
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, 2002 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

invisalign®

Align Technology, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation or organization)

94-3267295

(IRS Employer Identification Number)

821 Martin Avenue

Santa Clara, California 95050

(Address of principal executive offices including zip code)

(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 reports), and (2) has been subject to such filing requirements for the past 90 days. YES NO .

The number of shares of the Registrant's Common Stock outstanding as of October 31, 2002 was 48,129,176.

invisalign®

Align Technology, Inc.
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PART I -- FINANCIAL INFORMATION

ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

ALIGN TECHNOLOGY, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(IN THOUSANDS)
(UNAUDITED)

	September 30, 2002	December 31, 2001
ASSETS		
Current assets:		
Cash and cash equivalents.....	\$ 16,746	\$ 50,550
Restricted cash.....	373	723
Marketable securities, short-term.....	5,665	12,494
Accounts receivable, net.....	16,072	11,556
Inventories.....	1,461	1,549
Deferred costs.....	958	714
Other current assets.....	6,343	3,997
	47,618	81,583
Property and equipment, net.....	28,734	32,021
Marketable securities, long-term.....	--	2,627
Other assets.....	2,237	1,987
	\$ 78,589	\$ 118,218
	\$ 78,589	\$ 118,218
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable.....	\$ 1,941	\$ 4,376
Other accrued liabilities.....	11,697	11,909
Deferred revenue.....	2,016	1,551
	15,654	17,836
Capital lease obligations, net of current portion....	644	980
Contingencies (Note 4)		
Stockholders' equity:		
Common stock.....	5	5
Additional paid-in capital.....	347,355	355,055
Deferred stock-based compensation.....	(23,722)	(48,324)
Notes receivable from stockholders.....	(1,096)	(1,484)
Accumulated other comprehensive income	33	226
Accumulated deficit.....	(260,284)	(206,076)
	62,291	99,402
Total liabilities and stockholders' equity.....	\$ 78,589	\$ 118,218
	\$ 78,589	\$ 118,218

The accompanying notes are an integral part of these unaudited condensed consolidated 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,	
	2002	2001	2002	2001
Revenues.....	\$ 18,573	\$ 12,912	\$ 52,969	\$ 34,084
Cost of revenues.....	10,880	11,265	34,159	36,649
	7,693	1,647	18,810	(2,565)
Gross profit (loss).....				
Operating expenses:				
Sales and marketing.....	10,870	11,940	32,136	39,596
General and administrative.....	10,547	9,289	31,650	24,253
Research and development.....	2,997	3,444	9,096	11,204
Litigation settlement.....	--	--	--	400
	24,414	24,673	72,882	75,453
Total operating expenses.....				
Loss from operations.....	(16,721)	(23,026)	(54,072)	(78,018)
Interest and other income (expense), net....	(169)	523	(136)	1,263
	(16,890)	(22,503)	(54,208)	(76,755)
Net loss.....				
Dividend related to beneficial conversion feature of preferred stock.....	--	--	--	(11,191)
	\$ (16,890)	\$ (22,503)	\$ (54,208)	\$ (87,946)
Net loss available to common stockholders...	\$ (16,890)	\$ (22,503)	\$ (54,208)	\$ (87,946)
Net loss available to common stockholders, basic and diluted.....	\$ (0.36)	\$ (0.50)	\$ (1.16)	\$ (2.14)
	\$ (0.36)	\$ (0.50)	\$ (1.16)	\$ (2.14)
Shares used in computing net loss per share available to common stockholders, basic and diluted.....	46,934	45,035	46,556	41,098

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,	
	2002	2001
Cash Flows from Operating Activities:		
Net loss.....	\$ (54,208)	\$ (76,755)
Adjustments to reconcile net loss to net cash used in operating activities:		
Amortization of deferred stock compensation.....	12,447	16,786
Compensation expense for accelerated vesting of stock options.....	2,240	218
Stock-based compensation.....	1,781	--
Depreciation and amortization.....	10,078	5,221
Loss on retirement of assets.....	3	35
Allowance for doubtful accounts.....	712	1,231
Non-cash interest income on notes receivable.....	(45)	(131)
Non-cash interest expense on convertible subordinated note....	--	1,803
Non-cash accretion on marketable securities.....	66	(1,274)
Changes in Operating Assets and Liabilities:		
Accounts receivable.....	(5,228)	(6,134)
Deferred costs.....	(244)	1,576
Inventories.....	88	116
Other current assets.....	(2,346)	(1,263)
Accounts payable.....	(2,435)	(1,865)
Accrued liabilities.....	(234)	(3,848)
Deferred revenue.....	465	(1,301)
	(36,860)	(65,585)
Cash Flows from Investing Activities:		
Purchase of property, plant and equipment.....	(6,794)	(10,480)
Decrease in restricted cash.....	350	14,782
Purchase of marketable securities.....	(1,972)	(72,088)
Proceeds from sales and maturities of marketable securities.....	11,169	70,249
Change in other assets.....	(250)	(1,714)
	2,503	749
Cash Flows from Financing Activities:		
Proceeds from issuance of common stock, net.....	917	127,662
Proceeds from repayment of notes receivable from shareholders...	225	79
Repurchase of common stock.....	(275)	--
Payments on loan and capital leases.....	(314)	(339)
	553	127,402
Net (decrease) increase in cash and cash equivalents.....	(33,804)	62,566
Cash and cash equivalents at beginning of period.....	50,550	2,828
	\$ 16,746	\$ 65,394

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

ALIGN TECHNOLOGY, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS financial statements as of September 30, 2002, and for the three months and nine months ended September 30, 2002 and 2001, have been prepared in accordance with accounting principles generally accepted in the United States of America for interim financial statements and pursuant to the rules and regulations of the Securities and Exchange Commission, and include the accounts of Align Technology, Inc. and its wholly-owned subsidiaries (collectively "Align" or the "Company"). Certain information and footnote disclosures normally included in annual financial statements prepared in accordance with accounting principles generally accepted in the United States of America have been condensed or omitted pursuant to such rules and regulations. In the opinion of management, the unaudited condensed consolidated financial statements reflect all adjustments (consisting only of normal recurring adjustments) necessary for a fair presentation of the financial position of the Company. These unaudited condensed consolidated financial statements should be read in conjunction with the Company's audited consolidated financial statements and notes for the year ended December 31, 2001, included in the Company's Annual Report on Form 10-K.

The results of operations for the three months and nine months ended September 30, 2002 are not necessarily indicative of results that may be expected for any other interim period or for the full fiscal year ending December 31, 2002. The condensed consolidated balance sheet at December 31, 2001 has been derived from the audited consolidated financial statements at that date, but does not include all the information and footnotes required by accounting principles generally accepted in the United States of America for complete financial statements.

These financial statements contemplate the realization of assets and the satisfaction of liabilities in the normal course of business. The Company has sustained significant losses each year since inception. There can be no assurance that the Company will be able to obtain additional debt or equity financing, if and when needed, on terms acceptable to the Company. Any additional equity or debt financing may involve substantial dilution to the Company's stockholders, restrictive covenants or high interest costs. The failure to raise needed funds on sufficiently favorable terms could have a material adverse effect on the Company's business, operating results and financial condition. If the Company is unable to obtain the financing it requires in future periods, the Company may be required to further reduce operating expenses by, including but not limited to, reducing planned capital expenditures relating to enhancing the Company's manufacturing process and reducing worldwide staff. The Company's long-term liquidity also depends upon its ability to increase revenues from the sale of its products and achieve profitability. The failure to achieve these goals could have a material adverse effect on the operating results and financial condition of the Company.

2. INVENTORIES

Inventories comprise (in thousands):

	September 30, 2002	December 31, 2001
Raw materials.....	\$ 1,097	\$ 1,122
Work in progress.....	215	182
Finished goods.....	149	245
Total inventories.....	<u>\$ 1,461</u>	<u>\$ 1,549</u>

3. NET LOSS PER SHARE

Basic and diluted net loss per share is computed by dividing the net loss available to common stockholders for the period by the weighted average number of shares of common stock outstanding during the period. The calculation of diluted net loss per share excludes potential shares of common stock if their effect is anti-dilutive. Potential common stock consists of common stock subject to repurchase, incremental common shares issuable upon the exercise of stock options.

The following is a reconciliation of the numerator (net loss available to common stockholders) and the denominator (number of shares) used in the basic and diluted net loss per share calculations (in thousands, except per share data):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2002	2001	2002	2001
Basic and diluted:				
Net loss available to common stockholders.....	\$ (16,890)	\$ (22,503)	\$ (54,208)	\$ (87,946)
Weighted average common stock outstanding.....	47,988	47,880	47,950	44,300
Less: Weighted-average shares subject to repurchase.....	(1,054)	(2,845)	(1,394)	(3,202)
Weighted-average shares used in basic and diluted net loss per share.....	<u>46,934</u>	<u>45,035</u>	<u>46,556</u>	<u>41,098</u>
Net loss per share available to common stockholders.....	<u>\$ (0.36)</u>	<u>\$ (0.50)</u>	<u>\$ (1.16)</u>	<u>\$ (2.14)</u>

The following table sets forth potential shares of common stock that are not included in the basic and diluted net loss per share available to common stockholders because to do so would be anti-dilutive (in thousands):

	September 30,	
	2002	2001
Options to purchase common stock.....	7,650	5,583
Common stock subject to repurchase.....	953	2,437
	<u>8,603</u>	<u>8,020</u>

4. CONTINGENCIES

On May 1, 2002, GW Com, Inc. filed a complaint in Santa Superior Cour against us and James Lindsey, the owner of the premises located at 851 Martin Avenue, Santa Clara, California. We were parties with GW Com to a sub-sublease for such premises, the term of which expired on August 14, 2002. In early 2001, we engaged in negotiations with GW Com to amend the sub-sublease to add additional space and to extend the term through November 30, 2004. The proposed amendment, however, required the consent of the owner of the subject property, Mr. Lindsey. We withdrew from negotiations of the amendment, after, among other things, Mr. Lindsey's consent could not be obtained. GW Com's complaint against us and Mr. Lindsey alleges breach of contract against us and breach of contract and intentional interference with contract against Mr. Lindsey. In the complaint, GW Com seeks damages of more than \$4 million. The complaint is in its early stages and no trial date has been set. We intend to vigorously contest GW Com's allegations.

On April 9, 2002, we exercised our right to terminate an Exclusive Marketing Agreement dated October 18, 2001 with Discus Dental Impressions, Inc. pursuant to the express terms of the Agreement and we issued a press release reporting this termination. On or about May 14, 2002 we received a demand for arbitration submitted by Discus Dental with the American Arbitration Association in San Jose, California. In its arbitration demand, Discus Dental seeks damages of approximately \$30 million, including commissions and bonus payments it claims it would have received under the Agreement as well as other expenses, attorneys' fees and injunctive relief to prevent us from selling Invisalign to dentists in the U.S. and Canada. However, prior to terminating the Agreement, we conducted a thorough review of the Agreement and each party's performance thereunder. Based upon that review of the factual and legal issues, we deny all claims made by Discus Dental in its demand and contend that such claims are entirely without merit. In addition, on or about June 13, 2002 we submitted a counter-claim against Discus Dental in the arbitration seeking damages of approximately \$40 million arising out of our claims for misrepresentation, breach of

confidentiality provisions, and unfair competition, among others. The three arbitrators have been recently selected, and the matter is now set for arbitration on August 18, 2003.

The Company was involved in a patent infringement proceeding with a plaintiff asserting infringement of two of its patents. On June 30, 2000, the Company entered into a stipulation of dismissal with the plaintiff whereby the plaintiff agreed not to recommence a suit against the Company for two years with respect to the disputed patents. Pursuant to the agreement, if a patent is subsequently issued to the plaintiff and the plaintiff believes the Company is infringing it, then the plaintiff may commence suit after one year from the effective date of the agreement and include in such action claims involving the two previously disputed patents. If any such action is successful, it could result in a significant monetary damage judgment against the Company.

The Company is subject to claims and assessments from time to time in the ordinary course of business. Management does not believe that any such matters, individually or in the aggregate, will have a material adverse effect on the Company's financial condition, results of operations or cash flows.

5. ACCUMULATED OTHER COMPREHENSIVE INCOME

Accumulated other comprehensive income consists entirely of the change in unrealized gains or losses on available-for-sale securities at September 30, 2002 and December 31, 2001.

6. RESTRUCTURING

In July 2002, the Company announced a plan to streamline worldwide operations. The plan includes closing the Company's facilities in Pakistan and the United Arab Emirates. The operations performed at these facilities are being transitioned to the United States and Costa Rica. In addition, the plan included a global reduction in worldwide staff. The Company recorded severance charges relating to the plan of \$1.8 million for the period ending September 30, 2002, of which \$0.4 million were included in accrued liabilities as of September 30, 2002. Remaining charges related to the plan range from \$4.8 million to \$5.3 million. Our facility in Pakistan ceased production on October 25, 2002. Our facility in the U.A.E. is scheduled to cease production on December 13, 2002. It is estimated that the remainder of operational activities relating to the plan will conclude during the first quarter of 2003, although we will continue to engage in non-operational activities in both Pakistan and the U.A.E. until we have disposed of our assets in those countries.

Included in the estimated remaining charges is approximately \$2.1 million of property, plant and equipment located at our Pakistan facility, which represents the recorded net book value as of September 30, 2002. The Company is currently in the process of obtaining an independent fair market valuation of the property, plant and equipment. The Company is also in the process of locating a buyer in Pakistan for the property, plant and equipment. As of September 30, 2002, it is unknown whether the Company will be able to find such a buyer. The Company has no alternative use for the property, plant and equipment in Pakistan and, under Pakistani law, cannot move the assets outside the country.

7. RECENT ACCOUNTING PRONOUNCEMENTS

In August 2001, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standards No. 143, ("SFAS 143"), "Accounting for Asset Retirement Obligations," which is effective for fiscal years beginning after June 15, 2002. SFAS 143 addresses financial accounting and reporting for obligations associated with the retirement of tangible long-lived assets and the associated asset retirement costs. SFAS 143 applies to all entities. The Company believes that the adoption of SFAS 143 will not have a material impact on the consolidated financial position or results of operations of the Company.

In April 2002, the FASB issued Statement of Financial Accounting Standards No. 145 ("SFAS 145"), "Rescission of FASB Statements No. 4, 44 and 64, Amendment of FASB Statement No. 13, and Technical Corrections," which is effective for fiscal years beginning after May 15, 2002. Under SFAS 145, gains and losses from the extinguishment of debt should be classified as extraordinary items only if they meet the criteria of Accounting Principles Board Opinion No. 30. SFAS also addresses financial accounting and reporting for capital leases that are modified in such a way as to give rise to a new agreement classified as an operating lease. The Company believes that the adoption of SFAS 145 will not have a material impact on the consolidated financial position or results of the operations of the Company.

In June 2002, the FASB issued Statement of Financial Accounting Standards No. 146 ("SFAS 146"), "Accounting for Costs Associated with Exit or Disposal Activities," which is effective for exit or disposal activities initiated after December 31, 2002. SFAS 146 nullifies Emerging Issues Task Force Issue No. 94-3, "Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (including Certain Costs Incurred in a Restructuring)." Under SFAS 146, a liability is required to be recognized for a cost associated with an exit or disposal activity when the liability is incurred. SFAS 146 applies to costs associated with an exit activity that does not involve an entity newly acquired in a business combination or with a retirement or disposal activity covered by FASB Statements No. 143 and 144. The Company adopted SFAS during the quarter ended September 30, 2002, and it did not have a material impact on the consolidated financial position or results of the operations of the Company.

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

This quarterly report contains certain forward-looking statements (as such term is defined in Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934) and information relating to the Company that are based on the beliefs of the management of the Company as well as assumptions made by and information currently available to the management of the Company. For example, statements that are not based on historical facts, which can be identified by the use of such words as "likely," "will," "suggests," "target," "may," "would," "could," "anticipate," "believe," "estimate," "expect," "intend," "plan," "predict," and similar expressions and their variants, are forward-looking. Such statements reflect the judgment of the Company as of the date of this quarterly report and they involve many risks and uncertainties, such as those described below and those contained in "Factors That May Affect Future Operating Results." These factors could cause actual results to differ materially from those predicted in any forward-looking statements. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. Moreover, neither we nor any other person assumes responsibility for the accuracy and completeness of these forward-looking statements. The Company undertakes no obligation to update forward-looking statements.

The following discussion and analysis should be read in conjunction with the condensed consolidated financial statements and the notes thereto included in Item 1 in this quarterly report and our audited consolidated financial statements and notes for the year ended December 31, 2001, included in the Company's Annual Report on Form 10-K.

Overview

From our inception in April 1997, we were engaged in the design, manufacture and marketing of Invisalign, a proprietary new system for treating malocclusion, or the misalignment of teeth. In July 1999, we commenced commercial sales of Invisalign. Prior to July 1999, we devoted nearly all our resources to developing

our software and manufacturing processes, performing clinical trials of Invisalign and building our sales force, customer support and management teams. We exited the development stage in July 2000.

Invisalign has two components: ClinCheck and Aligners. ClinCheck is an Internet-based application that allows dental professionals to simulate treatment, in three dimensions, by modeling two-week stages of tooth movement. Aligners are thin, clear plastic, removable dental appliances that are manufactured in a series to correspond to each two-week stage of the ClinCheck simulation. Aligners are customized to perform the treatment prescribed for an individual patient by a dental professional using ClinCheck.

While our expansion outside of our domestic market (U.S. and Canada) is still in the initial stages, we do incur substantial operating costs outside of our domestic market.

Currently, two of our key production steps are performed in operations located outside of the U.S. At our facilities in Costa Rica and the United Arab Emirates, or the U.A.E., technicians use a sophisticated, internally developed computer-modeling program to prepare electronic treatment plans, which are transmitted electronically back to the U.S. Previously, these steps were also performed in our facility in Pakistan. These electronic files form the basis of our ClinCheck product and are used for the manufacture of Aligner molds. In addition, a third party manufacturer in Mexico fabricates and performs finishing work on completed Aligners and ships the completed products to our customers. Our costs associated with these operations are denominated in Costa Rican colons, U.A.E. dirhams, and Mexican pesos. Our reliance on international operations exposes us to risks and uncertainties that may affect our business or results of operations including, among others, difficulties in staffing and managing international operations, controlling quality of manufacture, political, social and economic instability, acts of war or terrorism, interruptions and limitations in telecommunication services, product or material transportation delays or disruption, and trade restrictions and changes in tariffs. However, we believe these risks in Costa Rica are mitigated by the fact that our operations there do not involve the shipping or manufacturing of any physical products, and in Mexico by the fact that our operations there are governed under the provisions of the North American Free Trade Agreement, or NAFTA.

In July 2002, the Company announced a plan to streamline worldwide operations. The plan includes closing the Company's facilities in Pakistan and the U.A.E. The operations previously performed at these facilities are being transitioned to the United States and Costa Rica. In addition, the plan includes a global reduction in worldwide staff. Our facility in Pakistan ceased production on October 25, 2002. Our facility in the U.A.E. is scheduled to cease production on December 13, 2002. It is estimated that the remainder of operational activities relating to the plan will conclude during the first quarter of 2003, although we will continue to engage in non-operational activities in both Pakistan and the U.A.E. until we have disposed of our assets in those countries.

We earn revenue primarily from the sale of Invisalign. We charge dental professionals for the Invisalign case upon shipment of the Aligners. All of the revenues associated with a given case, including ClinCheck fees, are recognized at the time the Aligners are shipped. The costs of producing the ClinCheck treatment plan, which are incurred prior to the production of Aligners, are deferred and recognized as related revenue is earned. In the event a dental professional does not proceed with Invisalign beyond ClinCheck, we charge a fixed fee for the treatment simulation. This fee is invoiced upon expiration or cancellation of the ClinCheck treatment simulation plan, and the related revenue is recognized upon invoicing. We also earn revenue when during the course of treatment, the refinement of a ClinCheck treatment plan, known as case refinement, requires the manufacture of new Aligners. We offer our dental professionals an optional enhanced warranty to cover any required case refinement. In cases covered by the enhanced warranty, the revenues associated with case refinement are recognized ratably over the duration of the treatment plan. In cases where the dental professional has declined to purchase the warranty coverage, case refinement revenues are recognized when the new Aligners are shipped. We believe that the frequency of case refinement will increase as clinical acceptance of Invisalign and its use in complex cases increases. This increased frequency may lead to changes in how we price refinement, which could in turn lead to changes in how we recognize revenue related to case refinement. In any Invisalign case where we expect a net loss, the entire loss is recognized immediately.

Results of Operations

Revenues. Revenues for the quarter ended September 30, 2002 increased 44% to \$18.6 million, compared with \$12.9 million for the quarter ended September 30, 2001. Revenues for the nine-month period ended September 30, 2002 increased 55% to \$53.0 million, compared with \$34.1 million for the same nine-month period in 2001. The increase in revenues was primarily due to the increase in Invisalign cases shipped, and for the nine-month period ended September 30, 2002 an increase in training revenue of \$3.6 million. Substantially all of our training revenue was derived from our agreement with Discus Dental, which was cancelled in April 2002. As a result, training revenue for the quarter ended June 30, 2002 decreased by \$1.7 million from the previous quarter. We commenced direct training of general practice dentists in the latter half of the quarter ending June 30, 2002. Although we expect training revenue to increase in future periods, we expect the majority of our revenues will be comprised of Invisalign revenue.

Cost of revenues. Cost of revenues for the quarter ended September 30, 2002 was \$10.9 million, compared with \$11.3 million for the quarter ended September 30, 2001. Cost of revenues for the nine-month period ended September 30, 2002 was \$34.2 million, compared with \$36.6 million for the same nine-month period in 2001. Cost of revenues includes the salaries of staff involved in production, the cost of materials and packaging used in production and shipping, depreciation on the capital equipment used in the production process, unabsorbed manufacturing capacity, training costs and an allocation of the cost of facilities. Gross margin for the quarter ended September 30, 2002 increased to 41%, compared with 13% for the quarter ended September 30, 2001. Gross margin for the nine-month period ended September 30, 2002 increased to 36%, compared with a negative gross margin of 8% for the same nine-month period in 2001. We achieved positive gross margins mainly due to efficiencies achieved in manufacturing as well as reducing overcapacity in many areas. Our gross margin is affected by changes in manufacturing volume, manufacturing capacity and changes in our pricing policies.

Sales and marketing expenses. Sales and marketing expenses for the quarter ended September 30, 2002 were \$10.9 million, compared with \$11.9 million for the quarter ended September 30, 2001. Sales and marketing expenses for the nine-month period ended September 30, 2002 were \$32.1 million, compared with \$39.6 million for the same nine-month period in 2001. Sales and marketing expenses include sales force compensation together with expenses of professional marketing, conducting training workshops and market surveys, advertising and attending dental professional trade shows. The decrease in sales and marketing expenses for the three-month period ended September 30, 2002 resulted primarily from decreased direct mail advertising of approximately \$1.4 million, partially offset by increases in payroll related expenses of \$0.5 million due to increased headcount related to our direct sales force. The decrease in sales and marketing expenses for the nine-month period ended September 30, 2002 resulted primarily from decreases in media and advertising expenses of approximately \$13.2 million and decreases in direct mail advertising of approximately \$1.3 million. Partially offsetting these decreases were increases in sales and marketing expenses at our international locations of approximately \$6.2 million and increases in payroll and related expenses of \$0.9 million due to the increased headcount related to our direct sales force.

General and administrative expenses. General and administrative expenses for the quarter ended September 30, 2002 were \$10.5 million, compared with \$9.3 million for the quarter ended September 30, 2001. General and administrative expenses for the nine-month period ended September 30, 2002 were \$31.7 million, compared with \$24.3 million for the same nine-month period in 2001. General and administrative expenses include costs for the compensation of administrative personnel, outside consulting services, facilities, legal expenses and general corporate expenses. The increase in general and administrative expenses for the three month period ended September 30, 2002 resulted primarily from an increase in expenses of approximately \$1.6 million due to the growth of our international operations. The increase in general and administrative expenses for the nine month period ended September 30, 2002 resulted primarily from increased expenses of approximately \$5.2 million related to the growth of our international operations and increases in payroll and related expenses of approximately \$3.0 million

due to increased headcount at our corporate headquarters to support being a public company. These increases were partially offset by decreased professional services of approximately \$0.9 million.

Research and development expenses. Research and development expenses for the quarter ended September 30, 2002 were \$3.0 million, compared with \$3.4 million for the quarter ended September 30, 2001. Research and development expenses for the nine-month period ended September 30, 2002 were \$9.1 million, compared with \$11.2 million for the same nine-month period in 2001. Research and development expenses include the costs associated with software engineering, the costs of designing, developing and testing our products and the conduct of both clinical and post-marketing trials. We expense our research and development costs as they are incurred. The decrease in research and development expenses for the three-month period ended September 30, 2002 was primarily due to a decrease in payroll and related expenses of approximately \$0.5 million due to decreased headcount. The decrease in research and development expenses for the nine-month period ended September 30, 2002 was primarily due to a decrease in outside consulting services of approximately \$1.4 million and a decrease in payroll and related expenses of approximately \$1.0 million due to decreased headcount.

Litigation settlement expenses. Litigation settlement expenses resulted from a settlement of a class action lawsuit. In February 2001, a class action lawsuit was filed on behalf of all licensed dentists (excluding orthodontists) in the U.S. The complaint alleged that Align's policy of selling the Invisalign System exclusively to orthodontists violated the U.S. antitrust laws. Without admitting any wrongdoing and pending approval from the court and the completion of definitive documentation, the Company reached an agreement in principle with the plaintiffs to settle the lawsuit. The remaining total legal and other settlement costs that Align agreed to pay were approximately \$0.4 million. Pursuant to the settlement, Align will undertake to train and certify 5,000 general practice dentists each year over the next four years.

Interest and other income (expense), net. Interest and other expense was \$0.2 million for the quarter ended September 30, 2002 compared to interest and other income of \$0.5 million for the quarter ended September 30, 2001. Interest and other expense for the nine month period ended September 30, 2002 was \$0.1 million, compared with interest and other income of \$1.3 million for the same nine-month period in 2001. Other expense for 2002 consisted of bank service charges related to credit card processing. Offsetting these charges was decreasing interest income in 2002, primarily due to the decrease in the Company's cash and cash equivalent balance and marketable securities balances. Interest income for the nine months ended September 30, 2001 was primarily generated from the Company's cash and cash equivalents balance and investments in short-term marketable securities. Offsetting this income in the first quarter of 2001 was non-cash interest expense of \$1.8 million, recorded in January 2001, related to the beneficial conversion feature embedded in convertible subordinated notes.

Dividend related to beneficial conversion feature of preferred stock. In 2000 we issued 9,535,052 shares of Series D preferred stock which were subject to an antidilution conversion price adjustment feature which we triggered when we granted options to purchase our common stock beyond the number of options that were authorized under our 1997 Plan at the time we commenced our Series D preferred stock offering in May 2000. The conversion feature provided that if, during the period between May 12, 2000 (the commitment date for our Series D preferred stock offering) and the earlier of the closing of an initial public offering or January 31, 2001, we had granted more than an aggregate of 3,331,978 options to purchase our common stock, then the conversion price of our Series D preferred stock would be adjusted downward from its original conversion price of \$10.625 per share. As of the end of January 2001, we had granted an aggregate of 3,591,458 options to purchase shares of our common stock in excess of the 3,331,978 options permitted, and we were therefore required to issue an additional 790,342 shares of common stock upon the conversion of the Series D preferred stock. These shares were in addition to the 419,700 additional shares of common stock that we were required to issue upon conversion of the Series D preferred stock as of December 31, 2000. As a result, we recorded a deemed dividend for the three months ended March 31, 2001 based on the fair value of the common stock at the commitment date of the Series D preferred stock offering of \$11.2 million related to the preferred stock sold and a charge to interest expense of \$1.8 million for the beneficial conversion feature embedded in convertible subordinated notes that were previously converted.

Stock-based compensation. In connection with the grant of stock options to employees and non-employees, we recorded deferred stock-based compensation as a component of stockholders' equity. Deferred stock-based compensation for options granted to employees is the difference between the fair value of our common stock on the date such options were granted and their exercise price. For stock options granted to non-employees, the fair value of the options, estimated using the Black-Scholes valuation model, is initially recorded on the date of grant. As the non-employee options become exercisable, we revalue the remaining unvested options, with the change in fair value from period to period represented as a change in the deferred compensation charge. This stock-based compensation is amortized as charges to operations over the vesting periods of the options. We recorded amortization of deferred compensation of \$3.8 million and \$5.0 million for the quarters ended September 30, 2002 and 2001, respectively. For the nine month periods ended September 30, 2002 and 2001, we recorded amortization of deferred compensation of \$12.4 million and \$16.8 million, respectively. Additionally, we recorded expenses of \$0.3 million for the quarter ended September 30, 2002 and \$1.8 million for the nine month period ended September 30, 2002, related to options granted to non-employees during the current fiscal year.

The Company accelerated the vesting of options to several employees in connection with severance packages. The accelerations were accounted for as a charge to the statement of operations. The charge was \$0.9 million for the quarter ended September 30, 2002 and \$0.2 million for the quarter ended September 30, 2001. For the nine month periods ended September 30, 2002 and 2001, we recorded \$2.2 million and \$0.2 million, respectively. The charge is equal to the intrinsic value difference between the exercise price of the accelerated options and the fair value of the common stock on the date of acceleration.

Liquidity and Capital Resources

Historically, we have funded our operations with the proceeds from the sale of our common and preferred stock, equipment leases and bridge loans. As of September 30, 2002, we had \$22.4 million in cash and cash equivalents and marketable securities and an accumulated deficit of \$260.3 million. Additionally, we had \$0.4 million of restricted cash.

Net cash used in operating activities totaled \$36.9 million and \$65.6 million for the nine-month periods ended September 30, 2002 and 2001, respectively. In each of these periods, net cash used by operating activities consisted primarily of net operating losses and increases in accounts receivable balances, partially offset by increases in depreciation and amortization, and amortization of deferred stock-based compensation.

Net cash provided by investing activities totaled \$2.5 million for the nine month period ended September 30, 2002 and \$0.7 million for the nine month period ended September 30, 2001. For the nine month period ended September 30, 2002, net cash provided by investing activities consisted primarily of sales and maturities of marketable securities, partially offset by purchases of property and equipment. For the nine month period ended September 30, 2001, net cash provided by investing activities consisted primarily of proceeds from the sales and maturities of marketable securities and a decrease in restricted cash, partially offset by purchases of marketable securities and purchases of property and equipment.

Net cash provided by financing activities was \$0.6 million and \$127.4 million for the nine-month periods ended September 30, 2002 and 2001, respectively. For the nine-month period ended September 30, 2001, net cash provided by financing activities consisted primarily of proceeds from the issuance of common stock. In January 2001, we completed our initial public offering of 10 million shares of common stock. In March 2001, the underwriters exercised an over-allotment option for 628,706 shares. Net proceeds to us were approximately \$126.2 million.

We expect that our operating expenses will increase with an overall increase in the level of our business activity, including increased sales and the related costs of products sold, our consumer advertising campaign and dental professional marketing efforts, continuing efforts to automate our manufacturing processes,

increases in the size of our sales force and dental professional training staff, continued international sales and marketing efforts, and development and improvements to our product. In addition, we may use cash to fund acquisitions of complementary businesses or technologies. We believe it will be appropriate to obtain additional equity or debt financing within the next 12 months. We may not be able to raise additional financing on acceptable terms or at all.

Recent Accounting Pronouncements

In August 2001, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standards No. 143, ("SFAS 143"), "Accounting for Asset Retirement Obligations," which is effective for fiscal years beginning after June 15, 2002. SFAS 143 addresses financial accounting and reporting for obligations associated with the retirement of tangible long-lived assets and the associated asset retirement costs. SFAS 143 applies to all entities. The Company believes that the adoption of SFAS 143 will not have a material impact on the consolidated financial position or results of operations of the Company.

In April 2002, the FASB issued Statement of Financial Accounting Standards No. 145 ("SFAS 145"), "Rescission of FASB Statements No. 4, 44 and 64, Amendment of FASB Statement No. 13, and Technical Corrections," which is effective for fiscal years beginning after May 15, 2002. Under SFAS 145, gains and losses from the extinguishment of debt should be classified as extraordinary items only if they meet the criteria of Accounting Principles Board Opinion No. 30. SFAS also addresses financial accounting and reporting for capital leases that are modified in such a way as to give rise to a new agreement classified as an operating lease. The Company believes that the adoption of SFAS 145 will not have a material impact on the consolidated financial position or results of the operations of the Company.

In June 2002, the FASB issued Statement of Financial Accounting Standards No. 146 ("SFAS 146"), "Accounting for Costs Associated with Exit or Disposal Activities," which is effective for exit or disposal activities initiated after December 31, 2002. SFAS 146 nullifies Emerging Issues Task Force Issue No. 94-3, "Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (including Certain Costs Incurred in a Restructuring)." Under SFAS 146, a liability is required to be recognized for a cost associated with an exit or disposal activity when the liability is incurred. SFAS 146 applies to costs associated with an exit activity that does not involve an entity newly acquired in a business combination or with a retirement or disposal activity covered by FASB Statements No. 143 and 144. The Company adopted SFAS 146 during the quarter ended September 30, 2002, and it did not have a material impact on the consolidated financial position or results of the operations of the Company.

Factors That May Affect Future Operating Results

Since we have a history of losses and negative operating cash flows, and because we expect our operating losses to continue, we may not achieve or maintain profitability in the future.

We have incurred significant operating losses, negative operating cash flows and have not achieved profitability. From inception through July 2000, we spent significant funds in organizational and start-up activities, recruiting key managers and employees, developing Invisalign and developing our manufacturing and customer support resources. We also spent significant funds on clinical trials and training programs to train dental professionals in the use of Invisalign. We expect to have net losses and negative operating cash flows for at least the next 12 months.

We continue to incur significant operating expenses to:

- develop new software and increase the automation of our manufacturing processes;
- execute our consumer advertising campaign and dental professional marketing efforts;
- increase the size of our sales force and dental professional training staff;
- execute clinical research and education plans;
- develop technological improvements to our products;
- continue our international sales and marketing efforts; and
- undertake quality assurance and improvement initiatives.

As a result, we will need to increase our revenue significantly, while controlling our expenses, to achieve profitability. It is possible that we will not achieve profitability, and even if we do achieve profitability, we may not sustain or increase profitability in the future.

We may be unable to raise additional capital if it should be necessary, which could harm our ability to compete.

We have incurred significant operating losses and negative operating cash flows since inception and have not achieved profitability. As of September 30, 2002, we had an accumulated deficit of approximately \$260.3 million.

We expect to expend significant capital to continue to build our national brand, expand our dental professional channel, automate our manufacturing processes and develop both product and process technology. The Company is in the process of obtaining debt financing in the form of an accounts receivable line of credit and an equipment line of credit. In addition, the Company is in the early stages of pursuing an equity financing. However, there can be no assurance that such additional financing will be available on a timely basis on terms acceptable to us, or at all, or that such financing will not be substantially dilutive to stockholders. If adequate funds are not available, we could be required to further reduce operating expenses by, including but not limited to, reducing planned capital expenditures relating to enhancing the Company's manufacturing process and reducing worldwide staff.

We have a limited operating history and expect our future financial results to fluctuate significantly, which may cause our stock price to decline.

We were incorporated in April 1997 and began sales of Invisalign in July 1999. Thus, we have a limited operating history, which makes an evaluation of our future prospects and your investment in our stock difficult. In addition, we expect our future quarterly and annual operating results to fluctuate as we increase our commercial sales. These fluctuations could cause our stock price to decline. Some of the factors that could cause our operating results to fluctuate include:

- changes in the timing of product orders;
- unanticipated delays in production caused by insufficient capacity, any disruptions in the manufacturing process or in the introduction of new production processes;
- inaccurate forecasting of revenue, production and other operating costs; and
- the development and marketing of directly competitive products by potential competitors.

To respond to these and other factors, we may need to make business decisions that could adversely affect our operating results. 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 revenue for a particular period falls below our expectations, we may be unable to adjust spending quickly enough to offset any unexpected shortfall in revenue growth or any decrease in revenue levels.

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.

We have limited product offerings, and if demand for Invisalign declines or fails to develop as we expect, our revenue will decline.

We expect that revenue from the sale of Invisalign will continue to account for a substantial portion of our total revenue. Continued and widespread market acceptance of Invisalign is critical to our future success. Invisalign may not achieve market acceptance at the rate at which we expect, or at all, which could reduce our revenue.

If dental professionals do not adopt Invisalign in sufficient numbers or as rapidly as we anticipate, our operating results will be harmed.

As of September 30, 2002, approximately 7,400 dental professionals have submitted one or more cases to us. Our success depends upon increasing acceptance of Invisalign by dental professionals. Invisalign requires dental professionals and their staff to undergo special training and learn to interact with patients in new ways. In addition, because Invisalign has only been in clinical testing since July 1997 and commercially available since July 1999, dental professionals may be reluctant to adopt it until more historical clinical results are available. Also, increasing adoption by dental professionals will depend on factors such as the capability, safety, efficacy, ease of use, price, quality and reliability of our products and our provision of effective sales support, training and service. In the future, unanticipated poor clinical performance of Invisalign could result in significant adverse publicity and consequently in reduced acceptance by dental professionals. If Invisalign does not achieve growing acceptance in the orthodontic and dental communities, our operating results will be harmed.

If consumers do not adopt Invisalign in sufficient numbers or as rapidly as we anticipate, our operating results will be harmed.

Invisalign represents a significant change from traditional orthodontic treatment, and patients may be reluctant to accept it or may not find it preferable to conventional treatment. In addition, patients may not comply with recommended treatment guidelines which could compromise the effectiveness of their treatment. We have generally received positive feedback from both dental professionals and patients 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. Our success will depend upon the acceptance of Invisalign by the substantially larger number of dental professionals and potential patients to which we are now actively marketing. We have had a limited number of complaints from patients and prospective patients generally related to shipping delays and minor manufacturing irregularities. Market acceptance will depend in part upon the recommendations of dental professionals, as well as other factors including effectiveness, safety, reliability, improved treatment aesthetics and greater comfort and hygiene compared to conventional orthodontic products. Furthermore, consumers may not respond to our direct marketing campaigns or we may be unsuccessful in reaching our target audience. Adoption by consumers may also be impacted by general macroeconomic conditions, levels of consumer confidence and consumer spending, all of which could be effected by United States military action in Iraq. If consumers prove unwilling to adopt Invisalign as rapidly or in the numbers that we anticipate, our operating results will be harmed.

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

Currently, two of our key production steps are performed in operations located outside of the U.S. At our facilities in Costa Rica and the U.A.E., where we create electronic treatment plans with the assistance of sophisticated software. Previously, these steps were also performed in our facility in Pakistan. In addition, we rely on third party manufacturers in Mexico to fabricate Aligners and to ship the completed product to customers. In July 2002, the Company announced a plan to streamline worldwide operations. The plan includes closing the Company's facilities in Pakistan and the U.A.E. The operations previously performed at these facilities are being transitioned to the United States and Costa Rica. In addition, the plan includes a global reduction in worldwide staff. Our facility in Pakistan ceased production on October 25, 2002. Our facility in the U.A.E. is scheduled to cease production on December 13, 2002. It is estimated that the remainder of operational activities relating to the plan will conclude during the first quarter of 2003, although we will continue to engage in non-operational activities in both Pakistan and the U.A.E. until we have disposed of our assets in those countries.

Our reliance on international operations exposes us to risks and uncertainties, including:

- political, social and economic instability;
- acts of terrorism and acts of war, particularly in light of the terrorist attacks of September 11, 2001;
- difficulties in staffing and managing international operations;
- controlling quality of manufacture;
- interruptions and limitations in telecommunication services;
- product or material transportation delays or disruption;
- burdens of complying with a wide variety of local country and regional laws;
- trade restrictions and changes in tariffs;
- import and export license requirements and restrictions;
- fluctuations in currency exchange rates; and
- potential adverse tax consequences.

If any of these risks materialize in the future, our operating results may be harmed.

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.

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 October 31, 2002, we have 23 issued U.S. patents and 61 pending U.S. patent applications. We have 20 foreign-issued patents and 114 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 issue as 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. In addition, 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 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 of our proprietary rights might allow competitors to copy our technology, which could adversely affect pricing and market share.

If we infringe the patents or proprietary rights of other parties, our ability to grow our business will 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 another party's patent in the past and, while that action has been dismissed, we may be the subject of patent or other litigation in the future.

In January 2000, Ormco Corporation filed suit against us asserting an infringement of U.S. Patent Nos. 5,447,432 and 5,683,243. The complaint sought unspecified monetary damages and equitable relief. The complaint alleged that Invisalign infringed certain claims of the two patents relating to computer modeling of an ideal dentition and the production of orthodontic appliances based upon the ideal dentition. The suit has been dismissed but can be recommenced under certain circumstances. See "Part II-Item 1--Legal Proceedings." If the Ormco suit were recommenced and if Ormco were to prevail, we would have to seek a license from Ormco, which license might not be available on commercially reasonable terms or at all. In that event, we could be subject to damages or an injunction, which could materially adversely affect our business.

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 valid and enforceable rights which 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 in a patent suit by Ormco or in any other 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 currently rely on third parties to provide key inputs to our manufacturing process, and if our access to these inputs is diminished, our business may be harmed.

We currently outsource key portions of our manufacturing process. We rely on a third party manufacturer in Mexico to fabricate Aligners and to ship the completed product to customers. As a result, if our third party manufacturer fails to deliver its components or if we lose its services, we may be unable to deliver our products in a timely manner and our business may be harmed. Finding a substitute manufacturer may be expensive, time-consuming or impossible.

In addition, 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. Our growth may exceed the capacity of these manufacturers to produce the needed equipment and materials in sufficient quantities to support our growth. In the event of delivery delays or shortages of these items, our business and growth prospects may be harmed.

We have experienced rapid growth, and our failure to manage this growth could harm our business.

We have expanded rapidly since we commenced commercial sales in 1999. Our headcount increased from approximately 50 employees as of September 30, 1999 to approximately 690 employees as of September 30, 2002. This expansion will continue to place significant demands on our management and other resources and will require us to continue to develop and improve our operational, financial and other internal controls both in the U.S. and internationally. In particular, rapid growth increases the challenges involved in a number of areas, including: recruiting and retaining sufficient skilled personnel, providing adequate training and supervision to maintain our high quality standards, and preserving our culture and values. Also, recent reductions in our workforce, although designed to not affect service levels and demand generation, may adversely affect these areas of our business. Our inability to effectively manage this level of growth would harm our business.

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 and management teams. The loss of the services of 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. In addition, 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.

We experience competition from manufacturers of traditional braces and expect aggressive competition in the future.

Currently, we compete directly against a product called Red, White and Blue that is manufactured and distributed by Ormco, which is a subsidiary of Sybron Dental Specialities. In addition, manufacturers of traditional braces, such as 3M Company, Sybron Dental Specialities and Dentsply International, Inc. 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. Large consumer products 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 our competitors, our business will be harmed.

Complying with the Food and Drug Administration (FDA) and other regulations is an expensive and time-consuming process, and any failure to comply could result in substantial penalties.

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

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

Noncompliance with applicable regulatory requirements can result in enforcement action which may include recalling products, ceasing product marketing, and paying significant fines and penalties, which could limit product sales, delay product shipment and adversely affect our profitability.

In the U.S., 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, which we have yet to undergo. If we or any third party manufacturer of our products do not conform to applicable Quality System regulations, 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., we must obtain FDA clearance or approval, which can be a lengthy and time-consuming process. Even though the devices we market have obtained the necessary clearances from the FDA through the pre-market notification provisions of Section 510(k) of the federal Food, Drug, and Cosmetic Act, we may be unable to maintain the necessary clearances in the future. Furthermore, we may be unable to obtain the necessary clearances for new devices that we market in the future.

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; and
- the marketing and advertising of our products.

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

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

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 other countries. We may also incur significant costs in attempting to obtain and in maintaining 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. We currently sell our product in Germany, France, the United Kingdom, Spain, Italy, Mexico, Brazil, Australia and Hong Kong, and may expand into other countries from time to time. We do not know whether orthodontists, dentists and consumers outside our domestic market will adopt Invisalign in sufficient numbers or as rapidly as we anticipate.

Our business exposes us to risks of product liability claims, and we may incur substantial expenses if we are sued for product liability.

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 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 could harm our business.

The market price for our common stock has declined significantly in 2002 and has been highly volatile.

The trading price of our common stock declined in 2002 and has been highly volatile and could be subject to wide fluctuations in price in response to various factors, many of which are beyond our control, including:

- 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;
- strategic actions by our competitors, such as product announcements or acquisitions; and
- general 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. In the past, following periods of volatility in the market price of a company's securities, class action litigation has often been brought against the company. If a securities class action suit is filed against us, we would incur substantial legal fees and our management's attention and resources would be diverted from operating our business in order to respond to the litigation.

Concentrations of ownership and agreements among our existing executive officers, directors and principal stockholders may prevent other stockholders from influencing significant corporate transactions.

The interest of management could conflict with the interest of our other stockholders. As of September 30, 2002, our executive officers, directors and principal stockholders beneficially owned, in total, approximately 52.3% of our outstanding common stock. These stockholders, if acting together, would be able to influence significantly all matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. This could have the effect of delaying or preventing a change of control of the Company, which in turn could reduce the market price of our stock.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Quantitative Disclosures

We are exposed to market risks inherent in our operations, primarily related to interest rate risk and currency risk. These risks arise from transactions and operations entered into in the normal course of business. We do not use derivatives to alter the interest characteristics of our marketable securities or our debt instruments. We have no holdings of derivative or commodity instruments.

Interest Rate Risk. We are subject to interest rate risks on cash and cash equivalents, available-for-sale marketable securities, existing long-term debts and any future financing requirements. Interest rate risks related to marketable securities are managed by managing maturities in our marketable securities portfolio. Our long-term debt at September 30, 2002 consists only of outstanding balances on lease obligations.

The fair value of our investment portfolio or related income would not be significantly impacted by changes in interest rates since the majority of marketable securities maturities do not exceed twelve months and the interest rates are primarily fixed. Our capital lease obligations of \$1.3 million at September 30, 2002 carry fixed interest rates of 6.53% and 11.15% per annum with principle payments due in 60 and 48 equal annual installments, respectively, and which originated in 2000.

Qualitative Disclosures

Interest Rate Risk. Our primary interest rate risk exposures relate to:

- The available-for-sale securities will fall in value if market interest rates increase.
- Our ability to pay long-term debts at maturity.
- The impact of interest rate movements on our ability to obtain adequate financing to fund future operations.

We have the ability to hold at least a portion of the fixed income investments until maturity and therefore would not expect the operating results or cash flows to be affected to any significant degree by a sudden change in market interest rates on our short- and long-term marketable securities portfolio.

We manage interest rate risk on our outstanding long-term debts through the use of fixed rate debt. Management evaluates our financial position on an ongoing basis.

Currency Rate Risk. Our primary currency rate risk exposures relate to:

- Our decentralized or outsourced operations, whereby approximately \$6.2 million of our expenses in the quarter ended September 30, 2002 are related to operations outside the United States, denominated in currencies other than the U.S. dollar.

We do not hedge any balance sheet exposures and intercompany balances against future movements in foreign exchange rates. The exposure related to currency rate movements would not have a material impact on future net income or cash flows.

ITEM 4. CONTROLS AND PROCEDURES

Based on their evaluation, as of a date within 90 days of the filing date of this Form 10-Q, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures (as defined in Rule 13a-14(c) and 15d-14(c) under the Securities Exchange Act of 1934, as amended) are effective. There have been no significant changes in internal controls or in other factors that could significantly affect these controls subsequent to the date of their evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

PART II. -- OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

On May 1, 2002, GW Com, Inc. filed a complaint in Santa Clara Superior Court against us and James Lindsey, the owner of the premises located at 851 Martin Avenue, Santa Clara, California. We were parties with GW Com to a sub-sublease for such premises, the term of which expired on August 14, 2002. In early 2001, we engaged in negotiations with GW Com to amend the sub-sublease to add additional space and to extend the term through November 30, 2004. The proposed amendment, however, required the consent of the owner of the subject property, Mr. Lindsey. We withdrew from the negotiations of the amendment, after, among other things, Mr. Lindsey's consent could not be obtained. GW Com's complaint against us and Mr. Lindsey alleges breach of contract against us and breach of contract and intentional interference with contract against Mr. Lindsey. In the complaint, GW Com seeks damages of more than \$4 million. The complaint is in its early stages and no trial date has been set. We intend to vigorously contest GW Com's allegations.

On April 9, 2002, we exercised our right to terminate an Exclusive Marketing Agreement dated October 18, 2001 with Discus Dental Impressions, Inc. pursuant to the express terms of the Agreement and we issued a press release reporting this termination. On or about May 14, 2002 we received a demand for arbitration submitted by Discus Dental with the American Arbitration Association in San Jose, California. In its arbitration demand, Discus Dental seeks damages of approximately \$30 million, including commissions and bonus payments it claims it would have received under the Agreement as well as other expenses, attorneys' fees and injunctive relief to prevent us from selling Invisalign to dentists in the U.S. and Canada. However, prior to terminating the Agreement, we conducted a thorough review of the Agreement and each party's performance thereunder. Based upon that review of the factual and legal issues, we deny all claims made by Discus Dental in its demand and contend that such claims are entirely without merit. In addition, on or about June 13, 2002 we submitted a

counter-claim against Discus Dental in the arbitration seeking damages of approximately \$40 million arising out of our claims for misrepresentation, breach of confidentiality provisions, and unfair competition, among others. The three arbitrators have been recently selected, and the matter is now set for arbitration on August 18, 2003.

In February 2001 Align Technology was named in a class action lawsuit filed on behalf of all licensed dentists (excluding orthodontists) in the U.S. The complaint alleged that Align Technology's policy of selling Invisalign exclusively to orthodontists violated the U.S. antitrust laws. Without admitting any wrongdoing, the company entered into a Stipulation and Agreement of Settlement with the plaintiffs to settle the lawsuit. The total legal and other settlement costs that Align has agreed to pay are approximately \$400,000. Pursuant to the settlement, Align will undertake to train and certify 5,000 general practice dentists each year over the next four years. In November 2001, the Court approved the Stipulation and Agreement of Settlement.

In January 2000, Ormco Corporation filed suit against us asserting infringement of U.S. Patent Nos. 5,447,432 and 5,683,243. The complaint sought unspecified and monetary damages and injunctive relief. In March 2000, we answered the complaint and asserted counterclaims seeking a declaration by the Court of invalidity and non-infringement of the asserted patents.

In June 2000, we entered into a Stipulation of Dismissal with Ormco. Ormco agreed for a period of at least two years not to pursue litigation with respect to these patents, except as set forth below. Further, Ormco agreed that it would not bring any patent action against us for at least a period of one year with respect to any as yet unissued patents. If Ormco were to bring such an action concerning as yet unissued patents after one year, the Stipulation of Dismissal would allow Ormco to include in such an action claims involving U.S. Patent Nos. 5,447,432 and 5,683,243. In August 2001, Ormco notified us of the issuance of U.S. Patent No. 6,244,861 and offered a license for this patent. No assurance can be given that Ormco will not bring another action against us or, that if brought, it will not be successful. Should the suit be recommenced and should our technology be found to infringe, we would have to seek a license from Ormco, which license might not be available on commercially reasonable terms or at all. In that event, we could be subject to damages or an injunction which could materially adversely affect our business. It is possible that, depending on the scope of any new patents that are issued to Ormco, Ormco will bring another patent action after a period of one year has passed.

The claims at issue in the Ormco suit relate to methods and systems for forming and manufacturing custom orthodontic appliances. The relevant claims are limited to the calculation of the final positioning of a patient's teeth based upon a derived or ideal dental archform of the patient. The treatment plan simulation developed in our facilities determines the final positioning of a patient's teeth but is not based on a derived or ideal dental archform of the patient.

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 which have been brought to our attention, there may be other more pertinent rights of which we are presently unaware.

ITEM 2. CHANGES IN SECURITIES AND USE OF PROCEEDS

Use of Proceeds from Sales of Registered Securities. On January 25, 2001 the Securities and Exchange Commission declared effective our Registration Statement on Form S-1 (File No. 333-49932) relating to our initial public offering of our common stock. The 10,000,000 shares offered by us under the Registration Statement were sold at a price of \$13.00 per share on January 31, 2001. The managing underwriters for the offering were Deutsche Banc Alex. Brown, Bear, Stearns & Co. Inc., JP Morgan and Robertson Stephens. The underwriters also exercised an overallotment option on March 15, 2001 for 628,706 shares. The overallotment shares were sold at a price of \$13.00 per share. The aggregate proceeds to the Company from the offering were \$128.5 million after deducting the underwriting discounts and commissions of \$9.7 million, and excluding expenses incurred in connection with the offering of approximately \$2.3 million.

Of the net proceeds, as of September 30, 2002, we have used net offering proceeds to purchase plant machinery and equipment, leasehold improvements and working capital in the amounts of approximately \$24.2 million, \$1.6 million and \$73.4 million, respectively. No direct or indirect payments were made to directors, officers, general partners of the issuer or their associates, or to persons owning 10% or more of any class of equity securities of the issuer, or to any affiliates of the issuer in connection with the offering.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. SUBMISSION OF MATTERS TO VOTE OF SECURITY HOLDERS

None.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K

(a) Exhibits

<u>Exhibit Number</u>	<u>Description of Document</u>
10.18	Employment Offer Letter for Roger E. George, Vice President of Legal Affairs & General Counsel
10.19	Employment Offer Letter for David S. Thrower, Vice President of Global Marketing
10.20	Employment Offer Letter for Eldon M. Bullington, Chief Financial Officer and Vice President, Finance
99.1	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
99.2	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

(b) Reports on Form 8-K

None.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Align Technology, Inc.

(Registrant)

Dated: November 13, 2002

By: /s/ Thomas M. Prescott

Thomas M. Prescott

Chief Executive Officer

By: /s/ Eldon M. Bullington

Eldon M. Bullington

Chief Financial Officer and Vice President, Finance

(Principal Financial and Principal Accounting Officer)

CERTIFICATIONS

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 quarterly 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 quarterly report;
3. Based on my knowledge, the financial statements, and other financial information included in this quarterly 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 quarterly report;
4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:
 - a) designed such disclosure controls and procedures 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 quarterly report is being prepared;
 - b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the "Evaluation Date"); and
 - c) presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):
 - a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
 - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and
6. The registrant's other certifying officers and I have indicated in this quarterly report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: November 13, 2002

By: /s/ Thomas M. Prescott

Thomas M. Prescott

Chief Executive Officer

CERTIFICATIONS (continued)

I, Eldon M. Bullington, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Align Technology, Inc.;
2. Based on my knowledge, this quarterly 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 quarterly report;
3. Based on my knowledge, the financial statements, and other financial information included in this quarterly 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 quarterly report;
4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:
 - a) designed such disclosure controls and procedures 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 quarterly report is being prepared;
 - b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the "Evaluation Date"); and
 - c) presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):
 - a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
 - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and
6. The registrant's other certifying officers and I have indicated in this quarterly report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: November 13, 2002

By: /s/ Eldon M. Bullington
Eldon M. Bullington
Chief Financial Officer and Vice President, Finance
(Principal Financial and Principal Accounting Officer)

INDEX TO EXHIBITS

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July 10, 2002

Re: Employment Terms

Dear Roger:

Align Technology Incorporated is pleased to offer you the position of Vice President and General Counsel.

Your anticipated start date is to be determined, and you will attend new hire orientation from 9:00 a.m. to 4:00 p.m. Your rate of pay will be a bi-weekly salary of \$7,692.31, which equals to an annual salary of \$200,000, less payroll deductions and all required withholdings. In addition, you will be eligible for an annual target bonus of 30% of your base salary based on meeting agreed upon performance objectives established between you and me. Align Technology will guarantee a 30% bonus based on your actual FY2002 base pay, payable in early 2003. We will discuss this in more detail shortly after you start.

You will be eligible for the standard Company benefits, including medical insurance, 17 days of paid vacation annually, and sick leave. You will be eligible to participate in most benefits on the first day of employment. Details about these benefit plans are available for your review.

Subject to the approval of the Board of Directors, Align Technology will grant you the option to purchase 165,000 shares of Align Technology common stock which shall vest as to 25% of the shares on the first anniversary of your employment and as to 1/48th of the shares at the end of each month thereafter, for full vesting after 4 years. The exercise price shall be 100% of the fair market value of the stock on the date of grant, which shall be the later of your employment date or the date the grant is approved by the board.

Align Technology may modify compensation and benefits from time to time as it deems necessary, with the exception of the stock purchase rights cited in the previous paragraph. The stock purchase rights cited in the previous paragraph may only be modified by mutual agreement between Align Technology, Inc. and yourself.

Your place of work will be at the offices of Align Technology, 851 Martin Ave, Santa Clara, CA 95050. Of course, Align Technology may change your position, duties, and work location from time to time as it deems necessary.

As an Align Technology employee, you will be expected to abide by Company rules and regulations, acknowledge in writing that you have read the Company's Employee Handbook, and sign and comply with a Proprietary Information and Inventions Agreement which prohibits unauthorized use or disclosure of Align Technology proprietary information.

Normal working hours are from 8:00 a.m. to 5:00 p.m., Monday through Friday. As an exempt employee, you may be expected to work additional hours as required by the nature of your work assignments.

You may terminate your employment with Align Technology at any time and for any reason whatsoever simply by notifying Align Technology. Likewise, Align Technology may terminate your employment at any time and for any reason whatsoever, with or without cause or advance notice. Also, Align Technology retains its discretion to make all other decisions concerning your employment (e.g. demotions, transfers, job responsibilities, compensation or any other managerial decisions) with or without cause. This at-will employment relationship cannot be changed except in writing signed by a Company officer.

Although your employment will be "at-will," if the Company terminates your employment at any time without "Cause" or if you resign for "Good Reason" you will be credited with one (1) year vesting of your options in addition to whatever vesting you have earned to date, provided that you sign a full release of all claims at the time your employment terminates.

For the purpose of additional vesting under this letter, "Cause" shall mean a Company-initiated termination for any of the following reasons: (a) failure to perform the material duties of your position; (b) being convicted of a crime; (c) committing an act of fraud against, or the misappropriation of property belonging to the Company; (d) intentional misconduct; or (e) a material breach by you of this Agreement or any confidentiality or proprietary information agreement between you and the Company. A termination by the Company for any other reason is a termination without Cause.

Also for the purposes of additional vesting under this agreement, "Good Reason" shall mean any reduction in your base salary, or if you are required to relocate more than 35 miles from the current location of the Company. A resignation by you for any other reason would be a resignation without Good Reason. You would be required to give the Company notice and a reasonable opportunity during which to cure before resigning for Good Reason. It is anticipated that Align Technology and you will enter into an Employment Agreement with terms satisfactory to both parties. Included in that agreement will be provisions to address the implications of a change of control on your stock option grant as well as termination.

It is anticipated that Align Technology and you will enter into an Employment Agreement with terms satisfactory to both parties. Included in that agreement will be provisions to address the implications of a change of control on your stock option grant as well as termination.

This letter, together with your Proprietary Information and Inventions Agreement, constitute the complete, final and exclusive embodiment of the entire agreement between you and the Company with respect to the terms and conditions of your employment, and these terms supersede any other agreements or promises made to you by anyone, whether oral or written. As required by law, this offer is subject to satisfactory proof of your right to work in the United States.

Please note that, in compliance with the Immigration Reform Act of 1986, all new employees are required to submit proof of U.S citizenship or legal alien status within three business days of employment with Align Technology. Enclosed is an I-9 Form that lists the documents that you can present to fulfill this requirement. Please bring your documents, along with a completed I-9 Form, on your first day of employment.

Please sign and date the original offer letter upon your acceptance, and mail back to me.

A copy of the offer letter is enclosed for your files. If you have any questions, please contact me at (408) 470-1112.

We look forward to your favorable reply and to a productive and enjoyable work relationship.

Sincerely,

/S/ Thomas M. Prescott

Thomas M. Prescott
President & CEO

Accepted

/S/ Roger E. George

Roger E. George

Date: July 10, 2002

July 15, 2002

Re: Employment Terms

Dear David:

Align Technology Incorporated is pleased to offer you the position of Vice President of Global Marketing.

Your anticipated start date is August 5, 2002, and you will attend new hire orientation from 9:00 a.m. to 4:00 p.m. Your rate of pay will be a bi-weekly salary of \$8,076.92, which equals to an annual salary of \$210,000, less payroll deductions and all required withholdings. In addition, you will be eligible for a discretionary annual target bonus of 30% of your base salary based on meeting agreed upon performance objectives established between you and me. You will be eligible for the target bonus on your actual FY2002 base pay, payable in early 2003. We will discuss this in more detail shortly after you start. Additionally, you will receive a sign on bonus in the amount of \$30,000.00, subject to all taxes and withholdings (the "Sign On Bonus"). In addition, you will be entitled to receive a bonus in the amount of \$120,000, that will be payable on November 30, 2002, subject to all taxes and withholdings, if you are still employed as of October 31, 2002 (the "November Bonus"). You will also be entitled to receive a second bonus in the amount of \$120,000, that will be payable on January 31, 2003, subject to all taxes and withholdings, if you are still employed as of December 31, 2002 (the "January Bonus"). Should your employment with the Company be terminated voluntarily within the first year of the respective payment date of each such bonus, the Sign On Bonus, the November Bonus, and the January Bonus (collectively, the "Offer Letter Bonuses") must be reimbursed to the Company based on the attached reimbursement agreement (See "Attachment A"). Align will cover the normal, reasonable costs associated with your relocation from Newbury Park, CA to the Bay Area. The scope of these covered costs will be provided as an amendment to this offer letter. Should your employment with the Company be terminated voluntarily within the first year of your employment, your relocation costs must be reimbursed to the Company based on the attached reimbursement agreement (See "Attachment B").

You will be eligible for the standard Company benefits, including medical insurance, 17 days of paid vacation annually, and sick leave. You will be eligible to participate in most benefits on the first day of employment. Details about these benefit plans are available for your review.

Subject to the approval of the Board of Directors, Align Technology will grant you the option to purchase 200,000 shares of Align Technology common stock which shall vest as to 25% of the shares on the first anniversary of your employment and as to 1/48th of the shares at the end of each month thereafter, for full vesting after 4 years. The exercise price shall be 100% of the fair market value of the stock on the date of grant, which shall be the later of your employment date or the date the grant is approved by the board.

Align Technology may modify compensation and benefits from time to time as it deems necessary, with the exception of the stock purchase rights cited in the previous paragraph. The stock purchase rights cited in the previous paragraph may only be modified by mutual agreement between Align Technology, Inc. and yourself.

Your place of work will be at the offices of Align Technology, 851 Martin Ave, Santa Clara, CA 95050. Of course, Align Technology may change your position, duties, and work location from time to time as it deems necessary.

As an Align Technology employee, you will be expected to abide by Company rules and regulations, acknowledge in writing that you have read the Company's Employee Handbook, and sign and comply with a Proprietary Information and Inventions Agreement which prohibits unauthorized use or disclosure of Align Technology proprietary information.

Normal working hours are from 8:00 a.m. to 5:00 p.m., Monday through Friday. As an exempt employee, you may be expected to work additional hours as required by the nature of your work assignments.

You may terminate your employment with Align Technology at any time and for any reason whatsoever simply by notifying Align Technology. Likewise, Align Technology may terminate your employment at any time and for any reason whatsoever, with or without cause or advance notice. Also, Align Technology retains its discretion to make all other decisions concerning your employment (e.g. demotions, transfers, job responsibilities, compensation or any other managerial decisions) with or without cause. This at-will employment relationship cannot be changed except in writing signed by a Company officer.

Although your employment will be "at-will," if the Company terminates your employment at any time without "Cause" or if you resign for "Good Reason" you will be credited with one (1) year vesting of your options in addition to whatever vesting you have earned to date, provided that you sign a full release of all claims at the time your employment terminates.

For the purpose of additional vesting under this letter, "Cause" shall mean a Company-initiated termination for any of the following reasons: (a) failure to perform the material duties of your position; (b) being convicted of a crime; (c) committing an act of fraud against, or the misappropriation of property belonging to the Company; (d) intentional misconduct; or (e) a material breach by you of this Agreement or any confidentiality or proprietary information agreement between you and the Company. A termination by the Company for any other reason is a termination without Cause.

Also for the purposes of additional of vesting under this agreement, "Good Reason" shall mean any reduction in your base salary, or if you are required to relocate more than 35 miles from the current location of the Company. A resignation by you for any other reason would be a resignation without Good Reason. You would be required to give the Company notice and a reasonable opportunity during which to cure before resigning for Good Reason.

It is anticipated that Align Technology and you will enter into an Employment Agreement with terms satisfactory to both parties. Included in that agreement will be provisions to address the implications of a change of control on your stock option grant, as well as the terms of your relocation allowance and loan, and termination.

Unless and until such aforementioned Employment Agreement is executed by the Company and you, this letter, together with your Proprietary Information and Inventions Agreement, constitute the complete, final and exclusive embodiment of the entire agreement between you and the Company with respect to the terms and conditions of your employment, and these terms supersede any other agreements or promises made to you by anyone, whether oral or written. As required by law, this offer is subject to satisfactory proof of your right to work in the United States.

Please note that, in compliance with the Immigration Reform Act of 1986, all new employees are required to submit proof of U.S citizenship or legal alien status within three business days of employment with Align Technology. Enclosed is an I-9 Form that lists the documents that you can present to fulfill this requirement. Please bring your documents, along with a completed I-9 Form, on your first day of employment.

Please sign and date the original offer letter upon your acceptance, and mail back to me.

A copy of the offer letter is enclosed for your files. If you have any questions, please contact me at (408) 470-1112.

We look forward to your favorable reply and to a productive and enjoyable work relationship.

Sincerely,

/S/ Thomas M. Prescott

Thomas M. Prescott
President & CEO

Accepted:

/S/David S. Thrower

David S. Thrower

Date: July 15, 2002

August 22, 2002

Re: Employment Terms

Dear Eldon:

Align Technology Incorporated is pleased to offer you the position of Chief Financial Officer and Vice President, Finance.

Your anticipated start date is to be determined, and you will attend new hire orientation from 9:00 a.m. to 4:00 p.m. Your rate of pay will be a bi-weekly salary of \$7,692.31, which equals to an annual salary of \$200,000, less payroll deductions and all required withholdings. In addition, you will be eligible for an annual target bonus of 30% of your base salary based on meeting agreed upon performance objectives established between you and me. Align Technology will guarantee a 30% bonus based on your actual FY2002 base pay, payable in early 2003. We will discuss this in more detail shortly after you start.

You will be eligible for the standard Company benefits, including medical insurance, 17 days of paid vacation annually, and sick leave. You will be eligible to participate in most benefits on the first day of employment. Details about these benefit plans are available for your review.

Subject to the approval of the Board of Directors, Align Technology will grant you the option to purchase 175,000 shares of Align Technology common stock which shall vest as to 25% of the shares on the first anniversary of your employment and as to 1/48th of the shares at the end of each month thereafter, for full vesting after 4 years. The exercise price shall be 100% of the fair market value of the stock on the date of grant, which shall be the later of your employment date or the date the grant is approved by the board.

Align Technology may modify compensation and benefits from time to time as it deems necessary, with the exception of the stock purchase rights cited in the previous paragraph. The stock purchase rights cited in the previous paragraph may only be modified by mutual agreement between Align Technology, Inc. and yourself.

Your place of work will be at the offices of Align Technology, 851 Martin Ave, Santa Clara, CA 95050. Of course, Align Technology may change your position, duties, and work location from time to time as it deems necessary.

As an Align Technology employee, you will be expected to abide by Company rules and regulations, acknowledge in writing that you have read the Company's Employee Handbook, and sign and comply with a Proprietary Information and Inventions Agreement which prohibits unauthorized use or disclosure of Align Technology proprietary information.

Normal working hours are from 8:00 a.m. to 5:00 p.m., Monday through Friday. As an exempt employee, you may be expected to work additional hours as required by the nature of your work assignments.

You may terminate your employment with Align Technology at any time and for any reason whatsoever simply by notifying Align Technology. Likewise, Align Technology may terminate your employment at any time and for any reason whatsoever, with or without cause or advance notice. Also, Align Technology retains its discretion to make all other decisions concerning your employment (e.g. demotions, transfers, job responsibilities, compensation or any other managerial decisions) with or without cause. This at-will employment relationship cannot be changed except in writing signed by a Company officer.

Although your employment will be "at-will," if the Company terminates your employment at any time without "Cause" or if you resign for "Good Reason" you will be credited with one (1) year vesting of your options in addition to whatever vesting you have earned to date, provided that you sign a full release of all claims at the time your employment terminates.

For the purpose of additional vesting under this letter, "Cause" shall mean a Company-initiated termination for any of the following reasons: (a) failure to perform the material duties of your position; (b) being convicted of a crime; (c) committing an act of fraud against, or the misappropriation of property belonging to the Company; (d) intentional misconduct; or (e) a material breach by you of this Agreement or any confidentiality or proprietary information agreement between you and the Company. A termination by the Company for any other reason is a termination without Cause.

Also for the purposes of additional vesting under this agreement, "Good Reason" shall mean any reduction in your base salary, or if you are required to relocate more than 35 miles from the current location of the Company. A resignation by you for any other reason would be a resignation without Good Reason. You would be required to give the Company notice and a reasonable opportunity during which to cure before resigning for Good Reason. It is anticipated that Align Technology and you will enter into an Employment Agreement with terms satisfactory to both parties. Included in that agreement will be provisions to address the implications of a change of control on your stock option grant as well as termination.

It is anticipated that Align Technology and you will enter into an Employment Agreement with terms satisfactory to both parties. Included in that agreement will be provisions to address the implications of a change of control on your stock option grant as well as termination.

This letter, together with your Proprietary Information and Inventions Agreement, constitute the complete, final and exclusive embodiment of the entire agreement between you and the Company with respect to the terms and conditions of your employment, and these terms supersede any other agreements or promises made to you by anyone, whether oral or written. As required by law, this offer is subject to satisfactory proof of your right to work in the United States.

Please note that, in compliance with the Immigration Reform Act of 1986, all new employees are required to submit proof of U.S citizenship or legal alien status within three business days of employment with Align Technology. Enclosed is an I-9 Form that lists the documents that you can present to fulfill this requirement. Please bring your documents, along with a completed I-9 Form, on your first day of employment.

Please sign and date the original offer letter upon your acceptance, and mail back to me.

A copy of the offer letter is enclosed for your files. If you have any questions, please contact me at (408) 470-1112.

We look forward to your favorable reply and to a productive and enjoyable work relationship.

Sincerely,

/S/ Thomas M. Prescott

Thomas M. Prescott
President & CEO

Accepted:

/S/ Eldon M. Bullington

Eldon M. Bullington

Date: August 22, 2002

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

In connection with the Quarterly Report of Align Technology, Inc. (the "Company") on Form 10-Q for the period ending September 30, 2002 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Thomas M. Prescott, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. 1350, as adopted pursuant to 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

/s/ Thomas M. Prescott

Thomas M. Prescott
Chief Executive Officer
November 13, 2002

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

In connection with the Quarterly Report of Align Technology, Inc. (the "Company") on Form 10-Q for the period ending September 30, 2002 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Eldon M. Bullington, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. 1350, as adopted pursuant to 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

/s/ Eldon M. Bullington

Eldon M. Bullington
Chief Financial Officer
November 13, 2002

