

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 June 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 July 31, 2002 was 48,018,588.

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)

June 30, December 31,
2002 2001

ASSETS	(unaudited)	
Current assets:		
Cash and cash equivalents.....	\$ 27,116	\$ 50,550
Restricted cash.....	338	723
Marketable securities, short-term.....	8,066	12,494
Accounts receivable, net.....	15,938	11,556
Inventories.....	1,604	1,549
Deferred costs.....	503	714
Other current assets.....	5,742	3,997
	-----	-----
Total current assets.....	59,307	81,583
Property and equipment, net.....	30,467	32,021
Marketable securities, long-term.....	169	2,627
Other assets.....	2,003	1,987
	-----	-----
Total assets.....	\$ 91,946	\$ 118,218
	=====	=====

LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable.....	\$ 3,657	\$ 4,376
Other accrued liabilities.....	11,268	11,909
Deferred revenue.....	2,377	1,551
	-----	-----
Total current liabilities.....	17,302	17,836
Capital lease obligations, net of current portion....	773	980
Contingencies (Note 4)		
Stockholders' equity:		
Common stock.....	5	5
Additional paid-in capital.....	349,077	355,055
Deferred stock-based compensation.....	(30,688)	(48,324)
Notes receivable from stockholders.....	(1,072)	(1,484)
Accumulated other comprehensive income (loss)	(57)	226
Accumulated deficit.....	(243,394)	(206,076)
	-----	-----
Total stockholders' equity.....	73,871	99,402
	-----	-----
Total liabilities and stockholders' equity.....	\$ 91,946	\$ 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		Six Months Ended	
	June 30,		June 30,	
	2002	2001	2002	2001
	-----	-----	-----	-----
Revenues.....	\$ 17,255	\$ 13,483	\$ 34,396	\$ 21,172
Cost of revenues.....	10,774	13,830	23,279	25,384
	-----	-----	-----	-----
Gross profit (loss).....	6,481	(347)	11,117	(4,212)
	-----	-----	-----	-----
Operating expenses:				
Sales and marketing.....	11,448	10,945	21,266	27,656
General and administrative.....	10,579	8,059	21,103	14,964
Research and development.....	3,006	3,816	6,099	7,760
Litigation settlement.....	--	400	--	400
	-----	-----	-----	-----
Total operating expenses.....	25,033	23,220	48,468	50,780
	-----	-----	-----	-----
Loss from operations.....	(18,552)	(23,567)	(37,351)	(54,992)
Interest and other income (expense), net....	(264)	1,273	33	740
	-----	-----	-----	-----
Net loss.....	(18,816)	(22,294)	(37,318)	(54,252)
Dividend related to beneficial conversion feature of preferred stock.....	--	--	--	(11,191)
	-----	-----	-----	-----
Net loss available to common stockholders... \$	(18,816)	\$ (22,294)	\$ (37,318)	\$ (65,443)
	=====	=====	=====	=====
Net loss available to common stockholders, basic and diluted.....	\$ (0.40)	\$ (0.50)	\$ (0.81)	\$ (1.67)
	=====	=====	=====	=====
Shares used in computing net loss per share available to common stockholders, basic and diluted.....	46,576	44,518	46,322	39,077
	=====	=====	=====	=====

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)

	Six Months Ended June 30,	
	2002	2001
Cash Flows from Operating Activities:		
Net loss.....	\$ (37,318)	\$ (54,252)
Adjustments to reconcile net loss to net cash used in operating activities:		
Amortization of deferred stock compensation.....	8,652	11,785
Compensation expense for accelerated vesting of stock optio	1,298	--
Stock-based compensation.....	1,498	--
Depreciation and amortization.....	6,034	3,243
Loss on retirement of assets.....	3	35
Allowance for doubtful accounts.....	712	340
Non-cash interest income on notes receivable.....	(19)	(88)
Non-cash interest expense on convertible subordinated note.	--	1,803
Non-cash accretion on marketable securities.....	33	(973)
Changes in Operating Assets and Liabilities:		
Accounts receivable.....	(5,094)	(5,750)
Deferred costs.....	211	(105)
Inventories.....	(55)	(311)
Other current assets.....	(1,745)	(1,389)
Accounts payable.....	(742)	(4,200)
Accrued liabilities.....	(691)	(2,282)
Deferred revenue.....	826	(37)
Net cash used in operating activities.....	(26,397)	(52,181)
Cash Flows from Investing Activities:		
Purchase of property, plant and equipment.....	(4,427)	(8,420)
Decrease in restricted cash.....	385	12,663
Purchase of marketable securities.....	(1,530)	(72,304)
Proceeds from sales and maturities of marketable securities..	8,100	30,837
Change in other assets.....	(16)	(1,120)
Net cash provided by (used in) investing activities.....	2,512	(38,344)
Cash Flows from Financing Activities:		
Proceeds from issuance of common stock, net.....	691	127,395
Proceeds from repayment of notes receivable from shareholders	225	28
Repurchase of common stock.....	(275)	--
Payments on loan and capital leases.....	(190)	(225)
Net cash provided by financing activities.....	451	127,198
Net (decrease) increase in cash and cash equivalents.....	(23,434)	36,673
Cash and cash equivalents at beginning of period.....	50,550	2,828
Cash and cash equivalents at end of period.....	\$ 27,116	\$ 39,501

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

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

1. BASIS OF PRESENTATION

The accompanying unaudited condensed consolidated financial statements as of June 30, 2002, and for the three months and six months ended June 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 six months ended June 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):

	June 30, 2002	December 31, 2001
Raw materials.....	\$ 1,330	\$ 1,122
Work in progress.....	125	182
Finished goods.....	149	245
Total inventories.....	<u>\$ 1,604</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 and warrants and shares issuable upon conversion of the preferred stock.

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 June 30,		Six Months Ended June 30,	
	2002	2001	2002	2001
Basic and diluted:				
Net loss available to common stockholders.....	\$ (18,816)	\$ (22,294)	\$ (37,318)	\$ (65,443)
Weighted average common stock outstanding.....	47,891	47,807	47,876	42,480
Less: Weighted-average shares subject to repurchase.....	(1,315)	(3,289)	(1,554)	(3,403)
Weighted-average shares used in basic and diluted net loss per share.....	<u>46,576</u>	<u>44,518</u>	<u>46,322</u>	<u>39,077</u>
Net loss per share available to common stockholders.....	<u>\$ (0.40)</u>	<u>\$ (0.50)</u>	<u>\$ (0.81)</u>	<u>\$ (1.67)</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 for the three and six month periods indicated (in thousands):

	June 30,	
	2002	2001
Options to purchase common stock.....	7,646	5,688
Common stock subject to repurchase.....	1,151	3,180
	<u>8,797</u>	<u>8,868</u>

4. CONTINGENCIES

On May 1, 2002, GW Com, Inc. filed a complaint in Santa Clara Superior Court against the Company and James Lindsey, the owner of the premises located at 851 Martin Avenue in Santa Clara, California. The Company and GW Com were parties to a sub-sublease for such premises, the term of which expired on August 14, 2002. In early 2001, the Company 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. The Company withdrew from the negotiations of the amendment, after, among other things, Mr. Lindsey's consent could not be obtained. GW Com's complaint against the Company and Mr. Lindsey alleges breach of contract against the Company 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 action is in its early stages and no trial date has been set. The Company intends to vigorously contest GW Com's allegations.

On April 9, 2002, the Company exercised its 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 the Company issued a press release reporting this termination. On or about May 14, 2002 the Company 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, the Company conducted a thorough review of the Agreement and each party's performance thereunder. Based upon that review of the factual and

legal issues, the Company denies all claims made by Discus Dental in its demand and contends that such claims are entirely without merit. In addition, on or about June 13, 2002, the Company 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. As of this date, the arbitrators that will hear the arbitration have not yet been selected and no arbitration date has been set.

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 (LOSS)

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

6. 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 is in the process of determining the impact on the consolidated financial position of the Company.

7. SUBSEQUENT EVENTS

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 will be transitioned to the United States and Costa Rica. In addition, the plan includes a global reduction in worldwide staff. One-time charges relating to the plan will range between \$7 million and \$9 million. It is estimated that the majority of activities relating to the plan will conclude by December 31, 2002. Additionally, due to the closure of the Pakistan facility, land held in Pakistan will be put up for sale.

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 our 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, 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. In our facilities in Pakistan, the United Arab Emirates, or the U.A.E., and Costa Rica, technicians use a sophisticated, internally developed computer-modeling program to prepare electronic treatment plans, which are transmitted electronically back to the U.S. These 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 Pakistani rupees, U.A.E. dirhams, Costa Rican colons 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 Pakistan, the U.A.E. and 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, we announced a plan to streamline worldwide operations. The plan includes closing our facilities in Pakistan and the U.A.E. The operations performed at these facilities will be transitioned to the United States and Costa Rica. In addition, the plan includes a global reduction in worldwide staff. One-time charges relating to the plan will range between \$7 million and \$9 million. It is estimated that the majority of activities relating to the plan will conclude by December 31, 2002.

We have not been profitable for any period since April 3, 1997 (our inception). As of June 30, 2002, we had an accumulated deficit of \$243.4 million. We expect to have net operating losses and negative operating cash flows for at least the next 12 months due, in part, to continued spending on our consumer advertising campaign, continued development of our distribution channels, enhancements in our manufacturing process, continued international sales and marketing efforts and continued research and development efforts. We will need to generate significant revenue growth to achieve profitability and positive operating cash flow. Even if we do achieve profitability and positive cash flow, we may not be able to sustain or increase profitability or positive operating cash flow on a quarterly or annual basis.

We earn revenue primarily from the sale of Invisalign. In our domestic market and in other selected international locations, our revenue consists of fees charged for both the ClinCheck and for Aligners. We charge dental professionals a fixed fee for the treatment simulation viewed via ClinCheck on our website, Invisalign.com. This fee is invoiced when the dental professional orders ClinCheck prior to the production of Aligners. In addition, we charge dental professionals a fee for Aligners upon shipment. In other international locations, the dental professionals are invoiced for the entire Invisalign case upon the shipment of the Aligners.

Fees from the sale of ClinCheck and Aligners, taken together, are treated as revenues from a single Invisalign case. 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 cases where we expect a net loss, the entire loss is recognized immediately.

Results of Operations

Revenues. Revenues for the quarter ended June 30, 2002 increased to \$17.3 million, compared with \$13.5 million for the quarter ended June 30, 2001. Revenues for the six-month period ended June 30, 2002 increased to \$34.4 million, compared with \$21.2 million for the same six-month period in 2001. The increase in revenues was primarily due to the increase in Invisalign cases shipped, and for the six-month period ended June 30, 2002, an increase in training revenue of \$3.2 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. We expect training revenue to increase in future periods due to the planned increase in offered training courses.

Cost of revenues. Cost of revenues for the quarter ended June 30, 2002 was \$10.8 million, compared with \$13.8 million for the quarter ended June 30, 2001. Cost of revenues for the six-month period ended June 30, 2002 was \$23.3 million, compared with \$25.4 million for the same six-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 that resulted from our substantial increase in our manufacturing capacity in fiscal 2001, training costs and an allocation of the cost of facilities. For the quarter ended and six-month period ended June 30, 2002, we achieved positive gross margins mainly due to increases in Invisalign case volume, 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 June 30, 2002 were \$11.4 million, compared with \$10.9 million for the quarter ended June 30, 2001. Sales and marketing expenses for the six-month period ended June 30, 2002 were \$21.3 million, compared with \$27.7 million for the same six-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 increase in sales and marketing expenses for the quarter ended June 30, 2002 was primarily due to an increase in international sales and marketing expenses of \$3.7 and an increase in expenses related to advanced training of dental professionals of \$0.4 million, partially offset by a decrease in our domestic advertising expenses of \$4.0 million. The decrease in sales and marketing expenses for the six-month period ended June 30, 2002 resulted primarily from a decrease of approximately \$13.6 million in our domestic advertising expenses, partially offset by an increase in international sales and marketing expenses of approximately \$4.1 million.

General and administrative expenses. General and administrative expenses for the quarter ended June 30, 2002 were \$10.6 million, compared with \$8.1 million for the quarter ended June 30, 2001. General and administrative expenses for the six-month period ended June 30, 2002 were \$21.1 million, compared with \$15.0 million for the same six-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 increases for both periods were primarily attributable to increased headcount and administrative costs relating to being a public company and due to the growth of our international operations.

Research and development expenses. Research and development expenses for the quarter ended June 30, 2002 were \$3.0 million, compared with \$3.8 million for the quarter ended June 30, 2001. Research and development expenses for the six-month period ended June 30, 2002 were \$6.1 million, compared with \$7.8 million for the same six-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. For the quarter ended June 30, 2002, research and development expenses decreased primarily due to the continued reduction in outside services by approximately \$0.6 million. For the six-month period ended June 30, 2002, research and development expenses decreased primarily due to the continued reduction in outside services by approximately \$1.3 million.

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

Interest and other income (expense), net. Interest and other expense was \$0.3 million for the quarter ended June 30, 2002 compared to interest and other income of \$1.3 million for the quarter ended June 30, 2001. Interest and other income for the six-month period ended June 30, 2002 was \$0.03 million, compared with \$0.7 million for the same six-month period in 2001. Other expense for the first six months of 2002 consisted of bank management fees and bank service charges. Partially offsetting these charges was interest income, which has been decreasing primarily due to the decrease in our cash and cash equivalents balances and marketable securities balances. Interest income for the six-months ended June 30, 2001 was primarily generated from the our cash and cash equivalents balances and investments in short-term marketable securities. Offsetting this income in 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 \$6.1 million for the quarters ended June 30, 2002 and 2001, respectively. For the six-month periods ended June 30, 2002 and 2001, we recorded amortization of deferred compensation of \$8.7 million and \$11.8 million, respectively. Additionally, we recorded expenses of \$0.8 million for the quarter ended June 30, 2002 and \$1.5 million for the six-month period ended June 30, 2002, related to options granted to non-employees during the current fiscal year.

During the quarter ended June 30, 2002, 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 \$1.2 million for the quarter ended June 30, 2002 and \$1.3 million for the six month period ended June 30, 2002. 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. There were no acceleration charges for the quarter or six-month periods ended June 30, 2001.

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 June 30, 2002, we had \$35.4 million in cash and cash equivalents and marketable securities and an accumulated deficit of \$243.4 million. Additionally, we had \$0.3 million of restricted cash.

Net cash used in operating activities totaled \$26.4 million for the six-month period ended June 30, 2002, and \$52.2 million for the six-month period ended June 30, 2001. 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 six month period ended June 30, 2002 and net cash used by investing activities totaled \$38.3 million for the six-month period June 30, 2001. For the six-month period ended June 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 six-month period ended June 30, 2001, net cash used in investing activities consisted primarily of purchase of property and equipment and marketable securities, partially offset by proceeds from the sales and maturities of marketable securities and a decrease in restricted cash.

Net cash provided by financing activities was \$0.5 million for the six-month period ended June 30, 2002, and \$127.2 million for the six-month period ended June 30, 2001. For the six-month period ended June 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 overallotment option for 628,706 shares. Net proceeds to us were approximately \$126.2 million.

We expect our operating expenses to decrease in conjunction with our plan to streamline worldwide operations, announced in July 2002. While we believe that our existing working capital will be sufficient to fund our operations and our capital investments through the next twelve months, we are in the process of obtaining additional financing in the form of an accounts receivable line of credit and an equipment line of credit. 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 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.

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 is in the process of determining the impact on the consolidated financial position 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;
- increase the size of our sales force and dental professional training staff;
- 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 June 30, 2002, we had an accumulated deficit of approximately \$243.4 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. While we believe that our existing working capital will be sufficient to fund our operations and its capital investments through the next twelve months, the Company is in the process of obtaining additional financing in the form of an accounts receivable line of credit and an equipment line of credit. 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 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 June 30, 2002, approximately 6,000 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. While 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, our success will depend upon the rapid acceptance of Invisalign by the substantially larger number of 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. 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.

Two of our key production steps are performed in manufacturing operations located outside the U.S. We currently rely on our facilities in Pakistan, the U.A.E. and Costa Rica to create electronic treatment plans with the assistance of sophisticated software. In addition, we rely on third party manufacturers in Mexico to fabricate Aligners and to ship the completed product to customers. In July 2002, we announced a plan to streamline worldwide operations. The plan includes closing our facilities in Pakistan and the U.A.E. The operations performed at these facilities will be transitioned to the United States and Costa Rica. In addition, the plan includes a global reduction in worldwide staff. It is estimated that the majority of activities relating to the plan will conclude by December 31, 2002.

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 and the war in Afghanistan;
- 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, 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 July 31, 2002, we have 19 issued U.S. patents and 63 pending U.S. patent applications. We have 15 foreign-issued patents and 119 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. In addition, third party rapid prototyping bureaus fabricate some molds from which the Aligners are formed. As a result, if any of our third party manufacturers fail to deliver their components or if we lose their services, we may be unable to deliver our products in a timely manner and our business may be harmed. Finding substitute manufacturers may be expensive, time-consuming or impossible. Although we are in the process of developing the capability to fabricate all molds and Aligners internally, we may not be successful and may continue to rely on outsourcing in the future.

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 June 30, 1999 to approximately 780 employees as of June 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.

We are not aware of any company that is marketing or developing a system directly comparable to Invisalign. However, 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 have recently launched sales of our product in Germany, France, the United Kingdom, Spain, Italy, Mexico, Brazil, Australia and Hong Kong, and we intend to further expand our international operations. We do not know whether orthodontists, dentists and consumers 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 may be highly volatile.

The trading price of our common stock is likely to be 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;
- 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 June 30, 2002, our executive officers, directors and principal stockholders beneficially owned, in total, approximately 47.2% 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 DISCLOSURE 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 June 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 June 30, 2002, which originated in 2000, carry fixed interest rates of 6.53% and 11.15% per annum with principle payments due in 60 and 48 equal annual installments, respectively.

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; and
- 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 \$6.9 million of our expenses in the quarter ended June 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.

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. As of this date, the arbitrators that will hear the arbitration have not yet been selected and no arbitration date has been set.

In February 2001, we were named in a class action lawsuit filed on behalf of all licensed dentists (excluding odontologists) in the U.S. The complaint alleged that our policy of selling Invisalign exclusively to odontologists violated the U.S. antitrust laws. Without admitting any wrongdoing, we entered into a Stipulation and Agreement of Settlement with the plaintiffs to settle the lawsuit. The total legal and other settlement costs that we agreed to pay were approximately \$400,000. Pursuant to the settlement, we will undertake to train and certify 5,000 general practice dentists each year over the four-year period following the settlement. 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 Pakistan 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.

In addition to these actions, we are involved from time to time in judicial, administrative and other legal proceedings incidental to our business. Although occasional adverse decisions or settlements may occur, we believe that the final disposition of such matters will not have a material adverse effect on our financial position or results of operations.

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 June 30, 2002, we have used net offering proceeds to purchase plant machinery and equipment, leasehold improvements and working capital in the amounts of approximately \$21.9 million, \$1.6 million and \$70.7 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

The annual meeting of shareholders was held on May 16, 2002. Both matters voted on were approved. The results are as follows:

PROPOSAL I

The following directors were elected at the meeting to serve until our annual meeting following the end of fiscal year 2002 or until their successors are duly elected and qualified:

	For	Authority Withheld
H. Kent Bowen	30,846,473	113,772
Zia Chishti	30,826,146	134,099
Brian Dovey	30,844,273	115,972
Joe Jacob	30,788,907	171,338
Thomas M. Prescott	30,399,164	561,081
Kelsey Wirth	30,815,773	144,472

PROPOSAL II

The proposal to ratify the selection of PricewaterhouseCoopers LLP as the Company's independent auditors for the fiscal year ending December 31, 2002 was approved.

For	Against	Abstained
30,852,977	102,690	4,578

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>
99.1	Certification of the Chief Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
99.2	Certification of the Chief Financial Officer 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.

SIGNATURE

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: August 14, 2002

By: /s/ Stephen J. Bonelli
Stephen J. Bonelli

INDEX TO EXHIBITS

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**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 June 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
August 14, 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 June 30, 2002 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Stephen J. Bonelli, 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/ Stephen J. Bonelli

Stephen J. Bonelli
Chief Financial Officer
August 14, 2002

