of strikes, lock-outs, acts of God, war, terrorism, earthquakes, unavailability of supplies or other events over which that Party has no control for so long as such events continue, and for a reasonable period of time thereafter.

13.12 Entire Agreement. This Agreement (along with the Settlement Agreement, Stock Purchase Agreement and the non-disclosure letter entered into among Ormco, Danaher and Company on August 9, 2009) constitutes the entire agreement and supersedes any prior agreements or understandings between the Parties hereto regarding the subject matter hereof, and no amendment, alteration or waiver of this Agreement shall be valid or binding unless made in writing and signed by both Parties.

13.13 Interpretation. Whenever the context requires, all words used in the singular number shall be deemed to include the plural and vice versa. The use of the word "approval" or "consent" shall mean the prior written approval or prior written consent. The titles of the Sections of this Agreement are for convenience of reference only and are not to be considered in construing this Agreement. The language in all parts of this Agreement shall be construed, in all cases, according to the Parties' intent and the Parties hereto acknowledge that each Party has reviewed and revised this Agreement and that the normal rule of construction to the effect that any ambiguities are to be resolved against

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the drafting Party shall not be employed in the interpretation of this Agreement.

13.14 Governing Law. This Agreement shall be governed by, and interpreted and construed in accordance with the laws of the State of Delaware without regard to conflict of laws principles.

13.15 Further Agreements. The Parties shall enter into good faith negotiations for the purposes of executing and delivering any additional agreement or modifications to this Agreement necessary for the purposes of carrying on the Project.

13.16 Severability. Any provision in this Agreement found to be void, voidable or unenforceable shall not affect the validity or enforceability of any other provision in this Agreement. In the event that any provision of this Agreement shall be declared void, voidable or unenforceable by a court of competent jurisdiction, said provision shall be deemed to be amended to provide the Party seeking to enforce this Agreement the greatest protection available under law.

13.17 Signatures. The signatories to this Agreement represent and warrant that they are properly authorized to execute this Agreement on behalf of the respective Party. Each Party agrees to be bound by its own telecopied or facsimiled signature, and that it accepts the telecopied or facsimiled signature of the other Party hereto.

13.18 Counterparts. This Agreement may be executed in any number of counterparts, each of which shall be an original, but all of which together shall be deemed to constitute one instrument. In the event this Agreement is translated into another language the English version shall govern.

[Signature Pages Follow]

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IN WITNESS WHEREOF , this Agreement has been duly executed and delivered by the duly authorized officers of the Parties hereto as of the date first herein above written.

ALIGN TECHNOLOGY, INC.

By: /s/ Thomas M. Prescott
Name: Thomas M. Prescott
Title: President & CEO

ORMCO CORPORATION

By: /s/ Donald L. Tuttle
Name: Donald L. Tuttle
Title: President

[Signature Page to Joint Development, Marketing and Sales Agreement]

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Exhibit A

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A-1

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CERTIFICATION

I, Thomas M. Prescott, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Align Technology, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 5, 2009

/s/ THOMAS M. PRESCOTT

Thomas M. Prescott
President and Chief Executive Officer

CERTIFICATION

I, Kenneth B. Arola, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Align Technology, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 5, 2009

/s/ KENNETH B. AROLA

Kenneth B. Arola

Chief Financial Officer and Vice President, Finance

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER
PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

I, Thomas M. Prescott, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Quarterly Report of Align Technology, Inc. on Form 10-Q for the quarter ended September 30, 2009 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in such Quarterly Report on Form 10-Q fairly presents in all material respects the financial condition and results of operations of Align Technology, Inc.

Date: November 5, 2009

By: /s/ THOMAS M. PRESCOTT

Name: Thomas M. Prescott

Title: President and Chief Executive Officer

I, Kenneth B. Arola, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Quarterly Report of Align Technology, Inc. on Form 10-Q for the quarter ended September 30, 2009 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in such Quarterly Report on Form 10-Q fairly presents in all material respects the financial condition and results of operations of Align Technology, Inc.

Date: November 5, 2009

By: /s/ KENNETH B. AROLA

Name: Kenneth B. Arola

Title: Chief Financial Officer and Vice President of Finance
