UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

[X] QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended March 31, 2001

[_] TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the Transition period from to

Commission File Number:0-32259

ALIGN TECHNOLOGY, INC.
(Exact name of registrant as specified in its charter)

Delaware	94-3267295
(State or other jurisdiction of incorporation or organization)	(I.R.S. employer identification No.)

851 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 such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes [X] No [_]

The number of shares of the Registrant's Common Stock outstanding as of March 31, 2001 was 47,790,022.

ALIGN TECHNOLOGY, INC.
TABLE OF CONTENTS

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

	March 31, 2001	December 31, 2000
ASSETS		
Current assets:		
Cash and cash equivalents	$ 56,605	$ 2,828
Restricted cash	8,939	15,986
Marketable securities, short-term	55,910	9,633
Accounts receivable, net	6,718	4,465
Inventories	2,614	2,024
Deferred costs	3,607	2,431
Other current assets	1,774	3,995
Total current assets	136,167	41,362
Property and equipment, net	26,502	21,100
Marketable securities, long-term	7,010	6,251
Other assets	1,872	1,848
Total assets	$ 171,551	$ 70,561
LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 2,180	$ 5,541
Accrued liabilities	16,948	14,753
Deferred revenue	2,951	2,350
Current portion of capital lease obligations	452	445
Total current liabilities	22,531	23,089
Capital lease obligations, net of current portion	1,337	1,455
Total liabilities	23,868	24,544
Contingencies (Note 5)		
Convertible preferred stock	-	130,691
Stockholders' equity (deficit):		
Common stock	5	1
Additional paid-in capital	365,794	105,828
Deferred stock-based compensation	(75,817)	(80,160)
Notes receivable from stockholders	(1,858)	(1,814)
Accumulated other comprehensive income	119	73
Accumulated deficit	(140,560)	(108,602)
Total stockholders' equity (deficit)	147,683	(84,674)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$ 171,551	$ 70,561

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

ALIGN TECHNOLOGY, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(IN THOUSANDS, EXCEPT PER SHARE DATA)
(UNAUDITED)

	Three Months Ended	
	March 31, 2001	March 31, 2000
Revenues	$ 7,689	$ 629
Cost of revenues	11,554	2,026
Gross loss	(3,865)	(1,397)
Operating expenses:		
Sales and marketing	16,711	3,438
General and administrative	6,905	2,156
Research and development	3,944	1,057
Total operating expenses	27,560	6,651
Loss from operations	(31,425)	(8,048)
Interest and other income (expense), net	(533)	(32)
Net loss	(31,958)	(8,080)
Dividend related to beneficial conversion feature of preferred stock	(11,191)	--
Net loss available to common stockholders	$(43,149)	$(8,080)
Net loss available to common stockholders, basic and diluted	$ (1.29)	$ (1.55)
Shares used in computing net loss per share available to common stockholders, basic and diluted	33,574	5,225

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

ALIGN TECHNOLOGY, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(IN THOUSANDS)
(UNAUDITED)

	Three Months Ended	
	March 31, 2001	March 31, 2000
Cash Flows from Operating Activities:		
Net loss	$(31,958)	$(8,080)
Adjustments to reconcile net loss to net cash used in operating activities:		
Amortization of deferred stock compensation	5,658	666
Depreciation and amortization	1,499	313
Loss on retirement of assets	61	-
Allowance for doubtful accounts	70	36
Non-cash interest income on notes receivable	(44)	-
Non-cash interest expense on convertible subordinated note	1,803	-
Non-cash accretion on marketable securities	(454)	(8)
Changes in Operating Assets and Liabilities:		
Accounts receivable	(2,323)	(352)
Deferred costs	(1,176)	(99)
Inventories	(590)	(118)
Other current assets	303	(989)
Accounts payable	(3,125)	(642)
Accrued liabilities	(2,027)	96
Deferred revenue	601	129
Net Cash Used in Operating Activities	(31,702)	(9,048)
Cash Flows from Investing Activities:		
Purchase of property, plant and equipment	(2,585)	(175)
Decrease in restricted cash	7,047	-
Purchase of marketable securities	(62,338)	-
Maturities of marketable securities	-	1,250
Proceeds from sale of marketable securities	15,837	999
Change in other assets	(24)	(94)
Net Cash (Used in) Provided by Investing Activities	(42,063)	1,980
Cash Flows from Financing Activities:		
Proceeds from issuance of common stock, net	127,654	14
Repurchase of common stock	(1)	-
Issuance of warrants	-	776
Payments on loan and capital leases	(111)	(26)
Net Cash Provided by Financing Activities	127,542	764
Net Increase (Decrease) in Cash and Cash Equivalents	53,777	(6,304)
Cash and Cash Equivalents at Beginning of Period	2,828	6,832
Cash and Cash Equivalents at End of Period	$ 56,605	$ 528

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

1. BASIS OF PRESENTATION

The accompanying unaudited condensed consolidated financial statements of Align Technology, Inc. have been prepared in accordance with generally accepted accounting principles for interim financial information and pursuant to the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements. In the opinion of management, all adjustments, consisting of normal recurring adjustments, considered necessary for a fair presentation have been included. Results for an interim period are not necessarily indicative of the results to be expected for the full fiscal year or any future interim periods. These interim unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto, together with management's discussion and analysis of financial condition and results of operations, for the year ended December 31, 2000, contained in the Company's Annual Report on Form 10-K/A as filed with the U.S. Securities and Exchange Commission (SEC).

2. INITIAL PUBLIC OFFERING

In January 2001, the Company completed an 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 the Company were approximately $126.2 million.

As of January 25, 2001, because the Company has issued 3,591,458 shares of common stock in excess of the 3,331,978 shares of common stock permitted, as defined in the certificate of incorporation, the Company is required to issue 790,342 shares of common stock upon the conversion of the preferred stock in addition to 419,700 shares as of December 31, 2000. As a result, the Company recorded a deemed dividend based on the fair value of the common stock at the commitment date of $11,191,000 related to the preferred stock sold and a charge to interest expense of $1,803,000 for the beneficial conversion feature embedded in convertible subordinated notes, that previously converted, in January 2001.

3. INVENTORIES

Inventories comprise (in thousands):

	March 31, 2001	December 31, 2000
	(unaudited)	
Raw materials	$1,238	$1,183
Work in progress	128	294
Finished goods	1,248	547
Total inventories	$2,614	$2,024

4. NET LOSS PER SHARE

Basic and diluted net loss per share are 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 (unaudited)):

	Three Months Ended	
	March 31, 2001	March 31, 2000
Basic and diluted:		
Net loss available to common stockholders.....	$(43,149)	$(8,080)
Weighted average common stock outstanding.....	37,094	5,697
Less: Weighted-average shares subject to repurchase..	(3,520)	(472)
Weighted-average shares used in basic and diluted net loss per share.....	33,574	5,225
Net loss per share available to common stockholders..	$ (1.29)	$ (1.55)

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

	Three Months Ended	
	March 31, 2001	March 31, 2000
Preferred stock (as if converted).....	-	16,253
Options to purchase common stock.....	5,058	1,934
Common stock subject to repurchase.....	3,416	312
Warrants.....	113	646
	8,587	19,145

5. CONTINGENCIES

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 damages 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.

6. COMPREHENSIVE INCOME

The following table sets forth changes in comprehensive income for the three month period ending March 31, 2001 (in thousands, unaudited):

Balance at December 31, 2000.....	$ 73
Unrealized gain on available-for-sale securities..	81
Unrealized translation loss.....	(35)
Balance at March 31, 2001.....	$119

7. SUPPLEMENTAL CASH FLOW INFORMATION

Supplemental cash flow information consists of the following (in thousands, unaudited):

	Three Months Ended	
	March 31, 2001	March 31, 2000
Non-Cash investing and financing activities:		
Fixed assets acquired under capital lease.....	$ -	$ 729
Fixed assets acquired with accounts payable or accrued liabilities.....	$ 4,377	$ 312
Accrual for IPO costs.....	$ 166	-
Issuance of warrants in conjunction with line of credit financing.....	$ -	$ 776
Deferred stock compensation.....	$ 1,315	$8,616
Conversion of preferred stock into common stock.....	$130,691	$ -

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

This Management's Discussion and Analysis of Financial Condition and Results of Operations contains descriptions of our expectations regarding future trends affecting our business. These forward-looking statements and other forward-looking statements made elsewhere in this document are made in reliance upon the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Please read the section below titled "Factors Affecting Future Results" to review conditions which we believe could cause actual results to differ materially from those contemplated by the forward-looking statements. Forward-looking statements are identified by words such as "believes", "anticipates", "expects", "intends", "plans", "will", "may" and similar expressions. In addition, any statements that refer to our plans, expectations, strategies or other characterizations of future events or circumstances are forward looking statements.

The following discussion should be read in conjunction with the unaudited condensed consolidated financial statements and notes thereto included in this Quarterly Report on Form 10-Q.

Overview

From our inception in April 1997 to July 2000, we were engaged in the design, manufacture and marketing of the Invisalign System, a proprietary new system for treating malocclusion, or the misalignment of teeth. In July 1999, we commenced commercial sales of our Invisalign System. Prior to July 1999, we devoted nearly all our resources to developing our software and manufacturing processes, clinical trials of the Invisalign System and building our sales force, customer support and management teams. We exited the development stage in July 2000.

The Invisalign System has two components: ClinCheck and Aligners. ClinCheck is an Internet-based application that allows orthodontists 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 an orthodontist using ClinCheck.

In the third quarter of 1999, we recognized revenue for the first time from the sale of the Invisalign System and related dental impression machines manufactured by ESPE America, Inc. We expect to sell dental impression machines to an orthodontist only once, if at all. Accordingly, sales of such machines are expected to represent a lower proportion of our revenue in the future. Substantially all our revenue is generated in the U.S. and Canada, which, taken together, we regard as our domestic market.

While our expansion outside of our domestic market is still in an exploratory stage, we do incur substantial operating costs outside of our domestic market. Two of our key production steps are performed in operations located outside of the U.S. In our facilities in Pakistan, technicians use a sophisticated,

internally developed computer-modeling program to prepare electronic treatment plans, which are transmitted via the Internet 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 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, 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 are mitigated in Pakistan 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.

As of March 31, 2001, we had an accumulated deficit of $140.6 million. We expect to have net losses and negative operating cash flows for at least the next 18 months due, in part, to our national consumer advertising campaign, the expansion of manufacturing capacity and continued research and development efforts.

We earn revenue primarily from the sale of our Invisalign System. Our revenue consists of the ClinCheck fee and the charge for each Aligner. We charge orthodontists a fixed fee for the treatment simulation viewed via ClinCheck on our website, Invisalign.com. This fee is invoiced when the orthodontist orders ClinCheck prior to the production of Aligners. In addition, we charge orthodontists a fee for Aligners as we ship them.

We also earn ancillary revenue from the sale to orthodontists of dental impression machines. To facilitate adoption of the Invisalign System, we sell machines to some of our customers to assist them in preparing the impressions required for submission of Invisalign cases. These machines, which cost approximately $600 each, are manufactured by ESPE America, Inc. Many of our customers have adequate dental impression making equipment or pay general dentists to take impressions on their behalf and, as such, do not purchase an impression machine from us.

Historically, we have shipped Aligners in batches. The first batch, which typically represented the first several months of treatment, was produced once the prescribing orthodontist approved ClinCheck. Thereafter, Aligners were sent at approximately six month intervals until completion of treatment. In mid-February 2001, for cases where ClinCheck was approved, we began shipping all the Aligners in a single batch. In addition, we began accelerating the shipments of Aligners for cases where ClinCheck was approved prior to mid- February 2001. Fees from the sale of ClinCheck and Aligners, taken together, are treated as revenues from a single System. For cases where ClinCheck was approved prior to mid-February, revenues associated with a given case and are recognized ratably as batches of Aligners are shipped to the orthodontist. For orders placed subsequent to notification of our change to single batch shipments, all of the revenues associated with a given case, including ClinCheck fees, will be recognized at the time the Aligners are shipped. Payment terms will range from 30 days from case acceptance to net 90 days from Aligner shipment.

The costs of producing the ClinCheck treatment plan, which are incurred prior to the production of Aligners, are capitalized and recognized as related revenue is earned. In the cases where we expect a net loss, the entire loss is recognized immediately.

Deferred 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 (deficit). 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 $5.7 million for the quarter ended March 31, 2001 and $666,000 for the quarter ended March 31, 2000.

Results of Operations

Revenues. Revenues for the quarter ended March 31, 2001 increased to $7.7 million compared to $629,000 for the quarter ended March 31, 2000. Sales of our Invisalign System accounted for $7.3 million of revenues for the quarter ended March 31, 2001 compared to $450,000 for the quarter ended March 31, 2000. The balance of our revenues for the quarter ended March 31, 2001 and 2000 represented sales of our dental impression machines. We expect to sell a dental impression machine to an orthodontist only once, if at all. Accordingly, sales of our Invisalign Systems are expected to continue to represent substantially all of our revenue in the future.

Cost of revenues. 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 and an allocation of the cost of facilities. Cost of revenues for the quarter ended March 31, 2001 increased to $11.6 million compared to $2.0 million for the quarter ended March 31, 2000. Cost of revenues for the quarter ended March 31, 2001 includes $2.9 million of unabsorbed manufacturing costs due to a substantial increase in our manufacturing capacity in 2000. As we employ this manufacturing capacity to produce higher volumes of the Invisalign System, combined with the resultant manufacturing efficiencies and our recent price increase, we expect to record positive gross margins. We currently believe it will be at least 9 months before we are able to achieve positive gross margins.

Sales and marketing. Sales and marketing expenses include sales force compensation together with expense of professional marketing, principally, conducting training workshops and market surveys, advertising and attending orthodontic trade shows. Sales and marketing expenses for the quarter ended March 31, 2001 increased to $16.7 million compared to $3.4 million for the quarter ended March 31, 2000. This increase resulted primarily from increases in advertising expenses of $9.0 million and increases in headcount and related expenses of $1.4 million.

General and administrative. General and administrative expenses include costs for the compensation of administrative personnel, outside consulting services, facilities, legal expenses and general corporate expenses. General and administrative expenses for the quarter ended March 31, 2001 increased to $6.9 million compared to $2.2 million for the quarter ended March 31, 2000 primarily due to increased headcount and administrative costs relating to being a public company. We expect administrative expenses to continue to increase in the future to support expanding business activities and additional administrative costs related to being a public company.

Research and development expenses. 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. Research and development is expensed as incurred. Research and development expenses for the quarter ended March 31, 2001 increased to $3.9 million compared to $1.1 million for the quarter ended March 31, 2000, primarily due to an increase in headcount and related expenses and increased expenses related to outsourced software development.

Interest and other income (expense), net. Net interest and other expense for the quarter ended March 31, 2001 increased to $533,000 compared to $32,000 for the quarter ended March 31, 2000. This increase, which was partially offset by interest income on marketable securities, resulted primarily from non-cash interest expense of $1.8 million related to the beneficial conversion feature embedded in convertible subordinated notes.

Dividend related to beneficial conversion feature of preferred stock. In January 2001, we recorded the final dividend related to the beneficial conversion feature of preferred stock of $11.2 million, which represents the difference between the conversion price and the fair value per share of the common stock on the commitment date for Series D preferred stock. This amount has been reflected as a preferred stock dividend in the March 31, 2001 condensed consolidated financial statements.

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 March 31, 2001, we had $119.5 million in cash and cash equivalents and marketable securities and an accumulated deficit of $140.6 million. Additionally, we have $8.9 million of restricted cash of which $8.4 million is held in an escrow account to fund our national advertising campaign.

Net cash used in operating activities totaled $31.7 million and $9.0 million for the quarters ended March 31, 2001 and 2000, respectively. In each of these periods net cash used by operating activities consisted primarily of net operating losses, partially offset by increases in depreciation and amortization and amortization of deferred stock-based compensation. Additionally, in the quarter ended March 31, 2001, operating losses were partially offset by non-cash interest expense derived from a beneficial conversion feature on a convertible subordinated note, subsequently converted to Series D preferred stock.

Net cash used in investing activities totaled $42.1 million for quarter ended March 31, 2001 versus net cash provided by investing activities of $2.0 million for the quarter ended March 31, 2000. For the quarter ended March 31, 2001, net cash used in investing activities consisted primarily of purchases of property and equipment and marketable securities offset by sales and maturities of marketable securities and a decrease in restricted cash. For the quarter ended March 31, 2000, net cash provided by investing activities consisted primarily of maturities and sales of marketable securities.

Net cash provided by financing activities was $127.5 million and $764,000 for the quarters ended March 31, 2001 and 2000, respectively. 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 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 national consumer advertising campaign, continuing efforts to expand our manufacturing capacity, research and development and other costs. We expect the change of pattern of Aligner shipments in February 2001 will have a negligible effect on our cash flows. In addition, we may use cash to fund acquisitions of complementary businesses or technologies. We believe the net proceeds from the initial public offering will be sufficient to meet our operating, working capital and capital expenditure requirements for at least the next 12 months. Thereafter, we may find it necessary to obtain additional equity or debt financing. In the event additional financing is required, we may not be able to raise it on acceptable terms or at all.

FACTORS THAT MAY AFFECT FUTURE RESULTS

Since we have a history of losses and negative operating cash flows, and we expect our operating expenses to continue to increase, 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 the Invisalign System and developing our manufacturing and customer support resources. We also spent significant funds on clinical trials and

training programs to train orthodontists in the use of the Invisalign System. We expect to have net losses and negative operating cash flows for at least the next 18 months.

We intend to increase our operating expenses as we continue to:

- scale our manufacturing operations;
- develop new software and increase the automation of our manufacturing processes;
- execute our national direct to consumer marketing campaign;
- increase the size of our sales force and orthodontist training staff;
- undertake quality assurance and improvement initiatives; and
- increase our general and administrative functions to support our growing operations.

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 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 have only recently begun selling our Invisalign System in commercial quantities. 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 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 our Invisalign System declines or fails to develop as we expect, our revenue will decline.

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

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

As of March 31, 2001, approximately 2,900 orthodontists have submitted one or more cases to us. Our success depends upon increasing acceptance by orthodontists and dentists of the Invisalign System. The Invisalign System requires orthodontists and their staff to undergo special training and learn to interact with patients in new ways and to interact with us as a supplier. In addition, because our Invisalign System has

only been in clinical testing since July 1997 and commercially available since July 1999, orthodontists may be reluctant to adopt it until more historical clinical results are available. Also, increasing adoption by orthodontists 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 the Invisalign System could result in significant adverse publicity and consequently in reduced acceptance by orthodontists. If our Invisalign System does not achieve growing acceptance in the orthodontic and dental communities, our operating results will be harmed.

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

Our Invisalign System 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 orthodontists and patients regarding our Invisalign System as both an alternative to braces and as a clinical method for treatment of malocclusion, our success will depend upon the rapid acceptance of our System 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 dentists and orthodontists, 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. If consumers prove unwilling to adopt our Invisalign System as rapidly or in the numbers that we anticipate, our operating results will 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 March 31, 2001, we have two issued U.S. patents and 46 pending U.S. patent applications. We have two foreign-issued patents and 111 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 the Invisalign System 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 have limited experience in manufacturing our products and if we encounter manufacturing problems or delays, our ability to generate revenue will be limited.

We have manufactured a limited number of our products to date. Our manufacturing processes rely on complex three-dimensional scanning, geometrical manipulation and modeling technologies that have historically not been used on the scale we require. Each item that we manufacture is geometrically unique and we have not manufactured our products in the commercial volumes which will be required to make us profitable. Accordingly, we may be unable to establish or maintain reliable, high-volume manufacturing capacity. Even if this capacity can be established and maintained, the cost of doing so may increase the cost of our products. We may encounter difficulties in scaling up production to meet demand, including:

- problems involving production yields;
- shortages of key manufacturing equipment;
- shortages of qualified personnel, in particular dental and orthodontic personnel;
- failure to develop new software processes; and
- compliance with applicable Quality System regulations enforced by the FDA.

Our manufacturing process is complex. Since all our products are designed for individual patients, we manufacture our products to fill purchase orders rather than maintaining inventories of assembled products. If demand for our products exceeds our manufacturing capacity, we could develop a substantial backlog of customer orders. If we are unable to establish and maintain larger- scale-manufacturing capabilities, our ability to generate revenue will be limited and our reputation in the marketplace would be damaged.

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 rapid 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 are dependent on our international manufacturing operations, which exposes us to foreign operational and political 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 to create electronic treatment plans with the assistance of sophisticated software. We employ approximately 508 people in Lahore, Pakistan, in this effort. We anticipate that we will need to expand our personnel and facilities in Pakistan in order to scale our manufacturing operations. In addition, we rely on third party manufacturers in Mexico to fabricate Aligners and to ship the completed product to customers. Our reliance on international operations exposes us to risks and uncertainties, including:

- difficulties in staffing and managing international operations;
- controlling quality of manufacture;
- political, social and economic instability;
- interruptions and limitations in telecommunication services;
- product or material transportation delays or disruption;
- 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.

We are growing rapidly, and our failure to manage this growth could harm our business. We have experienced significant growth in recent periods.

Our headcount increased from 50 employees as of June 30, 1999 to approximately 1,100 employees as of March 31, 2001. In mid-2000, we approved major renovations and expansions to our existing facilities. We expect that our growth will 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, continued 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. Our inability to manage this growth effectively 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. There is currently a

shortage of skilled clinical, engineering and management personnel and intense competition for these personnel, especially in Silicon Valley where our headquarters is located. 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 our Invisalign System. 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 operations, 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.

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.

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, negative operating cash flows since inception and have not achieved profitability. As of March 31, 2001, we had an accumulated deficit of approximately $140.6 million.

We expect to expend significant capital to establish a national brand, build manufacturing infrastructure and develop both product and process technology. We believe that the existing cash balances, the proceeds from our initial public offering in January 2001 and other potential financing alternatives will be sufficient to meet our capital and operating requirements for at least the next 12 months.

We are currently working towards our objective of realizing profitability by achieving the key goal of successfully marketing our product throughout the U.S. and internationally, while controlling our expenses. The failure to win increased acceptance by orthodontists and dentists of the Invisalign System could have a material adverse effect on our business, results of operations and financial conditions.

If we are unable to generate adequate operating cash flows, we may need to seek additional sources of capital through equity or debt financing, collaborative or other arrangements with other companies, bank financing and other sources in order to realize our objectives and to continue our operations. There can be no assurance that we will be able to obtain additional debt or equity financing on terms acceptable to us, or at all. If adequate funds are not available, we could be required to delay establishing a national brand,

building manufacturing infrastructure and developing our product and process technology, or to reduce our expenditures in general. Accordingly, the failure to obtain sufficient funds on acceptable terms when needed could have a material adverse effect on our business, results of operations and financial condition.

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 March 31, 2001, our executive officers, directors and principal stockholders beneficially owned, in total, approximately 53% of our outstanding common stock. As a result, these stockholders are able to exercise control over 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.

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. The long-term debt at March 31, 2001 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 marketable securities maturities do not exceed fiscal year 2002 and the interest rates are primarily fixed. Our capital lease obligations of $1.8 million at March 31, 2001 carry a

fixed interest rate of 6.53% and 11.15% per annum with principle payments due in 60 and 48, respectively, equal annual installments beginning 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 $2.3 million of our expenses are related to operations outside the United States, denominated in currencies other than the U.S. dollar.
- Our investments in a foreign subsidiary being directly from the U.S. parent, resulting in U.S. dollar investments in foreign currency functional companies.

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 February 22, 2001 a complaint was filed against us by Jon L. Richter in the United States District Court for the Eastern District of Pennsylvania. Mr. Richter, a general practice dentist, purports to sue on behalf of himself and all licensed dentists in the U.S., excluding orthodontists. Mr. Richter alleges that we reached an agreement with unspecified orthodontists to restrict the sales of the Invisalign System only to orthodontists, and thereby violated U.S. antitrust laws. The complaint seeks injunctive relief and damages. While the Invisalign System is not available to dentists, we have not entered into any agreements with orthodontists restricting the distribution of the Invisalign System. For this reason, among others, we believe the lawsuit is without merit.

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. 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 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 exclude expenses incurred in connection with the offering of approximately $2.3 million. During the first quarter, net ofering proceeds were used to purchase plant machinery and equipment, leasehold improvements and working capital in the amounts of approximately $1.9 million, $335,000 and $6.7 million, respectively. The remaining balance of $119.5 million is in bank deposits and marketable securities. 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

On January 19, 2001 an Action by Written Consent of the Stockholders of Align Technology, Inc. was circulated to the Company's stockholders. The matters which were voted on were an amendment to the Company's certificate of incorporation and bylaws to reflect the Company's transition to a public company; the approval of an indemnification agreement between the Company and each of its directors; the approval of the 2001 Stock Incentive Plan; the approval of the Employee Stock Purchase Plan; and the approval of stock option grants to the Company's Chief Executive Officer and the Company's President. Each of the proposals was approved with greater than 55% of the common stock, 96% of the Series A preferred stock, 79% of the Series B preferred stock, 92% of the Series C preferred stock, and 97% of the Series D preferred stock voting in favor of the proposals.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K

(a) Exhibits

21.1 Subsidiaries of the Registrant

(b) Reports on Form 8-K

On March 1, 2001 the Registrant filed a Current Report on Form 8-K to report under Item 5 (Other Events) that it had been named in a class action lawsuit.

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)

Date: May 15, 2001

By: /s/ Stephen J. Bonelli

Stephen J. Bonelli
Chief Financial Officer
and Vice President, Finance
(Principal Financial and
Principal Accounting Officer)

INDEX TO EXHIBITS

EXHIBIT 21.1

Subsidiaries of the Registrant

- Align Technology Europe Limited
- Align Technology GmbH
- Align Technology SAS