
**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, 2004**

OR

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

For the transition period from _____ to _____

Commission file number: **0-32259**

Align Technology, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

94-3267295
(I.R.S. Employer
Identification Number)

881 Martin Avenue

Santa Clara, California 95050
(Address of principal executive offices) (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 No

Indicate by check mark whether the Registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act). Yes No

The number of shares outstanding of the registrant's Common Stock, \$0.0001 par value, as of July 31, 2004 was 60,357,259.

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ALIGN TECHNOLOGY, INC.

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PART I—FINANCIAL INFORMATION
ITEM 1 FINANCIAL STATEMENTS
ALIGN TECHNOLOGY, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands)
(unaudited)

| | June 30, 2004 | December 31, 2003 |
|---|------------------|----------------------|
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 56,099 | \$ 44,939 |
| Restricted cash | 281 | 439 |
| Marketable securities, short-term | — | 2,292 |
| Accounts receivable, net of allowance | 25,737 | 21,265 |
| Inventories | 1,359 | 1,395 |
| Deferred costs | 1,042 | 939 |
| Prepaid expenses and other current assets | 5,350 | 5,845 |
| | <hr/> | <hr/> |
| Total current assets | 89,868 | 77,114 |
| Property and equipment, net | 23,174 | 23,121 |
| Other assets | 1,914 | 1,967 |
| | <hr/> | <hr/> |
| Total assets | \$ 114,956 | \$ 102,202 |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current liabilities: | | |
| Accounts payable | \$ 3,314 | \$ 3,095 |
| Accrued liabilities | 19,496 | 19,180 |
| Deferred revenues | 13,132 | 13,113 |
| Debt | 1,914 | 1,989 |
| | <hr/> | <hr/> |
| Total current liabilities | 37,856 | 37,377 |
| Debt, net of current portion | 931 | 1,849 |
| | <hr/> | <hr/> |
| Total liabilities | 38,787 | 39,226 |
| Commitments and contingencies (Note 4) | | |
| Stockholders' equity: | | |
| Preferred stock: \$0.0001 par value; Authorized: 5,000 shares; Issued and outstanding: none at June 30, 2004 and December 31, 2003 | — | — |
| Common stock: \$0.0001 par value; Authorized: 200,000; Issued: 60,068 and 58,793 at June 30, 2004 and December 31, 2003, respectively; Outstanding: 60,028 and 58,753 shares at June 30, 2004 and December 31, 2003, respectively | 6 | 6 |
| Additional paid-in capital | 373,874 | 368,796 |
| Deferred compensation | (1,443) | (5,219) |
| Notes receivable from stockholders | — | (17) |
| Accumulated other comprehensive income | (5) | 2 |
| Accumulated deficit | (296,263) | (300,592) |
| | <hr/> | <hr/> |
| Total stockholders' equity | 76,169 | 62,976 |
| | <hr/> | <hr/> |
| Total liabilities and stockholders' equity | \$ 114,956 | \$ 102,202 |
| | <hr/> | <hr/> |

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 June 30, | | Six Months Ended June 30, | |
|---|--------------------------------|------------|------------------------------|-------------|
| | 2004 | 2003 | 2004 | 2003 |
| Revenues | \$ 44,204 | \$ 29,225 | \$ 83,409 | \$ 52,185 |
| Cost of revenues | 14,250 | 13,269 | 27,643 | 25,193 |
| Gross profit | 29,954 | 15,956 | 55,766 | 26,992 |
| Operating expenses: | | | | |
| Sales and marketing | 13,399 | 11,416 | 26,671 | 22,046 |
| General and administrative | 8,656 | 9,014 | 16,933 | 16,908 |
| Research and development | 3,558 | 3,712 | 6,904 | 6,697 |
| Total operating expenses | 25,613 | 24,142 | 50,508 | 45,651 |
| Profit (loss) from operations | 4,341 | (8,186) | 5,258 | (18,659) |
| Interest and other income (expense), net | (175) | 427 | (402) | 230 |
| Net profit (loss) before provision for income taxes | 4,166 | (7,759) | 4,856 | (18,429) |
| Provision for income taxes | (394) | — | (527) | (1) |
| Net profit (loss) | \$ 3,772 | \$ (7,759) | \$ 4,329 | \$ (18,430) |
| Net profit (loss) per share, basic | \$ 0.06 | \$ (0.13) | \$ 0.07 | \$ (0.32) |
| Shares used in computing net profit (loss) per share, basic | 59,692 | 57,489 | 59,391 | 57,339 |
| Net profit (loss) per share, diluted | \$ 0.06 | \$ (0.13) | \$ 0.07 | \$ (0.32) |
| Shares used in computing net profit (loss) per share, diluted | 64,461 | 57,489 | 64,392 | 57,339 |

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, | |
|--|------------------------------|------------------|
| | 2004 | 2003 |
| Cash Flows from Operating Activities: | | |
| Net profit (loss) | \$ 4,329 | \$ (18,430) |
| Adjustments to reconcile net profit (loss) to net cash provided by operating activities: | | |
| Depreciation and amortization | 4,351 | 4,640 |
| Stock-based compensation expense | 3,999 | 8,611 |
| Loss on retirement and disposal of fixed assets | 46 | 145 |
| Provision for doubtful accounts | 166 | (61) |
| Non-cash interest income on notes receivable from stockholders | — | (35) |
| Changes in operating assets and liabilities: | | |
| Accounts receivable | (4,638) | (1,746) |
| Inventories | 36 | (128) |
| Deferred costs | (103) | 96 |
| Other current assets | 495 | (1,201) |
| Accounts payable | (37) | (40) |
| Accrued liabilities | 316 | 4,946 |
| Deferred revenue | 19 | 3,763 |
| Net cash provided by operating activities | <u>8,979</u> | <u>560</u> |
| Cash Flows from Investing Activities: | | |
| Purchase of property and equipment | (5,052) | (3,511) |
| Proceeds from sale of property and equipment | 851 | — |
| Decrease (increase) in restricted cash | 158 | (13) |
| Purchases of marketable securities | — | (3,392) |
| Maturities of marketable securities | 2,292 | 2,669 |
| Other assets | 53 | (353) |
| Net cash used in investing activities | <u>(1,698)</u> | <u>(4,600)</u> |
| Cash Flows from Financing Activities: | | |
| Proceeds from issuance of common stock | 4,855 | 720 |
| Proceeds from payment on stockholders' notes receivable | 17 | 573 |
| Repurchase of common stock | — | (5) |
| Payments on debt obligations | (993) | (1,085) |
| Net cash provided by financing activities | <u>3,879</u> | <u>203</u> |
| Net increase (decrease) in cash and cash equivalents | 11,160 | (3,837) |
| Cash and cash equivalents at beginning of period | 44,939 | 35,552 |
| Cash and cash equivalents at end of period | <u>\$ 56,099</u> | <u>\$ 31,715</u> |

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

ALIGN TECHNOLOGY, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(unaudited)

1. Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared by Align Technology, Inc. (the "Company" or "Align") in accordance with the rules and regulations of the Securities and Exchange Commission. Certain information and footnote disclosures normally included in consolidated financial statements prepared in accordance with accounting principles generally accepted in the United States of America have been condensed or omitted in accordance with such rules and regulations. In the opinion of management, the accompanying unaudited condensed consolidated financial statements reflect all adjustments, consisting only of normal recurring adjustments, necessary to present fairly the financial position of the Company as of June 30, 2004 and December 31, 2003, and its results of operations and cash flows for the three and six months ended June 30, 2004 and 2003. These unaudited condensed consolidated financial statements should be read in conjunction with the annual audited consolidated financial statements and notes as of and for the year ended December 31, 2003 included in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 9, 2004.

The results of operations for the three and six months ended June 30, 2004 are not necessarily indicative of the results that may be expected for the year ending December 31, 2004 or any other interim period, and the Company makes no representations related thereto.

The condensed consolidated financial statements include the accounts of the Company and its subsidiaries. All significant intercompany accounts and transactions have been eliminated in consolidation.

Certain risks and uncertainties

The Company's operating results depend on, to a significant extent, the Company's ability to market and develop its products. The life cycles of the Company's products are difficult to estimate due in part to the effect of future product enhancements and competition. The Company's inability to successfully develop and market its products as a result of competition or other factors would have a material adverse effect on the Company's business, financial condition and results of operations.

Financial instruments which potentially expose the Company to concentrations of credit risk consist primarily of cash equivalents and accounts receivable. The Company invests excess cash primarily in commercial paper. The Company provides credit to customers in the normal course of business. Collateral is not required for accounts receivable, but ongoing evaluations of customers' credit worthiness are performed. The Company maintains reserves for potential credit losses and such losses have been within management's expectations. No individual customer accounted for 10% or more of the Company's accounts receivable at June 30, 2004 or at December 31, 2003, or net revenues for the three and six months ended June 30, 2004 or 2003.

The Food and Drug Administration ("FDA") regulates the design, manufacture, distribution, preclinical and clinical study, clearance and approval of medical devices. Products developed by the Company may require approvals or clearances from the FDA or other international regulatory agencies prior to commercialized sales. There can be no assurance that the Company's products will receive any of the required approvals or clearances. If the Company were to be denied approval or clearance or such approval were to be delayed, it may have a material adverse impact on the Company.

The Company has manufacturing operations located outside the United States of America. The Company currently relies on its manufacturing facilities in Costa Rica to create virtual treatment plans with the assistance of sophisticated software. In addition, the Company relies on a third party manufacturer in Mexico to fabricate Aligners and to ship the completed product to the Company's customers. The Company's reliance on international operations exposes it to related risks and uncertainties, including: difficulties in staffing and managing international operations, controlling quality of the manufacturing process, political, social and economic instability, interruptions and limitations in telecommunication services, product and/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, the Company's international manufacturing operations, as well as its operating results, may be harmed.

The Company receives certain of its components from sole suppliers. Additionally, the Company relies on a limited number of hardware manufacturers. The inability of any supplier or manufacturer to fulfill supply requirements of the Company could materially impact future operating results.

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2. Net Profit (Loss) Per Share

Basic net profit (loss) per share is computed using the weighted average number of shares of common stock during the year. Diluted net profit (loss) per share is computed using the weighted average number of shares of common stock, adjusted for the dilutive effect of potential common stock. Potential common stock, computed using the treasury stock method, includes options and unvested shares subject to repurchase.

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

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|--|--------------------------------|------------|------------------------------|-------------|
| | 2004 | 2003 | 2004 | 2003 |
| Numerator: | | | | |
| Net profit (loss) | \$ 3,772 | \$ (7,759) | \$ 4,329 | \$ (18,430) |
| Denominator: | | | | |
| Weighted-average common shares outstanding | 59,785 | 57,936 | 59,519 | 57,851 |
| Less: Unvested common shares subject to repurchase | (93) | (447) | (128) | (512) |
| Total shares, basic | 59,692 | 57,489 | 59,391 | 57,339 |
| Effect of dilutive securities: | | | | |
| Add: Dilutive common stock equivalents | 4,676 | — | 4,873 | — |
| Unvested shares subject to repurchase | 93 | — | 128 | — |
| Total shares, diluted | 64,461 | 57,489 | 64,392 | 57,339 |
| Basic net profit (loss) per share | \$ 0.06 | \$ (0.13) | \$ 0.07 | \$ (0.32) |
| Diluted net profit (loss) per share | \$ 0.06 | \$ (0.13) | \$ 0.07 | \$ (0.32) |

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

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|------------------------------------|--------------------------------|-------|------------------------------|-------|
| | 2004 | 2003 | 2004 | 2003 |
| Options to purchase common stock | 242 | 5,315 | 168 | 4,486 |
| Common stock subject to repurchase | — | 410 | — | 410 |
| | 242 | 5,725 | 168 | 4,896 |

3. Stock-based Compensation

The Company accounts for stock-based employee compensation using the intrinsic value method under Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees" ("APB 25") and related interpretations and complies with the disclosure requirements of SFAS 148, Accounting for Stock-Based Compensation—Transition and Disclosure—an amendment of FASB Statement No. 123 ("SFAS 148"). The following table illustrates the effect on net profit (loss) and net profit (loss) per common share if the Company had applied the fair value recognition provisions of SFAS 123 to stock-based employee compensation (in thousands, except per share data):

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|--------------------------------|-------------|------------------------------|-------------|
| | 2004 | 2003 | 2004 | 2003 |
| Net profit (loss), as reported | \$ 3,772 | \$ (7,759) | \$ 4,329 | \$ (18,430) |
| Add: Stock-based employee compensation expense included in reported net profit (loss) | 1,663 | 3,787 | 3,629 | 7,685 |
| Deduct: Total stock-based employee compensation determined under fair value based method for all awards | (5,068) | (6,140) | (9,902) | (12,014) |
| Pro forma net profit (loss) | \$ 367 | \$ (10,112) | \$ (1,944) | \$ (22,759) |
| Basic and diluted net profit (loss) per common share: | | | | |
| As reported | \$ 0.06 | \$ (0.13) | \$ 0.07 | \$ (0.32) |
| Pro forma | \$ 0.01 | \$ (0.18) | \$ (0.03) | \$ (0.40) |

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Such pro forma disclosure may not be representative of future compensation cost because options vest over several years and additional grants are anticipated to be made each year.

The fair value of each option grant is estimated on the date of grant using the Black-Scholes option pricing model. The following are the weighted average assumptions:

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|-------------------------|--------------------------------|---------|------------------------------|---------|
| | 2004 | 2003 | 2004 | 2003 |
| Risk free interest rate | 3.67% | 2.93% | 2.95% | 2.96% |
| Expected life | 5 years | 5 years | 5 years | 5 years |
| Expected volatility | 54% | 110% | 59% | 112% |

4. Commitments and Contingencies

Short-term and Long-term Obligations

As of June 30, 2004, future minimum payments under lease obligations and financing agreements are as follows (in thousands):

| | 2004 | 2005 | 2006 | 2007 | 2008 | Thereafter | Total |
|---------------------------|----------|----------|--------|--------|--------|------------|----------|
| Operating leases | \$ 2,057 | \$ 2,433 | \$ 868 | \$ 612 | \$ 508 | \$ — | \$ 6,478 |
| Capital lease obligations | 173 | 187 | — | — | — | — | 360 |
| Equipment-based term loan | 833 | 1,667 | — | — | — | — | 2,500 |
| Total | \$ 3,063 | \$ 4,287 | \$ 868 | \$ 612 | \$ 508 | \$ — | \$ 9,338 |

Product Warranty

The Company generally warrants its products for a specific period of time against material defects in materials and workmanship. The Company provides for the estimated future costs of warranty obligations in costs of goods sold when the related product is shipped. Accrued estimated warranty costs are primarily based on historical experience as to product failures as well as current information on replacement costs. Management periodically reviews the accrued balances and updates the historical warranty cost trends. Actual warranty costs incurred have not materially differed from those accrued.

Aligners are subject to the Invisalign product warranty, which covers defects in materials and workmanship, and is contingent upon proper use of the Aligners. The Invisalign product warranty is in force until the case is completed. In the event the Aligners fall within the scope of the Invisalign product warranty, the Company will replace the Aligners at its expense. If a patient chooses not to wear the Aligners, and as a result, requests additional Invisalign treatment, the dental professional pays for the additional expense. The Invisalign product warranty does not provide any assurances regarding the outcome of treatment using Invisalign.

The following table reflects the change in the Company's warranty accrual during the six months ended June 30, 2004 (in thousands):

| | |
|-------------------------------------|--------|
| Warranty accrual, December 31, 2003 | \$ 862 |
| Charged to cost and expenses | 1,003 |
| Actual warranty expenses | (987) |
| Warranty accrual, June 30, 2004 | \$ 878 |

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Contingencies

In October 2003, the Company entered into a Loan Agreement with General Orthodontics, LLC (“GO”), whereby the Company agrees to make loan advances to GO of amounts not to exceed an aggregate principle balance of \$200,000. The commitment by the Company to make advances to GO shall expire upon GO obtaining alternative financing. Interest on the loans will accrue on the unpaid principal amount of the outstanding loans at an annual rate of 5%. All loan advances and accrued interest are due and payable no later than October 2006. No advances were made by the Company to GO as of June 30, 2004.

Legal Proceedings

On January 6, 2003, Ormco Corporation (“Ormco”) filed suit against the Company in the United States District Court for the Central District, Orange County Division, asserting infringement of U.S. Patent Nos. 5,447,432, 5,683,243 and 6,244,861. The complaint seeks unspecified monetary damages and injunctive relief. On February 18, 2003, the Company answered the complaint and asserted counterclaims seeking a declaration by the Court of invalidity and non-infringement of the asserted patents. In addition, the Company counterclaimed for infringement of its U.S. Patent No. 6,398,548, seeking unspecified monetary damages and injunctive relief. Ormco filed a reply to the Company’s counterclaims on March 10, 2003 and asserted counterclaims against the Company seeking a declaration by the Court of invalidity and non-infringement of U.S. Patent No. 6,398,548. The Company responded to Ormco’s counterclaims on April 2, 2003. The Company amended its counterclaim to add Allesee Orthodontic Appliances, Inc. (“AOA”), a wholly-owned subsidiary of Ormco, as a counterdefendant in regard to the Company’s counterclaim of infringement of U.S. Patent No. 6,398,548. The Court then permitted Ormco to amend its Complaint and permitted the Company to amend its counterclaim to add an additional patent each. Ormco filed a first amended complaint for infringement of U.S. Patent No. 6,616,444 on October 15, 2003. On October 27, 2003, the Company filed an answer to Ormco’s first amended complaint and a counterclaim for invalidity and non-infringement of U.S. Patent No. 6,616,444 and for infringement of U.S. Patent No. 6,554,611.

At a Scheduling Conference held on November 24, 2003, the Court set a June 10, 2004 discovery cutoff (later moved to June 28, 2004), a September 10, 2004 Pretrial Conference, and an October 2004 trial date.

The Company filed a motion for summary judgment of non-infringement of each of Ormco’s asserted patents earlier this year. On May 14, 2004, the Court granted the Company’s motion for summary judgment of non-infringement as to each of Ormco’s patents. Accordingly, the Company has been found not to infringe Ormco’s U.S. Patent Nos. 5,477,432, 5,683,243, 6,244,861 and 6,616,444. Ormco has indicated that it intends to appeal this decision following final judgment in this case. On July 2, 2004, the Court ruled that the Company will be permitted to pursue its counterclaim that Ormco’s patents are invalid.

On April 26, 2004, the Company filed a motion for summary judgment that Ormco and AOA’s Red, White and Blue system of appliances infringe the Company’s U.S. Patent Nos. 6,398,548 and 6,554,611, which relate to methods and systems for incrementally moving teeth using a series of appliances designed to be placed successively on the patient’s teeth. On May 14, 2004, AOA and Ormco filed a motion for summary judgment of non-infringement. The Court consolidated the motions for hearing on June 28, 2004. On July 2, 2004, the Court granted the Company’s motion for summary judgment, finding that Ormco’s and AOA’s Red, White and Blue product infringes the Company’s two patents noted above (U.S. Patent No. 6,398,548 and 6,554,611). Claims found to be infringed upon by Ormco and AOA are claims 1-3 and 11-13 of U.S. Patent No. 6,398,548, which require that the appliances are marked to indicate their order of use and claims 1-3, 7 and 17 of U.S. Patent No. 6,554,611 which require that the appliances are provided in a single package to the patient.

From time to time, the Company has received and may in the future receive letters from third parties drawing its attention to their patent rights. While the Company does not believe that it infringes upon any valid and enforceable rights that have been brought to its attention, there may be other more pertinent rights of which the Company is presently unaware. The defense and prosecution of intellectual property suits, interference proceedings and related legal and administrative proceedings could result in substantial expense to the Company and significant diversion of effort by its technical and management personnel. In the event the court’s decision in the Ormco litigation discussed above is overturned on appeal, or if the Company is subject to an adverse determination in a patent suit by Ormco or in any other litigation or interference proceeding to which the Company may become a party, the Company could be subject to significant liabilities. An adverse determination of this nature could also put the Company’s patents at risk of being invalidated or interpreted narrowly or require the Company to seek licenses from third parties. Licenses may not be available on commercially reasonable terms or at all, in which event, the Company’s business would be materially adversely affected.

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.

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

In addition to historical information, this Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. These statements include, among other things, statements concerning our expectations regarding the anticipated benefit of increased collaboration between orthodontists and general practitioner dentists on our revenue growth, our expectation that the percentage of revenue generated by general practitioner dentists may, in the future, represent a larger percentage of our revenue than revenue generated by orthodontists, the number of new doctors we anticipate certifying in 2004, our anticipated revenue growth for fiscal 2004, our expectation that sales and marketing expense as well as our research and development spending will increase as well as other statements regarding our future operations, financial condition and prospects and business strategies. These statements may contain words such as "expects," "anticipates," "intends," "plans," "believes," "estimates," or other words indicating future results. These forward-looking statements are subject to certain risks and uncertainties that could cause actual results to differ materially from those reflected in the forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the following discussion, and in particular, the risks discussed below under the subheading "Risk Factors" and in other documents we file with the Securities and Exchange Commission. We undertake no obligation to revise or publicly release the results of any revision to these forward-looking statements. Given these risks and uncertainties, readers are cautioned not to place undue reliance on such forward-looking statements.

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

Overview

Align Technology, founded in March 1997, designs, manufactures and markets Invisalign, a proprietary method for treating malocclusion, or the misalignment of teeth. Invisalign corrects malocclusion using a series of clear, nearly invisible, removable appliances that gently move teeth to a desired final position. Because it does not rely on the use of metal or ceramic brackets and wires, Invisalign significantly reduces the aesthetic and other limitations associated with braces. Invisalign is appropriate for treating adults and teens with mature dentition. Align Technology received FDA clearance to market Invisalign in 1998.

The Invisalign product has two components: ClinCheck™ and Aligners. ClinCheck™ is an internally developed computer-modeling program used to prepare electronic treatment plans. These treatment plans are developed in our operations facility in Costa Rica and are transmitted electronically back to the U.S. ClinCheck™ allows dental professionals to simulate treatment in three dimensions by modeling two-week stages of tooth movement. The electronic files which form the basis for ClinCheck™ are used in conjunction with stereolithography technology to manufacture Aligner molds. 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 dental professionals using ClinCheck™. A third party manufacturer in Mexico fabricates Aligners from the molds and ships the completed products to our customers.

Align has two customer channels: the orthodontist and the general practitioner, or GP dentist. We have historically generated a majority of our revenues from orthodontists, and we expect to continue to do so for the foreseeable future. There exists, however, a significantly greater number of GPs in North America than orthodontists. As the primary care dental provider, GPs have access to a greater number of patients than orthodontists, possess a unique opportunity to educate these patients and introduce them to Invisalign, have the ability to refer appropriate cases to orthodontists and, in certain instances, may choose to treat less complex cases themselves. We are committed to improving the collaboration and referral relationships between orthodontists and GPs. We believe that improved collaboration is beneficial to the orthodontist and the GP and will accelerate growth in Invisalign cases and consequently increase our revenues. In addition, although we expect that orthodontists will continue to treat the majority of complex cases and continue to drive research for expanding Invisalign applications, we expect that the percentage of revenue generated by GPs will increase, largely due to the fact that there are significantly more GPs than orthodontists, and may, in the future, represent a larger percentage of our revenue than revenue generated by orthodontists. We believe the expected increase in the number of cases treated by GPs will represent an increase in the overall market growth as patients that would not have otherwise sought orthodontic treatment are introduced to Invisalign by GPs.

Our domestic orthodontist and GP dentist customers represented over 90% of our total product revenue during the first half of fiscal 2004. We expect to continue to increase our market penetration into the North American market. We will also focus our efforts towards the expansion of our international markets. We currently have patients in treatment in over 30 countries. In 2004, we expect to increase our infrastructure and support in key countries in Europe and initiate strategic moves in Asia, more specifically in Japan, in order to take advantage of the emerging opportunity.

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Clinical education and ongoing training are critical to our customers' success with Invisalign. We certify several thousand new doctors to use Invisalign annually, including approximately 4,000 newly trained doctors we expect to certify during fiscal 2004. Additionally, we share product enhancements, treatment tips and techniques, and clinical research data with our customers on an ongoing basis through continuing education in the form of hundreds of provider workshops, study clubs and third-party online educational centers. This information ensures that our customers understand Invisalign's expanding applications and best uses, and that they feel confident about treating more of their patients with Invisalign.

Net revenue for the second quarter of fiscal 2004 was \$44.2 million, an increase of 51% as compared to \$29.2 million for the second quarter of fiscal 2003. The increase was driven primarily from increases in the number of cases submitted for both the domestic orthodontic and general practitioner channels. Revenues are expected to continue to grow during the remainder of fiscal 2004. Net profit was \$3.8 million, or \$0.06 net profit per share, basic and diluted, compared to a net loss of \$7.8 million, or \$0.13 net loss per share, basic and diluted, for the second quarter of fiscal 2003.

Results of Operations

Revenues. Invisalign product revenues by channel and other revenue, which represented training and sales of ancillary products, for the three and six-months periods ended June 30, 2004 and 2003 are as follows:

| (Amounts in \$ million) | Three Months Ended | | | | Six Months Ended | | | |
|-------------------------|--------------------|----------------|----------------|---------------------|------------------|----------------|----------------|---------------------|
| | June 30, 2004 | June 30, 2003 | Increase* | Percentage Increase | June 30, 2004 | June 30, 2003 | Increase* | Percentage Increase |
| Domestic: | | | | | | | | |
| Orthodontic | \$ 22.6 | \$ 17.3 | \$ 5.3 | 31% | \$ 44.2 | \$ 32.0 | \$ 12.2 | 38% |
| GP | \$ 15.0 | \$ 6.8 | \$ 8.2 | 121% | \$ 27.6 | \$ 11.4 | \$ 16.2 | 142% |
| International | \$ 4.2 | \$ 3.2 | \$ 1.0 | 31% | \$ 7.7 | \$ 5.5 | \$ 2.2 | 40% |
| Total Product | \$ 41.8 | \$ 27.3 | \$ 14.5 | 53% | \$ 79.5 | \$ 48.9 | \$ 30.6 | 63% |
| Other revenue | \$ 2.4 | \$ 1.9 | \$ 0.5 | 26% | \$ 3.9 | \$ 3.3 | \$ 0.6 | 18% |
| Total Revenue | \$ 44.2 | \$ 29.2 | \$ 15.0 | 51% | \$ 83.4 | \$ 52.2 | \$ 31.2 | 60% |

* **Primary reasons for increase:** For the quarter and six-months ended June 30, 2004, growth in the domestic orthodontic and general practitioner channels over the same periods in fiscal 2003 resulted primarily from higher case volumes driven by an increase in the number of participating clinicians and utilization within their practices. Higher product sales during the three and six-month periods ended June 30, 2004 as compared to the same periods in fiscal 2003 also benefited from increased promotional advertising campaigns and sales initiatives in effect during the first half of fiscal 2004.

Cost of revenues. Cost of revenues for the quarter ended June 30, 2004 was \$14.3 million compared to \$13.3 million for the quarter ended June 30, 2003. Cost of revenues for the six-month period ended June 30, 2004 was \$27.6 million compared to \$25.2 million for the six-month period ended June 30, 2003. Cost of revenues include the salaries for staff involved in production, the cost of materials and packaging, shipping costs, depreciation on the capital equipment used in the production process, training costs and the cost of facilities. Also included in cost of revenues are stock-based compensation expenses of \$0.3 million and \$0.7 million for the second quarters of fiscal 2004 and 2003, respectively, and stock-based compensation expenses of \$0.7 million and \$1.4 million for the six-month periods ended June 30, 2004 and 2003, respectively. Gross profit for the quarter ended June 30, 2004 was \$30.0 million or 68% of revenue, compared to a gross profit of \$16.0 million or 55% of revenue for the quarter ended June 30, 2003. Gross profit for the six-month period ended June 30, 2004 was \$55.8 million or 67% of revenue, compared to a gross profit of \$27.0 million or 52% of revenue for the six-month period ended June 30, 2003. The higher gross profit in the second quarter and six-month period ended June 30, 2004 as compared to the quarter and six-month period ended June 30, 2003 is primarily attributable to improved fixed cost absorption related to increasing case volumes and continued manufacturing process efficiencies.

Sales and marketing. Sales and marketing expenses for the quarter ended June 30, 2004 were \$13.4 million compared to \$11.4 million for the quarter ended June 30, 2003. Sales and marketing expenses for the six-month period ended June 30, 2004 were \$26.7 million compared to \$22.0 million for the six-month period ended June 30, 2003. Sales and marketing expenses include sales force compensation (combined with travel related costs and expenses for professional marketing programs), conducting workshops and market surveys, advertising and dental professional trade show attendance. Sales and marketing expenses include stock-based compensation expenses of \$0.2 million and \$0.6 million in the second quarters of fiscal 2004 and 2003, respectively, and stock-based compensation expenses of \$0.5 million and \$1.2 million for the six-month periods ended June 30, 2004 and 2003, respectively. The increase in sales and marketing expense of \$2.0 million for the second quarter of fiscal 2004 as compared to the second quarter of fiscal 2003 resulted primarily from an increase in spending of \$1.0 million related to incremental headcount in our North American sales and marketing work force, \$0.1 million related to North America sales force training, \$0.8 million related to our international

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workforce and consulting services, and \$0.5 million related to increases in media, advertising costs and marketing promotions. The increase in spending was partially offset by the decrease of \$0.4 million in stock-based compensation expense. The increase in sales and marketing expense of \$4.7 million for the six-month period ended June 30, 2004 as compared to the six-month period ended June 30, 2003 resulted primarily from an increase in spending of \$1.9 million related to incremental headcount in our North American sales and marketing work force, \$0.6 million related to North America sales force training, \$1.8 million related to our international workforce and consulting services, and \$1.1 million related to increases in media, advertising costs and marketing promotions. The increase in spending was partially offset by the decrease of \$0.7 million in stock-based compensation expense. The increases during the first half of fiscal 2004 have been consistent with our marketing and sales initiatives and we expect these initiatives to continue in the second half of fiscal 2004. Accordingly, we expect sales and marketing expense to increase throughout fiscal 2004 as we invest more in sales force staffing, clinical education, direct-to-consumer advertising and related consumer programs.

General and administrative. General and administrative expenses for the quarter ended June 30, 2004 were \$8.7 million compared to \$9.0 million for the quarter ended June 30, 2003. General and administrative expenses for the six-month periods ended June 30, 2004 and 2003 were \$16.9 million. General and administrative expenses included salaries for administrative personnel, outside consulting services, legal expenses and general corporate expenses. General and administrative expenses include stock-based compensation expenses of \$1.0 million and \$1.9 million for the second quarters of fiscal 2004 and 2003, respectively, and stock-based compensation expenses of \$2.1 million and \$4.1 million for the six-month periods ended June 30, 2004 and 2003, respectively. The decrease in general and administrative expense of \$0.3 million for the quarter ended June 30, 2004 as compared to the quarter ended June 30, 2003 was primarily due to a \$1.4 million sales tax charge included in the quarter ended June 30, 2003 and a decrease in stock-based compensation expense of \$0.9 million. Partially offsetting the decreases were \$1.4 million in incremental payroll from additional headcount and \$0.6 million in incremental general corporate expenses for the second quarter of fiscal 2004 as compared to the second quarter of fiscal 2003. For the six-month period ended June 30, 2004 as compared to the six-month period ended June 30, 2003 for which general and administrative expenses were approximately equal, decreased stock-based compensation expense of \$2.0 million and the previously mentioned sales tax charge of \$1.4 million in fiscal 2003 were offset by \$0.6 million in incremental outside legal and professional services, \$1.6 million in incremental payroll expenses and \$1.2 million in incremental general corporate expenses.

Research and development. Research and development expenses for the quarter ended June 30, 2004 were \$3.6 million and \$3.7 million for the quarter ended June 30, 2003. Research and development expenses for the six-month period ended June 30, 2004 were \$6.9 million and \$6.7 million for the six-month period ended June 30, 2003. Research and development expenses include the costs associated with software engineering, the cost of designing, developing and testing our products and conducting clinical and post-marketing trials. We expense our research and development costs as they are incurred. Research and development expenses included \$0.3 million and \$1.2 million of stock-based compensation for the second quarters of fiscal 2004 and 2003, respectively, and \$0.7 million and \$1.9 million of stock-based compensation for the six-month periods ended June 30, 2004 and 2003, respectively. The decrease in research and development expense of \$0.1 million for the quarter ended June 30, 2004 as compared to the quarter ended June 30, 2003 resulted primarily from the decrease in stock-based compensation expense of \$0.9 million, offset by increased spending of \$0.8 million for product improvement initiatives. For the six-month period ended June 30, 2004 as compared to June 30, 2003, the increase of \$0.2 million resulted from increased spending of \$1.4 million for product improvement initiatives, partially offset by a \$1.2 million decrease in stock-based compensation expense. For the remainder of fiscal 2004, we expect to increase research and development spending for clinical research and product improvement initiatives.

Interest and other income (expense), net. Interest and other expense was (\$0.2) million for the quarter ended June 30, 2004 as compared to interest and other income of \$0.4 million for the quarter ended June 30, 2003. Interest and other expense was (\$0.4) million for the six-month period ended June 30, 2004 as compared to interest and other income of \$0.2 million for the quarter ended June 30, 2003. Interest and other income (expense), net, include interest income earned on cash balances, interest expense on debt, foreign currency translation gains and losses for the dollar against other currencies related to international businesses and other miscellaneous charges. For the quarter ended June 30, 2004 as compared to the quarter ended June 30, 2003, interest and other expenses increased \$0.2 million. Additionally, the foreign currency translation loss was \$0.1 million for the quarter ended June 30, 2004 compared to a foreign currency translation gain of \$0.3 million for the quarter ended June 30, 2003. For the six-month period ended June 30, 2004 as compared to the six-month period ended June 30, 2003, interest and other expenses increased \$0.1 million. Additionally, the foreign currency translation loss was \$0.3 million for the six-month period ended June 30, 2004 compared to a foreign currency translation gain of \$0.2 million for the six-month period ended June 30, 2003.

Provision for income taxes. Provision for income taxes were \$0.4 and \$0.5 million for the quarter and six-month periods ended June 30, 2004, respectively, and was as a result of taxable income during the first half of fiscal 2004. There was no provision for income taxes for the quarter and six-month periods ended June 30, 2003 due to the net loss during the first half of fiscal 2003. We expect tax expense for fiscal year 2004 to be at an effective tax rate of approximately 10%.

Stock-based compensation. In connection with the grant of stock options to employees and non-employees prior to 2001, 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

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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 vest, we revalue the remaining unvested options, with the change in fair value from period to period represented as a change in deferred compensation. This stock-based compensation is amortized as charges to operations over the vesting periods of the options. For the quarters ended June 30, 2004 and 2003, we recorded amortization of deferred compensation of \$1.7 million and \$3.6 million, respectively. For the six-month periods ended June 30, 2004 and 2003, we recorded amortization of deferred compensation of \$3.8 million and \$7.2 million, respectively. We recorded expenses of \$0.1 million and \$0.3 million for the quarters ended June 30, 2004 and 2003, respectively, related to options granted to non-employees after 2001. We recorded expenses of \$0.3 million and \$0.6 million for the six-month periods ended June 30, 2004 and 2003, respectively, related to options granted to non-employees after 2001.

Historically, we have accelerated the vesting of options to several employees in connection with severance packages. This acceleration was accounted for as a charge to the condensed consolidated statements of operations. We had no such charge for the quarter and six-months ended June 30, 2004. We recorded a charge of \$0.4 million and \$0.8 million for the quarter and six-month period ended June 30, 2003. This 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. During the third quarter of fiscal 2004, we will incur an additional charge of approximately \$0.8 million for accelerated vesting of stock options related to the departure of Align's vice president of engineering.

Liquidity and Capital Resources

We have funded our operations with the proceeds from the sale of our common and preferred stock, an equipment-based term loan and bridge loans. We have incurred operating losses from inception through the third quarter of 2003.

As of June 30, 2004, we had \$56.1 million of cash and cash equivalents and \$0.3 million of restricted cash. We had an accumulated deficit of \$296.3 million as of June 30, 2004.

Net cash provided by operating activities totaled \$9.0 million and \$0.6 million for the six-month periods ended June 30, 2004 and 2003, respectively. Net cash provided by operating activities for the six-month period ended June 30, 2004 resulted primarily from operating profit and changes in operating assets and liabilities. For the six-month period ended June 30, 2003, net cash provided by operating activities resulted primarily from increases in accrued liabilities and deferred revenue, partially offset by operating losses.

Net cash used in investing activities totaled \$1.7 million for the six-month period ended June 30, 2004 and \$4.6 million for the six-month period ended June 30, 2003. For the six-month period ended June 30, 2004, net cash used in investing activities resulted primarily from the purchase of property and equipment for capacity expansion and manufacturing improvements, partially offset by proceeds from the sale of equipment and maturities of marketable securities. For the six-month period ended June 30, 2003, net cash used in investing activities resulted primarily from the purchase of property and equipment for capacity expansion and manufacturing improvements and purchases of marketable securities, partially offset by maturities of marketable securities.

Net cash provided by financing activities was \$3.9 million and \$0.2 million for the six-month periods ended June 30, 2004 and 2003, respectively. For the six-month period ended June 30, 2004, net cash provided by financing activities consisted of proceeds from the issuance of common stock, primarily from the exercising of employee stock options, partially offset by payments on debt obligations related to the equipment-based term loan and capital lease obligations. For the six-month periods ended June 30, 2003, net cash provided by financing activities consisted of proceeds from the issuance of common, primarily from the exercising of employee stock options, and proceeds from payment on stockholders' notes receivable, partially offset by payments on debt obligations related to the equipment-based term loan and capital lease obligations.

Contractual Obligations. There have been no material changes to our contractual obligations outside the ordinary course of business from those disclosed in our annual report on Form 10-K for the fiscal year ended December 31, 2003.

In December 2003, we increased our accounts receivable-based revolving line of credit from \$10.0 million to \$15.0 million, and negotiated more favorable terms. Accessing the revolving line of credit is restricted based on qualifying accounts receivable and compliance with certain loan covenants. As of June 30, 2004, we had not utilized the revolving line of credit. In December 2002, we secured an equipment-based term loan of \$5.0 million, which was fully drawn down in December 2002. As of June 30, 2004, the equipment-based term loan had an outstanding balance of \$2.5 million.

We expect that the increase in our operating expenses will be commensurate with an overall increase in the level of our business activity, including increased sales and the related costs of products sold, our consumer advertising campaign and dental professional marketing efforts, continuing efforts to automate our manufacturing processes, increases in the size of our sales force and dental professional training staff, continued international sales and marketing efforts, and development and improvements to our product. In addition, we may use cash to fund acquisitions of complementary businesses or technologies. Our capital requirements depend on market acceptance of our products and our ability to market, sell and support our products on a worldwide basis.

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We believe that our current cash and cash equivalents will be sufficient to fund our operations for at least the next 12 months. If we are unable to generate adequate operating cash flows, we may need to seek additional sources of capital through equity or debt financing, collaborative or other arrangements with other companies, bank financing and other sources in order to realize our objectives and to continue our operations. There can be no assurance that we will be able to obtain additional debt or equity financing on terms acceptable to us, or at all. If adequate funds are not available, we 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.

Critical Accounting Policies

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

We believe the following critical accounting policies affect our more significant judgments and estimates used in the preparation of our condensed consolidated financial statements.

Revenue Recognition

We recognize revenue in accordance with SEC Staff Accounting Bulletin, or SAB, No. 104, Revenue Recognition, and EITF 00-21. SAB No. 104 requires that four basic criteria must be met before revenue can be recognized: persuasive evidence of an arrangement exists; shipments have occurred; the fee is fixed and determinable; and collectibility is reasonably assured. Determination of whether persuasive evidence of an arrangement exists and whether delivery has occurred or services have been rendered are based on management's judgments based on whether the fee is fixed or determinable based on the payment terms associated with the transaction and whether the sales price is subject to refund or adjustment. EITF 00-21 addresses the issue of accounting for arrangements that involve the delivery of multiple products or services. Should changes in conditions cause management to determine these criteria are not met for certain future transactions, revenue recognized for any reporting period could be adversely affected.

Revenue from the sale of Invisalign and ancillary products is recognized upon product shipment, provided that no significant obligations remain, transfer of title has occurred and collection of the receivable is deemed probable. The costs of producing the ClinCheck™ treatment plan, which are incurred prior to the production of Aligners, are deferred and recognized as related revenues are earned, i.e. upon shipment of the Aligners.

In cases where the dental professional elects to finish the treatment plan using Invisalign, the dental professional orders case refinement. From June 2001 through April 2003, we offered our dental professionals the opportunity to purchase case refinement in advance at a discount. The advance purchase price was non-refundable. Revenue, in the amount of the stand-alone sales price of the undelivered element, is deferred until the earlier of shipment of the case refinement or case expiration. In cases where the dental professional did not purchase case refinement in advance, case refinement revenues are recognized when the new Aligners are shipped.

We updated our domestic and international pricing policies in May 2003 and January 2004, respectively, to include the future delivery of one case refinement in the price of each case and to offer additional case refinements at a price of \$125 each and at a comparable price internationally, which we believe represents its fair value based on competitive product offerings. Revenue deferrals associated with future case refinement after May 1, 2003 are \$125 per case and a comparable price internationally after January 2004. This revenue deferral amount represents the fair value of a case refinement as determined in accordance with EITF 00-21, which addresses the issue of accounting for arrangements that involve the delivery of multiple products or services. These revenue deferrals will be recognized when the case refinement has been utilized or upon case expiration, whichever is earliest.

Service revenues earned for training of dental professionals and staff for Invisalign are recorded as the services are performed. Service revenues earned under agreements with third parties are based on negotiated rates, which are intended to approximate a mark-up on our anticipated costs.

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We estimate and record a provision for amounts of estimated losses on sales, if any, in the period such sales occur. Provisions for discounts and rebates to customers are provided for in the same period that the related product sales are recorded based upon historical discounts and rebates.

Warranty Expense

Aligners are subject to the Invisalign product warranty, which covers defects in materials and workmanship. Our materials and workmanship warranty is in force until the Invisalign case is completed. In the event the Aligners fall within the scope of the Invisalign product warranty, we will replace the Aligners at our expense. Our warranty is contingent upon proper use of the Aligners for the purposes for which they are intended. If a patient chooses not to wear the Aligners, and as a result, requests additional Invisalign treatment, the dental professional pays for the additional expense. The Invisalign product warranty does not provide any assurances regarding the outcome of treatment using Invisalign.

We generally warrant our products for a specific period of time against material defects. We accrue for estimated warranty costs upon shipment of products. We provide for the estimated future costs of warranty obligations in costs of goods sold when the related revenue is recognized. The accrued warranty costs represent the best estimate at the time of sale of the total costs that we expect to incur to repair or replace product which fails while still under warranty. The amount of accrued estimated warranty costs are primarily based on historical experience as to product failures as well as current information on repair costs. Actual warranty costs could differ from the estimate amounts. We regularly review the accrued balances and updates the historical warranty cost trends. Actual warranty costs incurred have not materially differed from those accrued. If we were to experience higher rates of warranty events, we would be required to accrue additional warranty costs, which would negatively affect our operating results.

Allowance for Doubtful Accounts

We maintain allowances for doubtful accounts for estimated losses resulting from the inability of our customers to make payments. We periodically review these estimated allowances, including an analysis of the customers' payment history and information regarding the customers' creditworthiness. If the financial condition of any of our customers were to deteriorate, resulting in their inability to make payments, an additional allowance may be required and would negatively impact our operating results.

Accounting for long-lived assets

We assess the impairment of long-lived assets periodically in accordance with the provisions of SFAS No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets." An impairment review is performed whenever events or changes in circumstances indicate that the carrying value may not be recoverable. Factors that could trigger an impairment review include, but are not limited to, significant underperformance relative to expected historical or projected future operating results, significant changes in the manner of use of the acquired assets or the strategy for the overall business, significant negative industry or economic trends, a significant decline in the stock price for a sustained period and the market capitalization relative to net book value. If these factors or their related assumptions change in the future, we may be required to record impairment charges which would negatively impact operating results.

Legal contingencies

We are currently involved in certain legal proceedings as discussed in Note 4 to our condensed consolidated financial statements. Because of uncertainties related to both the potential amount and range of loss from pending litigation, management is unable to make a reasonable estimate of the liability that could result if there is an unfavorable outcome in these legal proceedings. As additional information becomes available, we will assess the potential liability related to this pending litigation and revise our estimates accordingly. Revisions of our estimates of such potential liability could materially impact our results of operations and financial condition.

Deferred Tax Valuation Allowance

We have established a full valuation allowance to reduce our deferred tax assets to the amount that is more likely than not to be realized. Deferred tax assets and liabilities are determined based on the difference between the financial statement and tax bases of assets and liabilities using the enacted tax rates in effect for the year in which the differences are expected to affect taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to the amounts expected to be realized.

While we have considered potential future taxable income and ongoing prudent and feasible tax planning strategies in assessing the need for the full valuation allowance, in the event that we were to determine that we would be able to realize our deferred tax assets in the future, an adjustment to the deferred tax asset would increase net income in the period such determination was made.

RISK FACTORS

We have experienced significant revenue growth and have only recently achieved profitability. If we fail to sustain or increase profitability or revenue growth in future periods or otherwise fail to meet the expectations of analysts or investors, the market price of our common stock will likely decline.

You should consider our business and prospects in light of the risks, expenses and difficulties encountered by a company in an early stage of operations. Since inception, we incurred significant operating losses and we have only achieved profitability since the fourth quarter of fiscal 2003. From inception through July 2000, we spent significant funds on 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 continue to incur significant operating expenses to:

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

As noted above, we have only recently achieved profitability, as a result, to sustain or increase profitability in future periods, we will need to continue to increase our revenue, while controlling our expenses. We generated positive operating cash flow for the first time during fiscal year 2003, and we cannot be certain that we will be able to sustain or increase such positive cash flow from operations, from period to period, in the future. In addition, we have recently experienced significant revenue growth. Because our business is evolving it is difficult to predict our future operating results or levels of growth and we may not be able to sustain such growth levels in future periods. If we do not sustain or increase profitability or revenue growth or if we fail to meet the expectations of securities analysts or investors, the market price of our common stock will likely decline.

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

We were incorporated in April 1997 and began sales of Invisalign in July 1999. Thus, we have a limited operating history, which makes it difficult to evaluate our future prospects and your investment in our stock. 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 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.

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

We rely on the efficient and uninterrupted operation of complex information technology systems. All information technology systems are vulnerable to damage or interruption from a variety of sources. For instance, as our business has grown in size and complexity, the growth has placed, and will continue to place, significant demands on our information technology systems. To effectively manage this growth, we will need to continually upgrade and enhance our information systems to more effectively manage our operations.

We plan to implement a new version of our enterprise resource planning system and new software for manufacturing execution during the second half of fiscal 2004 to more efficiently integrate with our other system applications, such as customer facing and manufacturing tools. System upgrades and enhancements will require significant capital expenditures and allocation of valuable employee resources. Delays in integration or disruptions to our business from implementation of these new or upgraded systems could have a material adverse impact on our financial condition and operating results.

In addition, experienced computer programmers and hackers may be able to penetrate our network security and misappropriate our confidential information or that of third parties, create system disruptions or cause shutdowns. Furthermore, sophisticated hardware and operating system software and applications that we either internally produce or procure from third parties may contain defects in design and manufacture, including “bugs” and other problems that can unexpectedly interfere with the operation of the system. The costs to eliminate or alleviate security problems, viruses and bugs could be significant, and the efforts to address these problems could result in interruptions that may have a material adverse impact on our operations, sales and operating results.

If we fail to maintain the adequacy of our internal controls, our ability to provide accurate financial reports could be impaired, and any failure to maintain our internal controls and provide accurate financial reports would cause our market price to decrease substantially.

Effective internal controls are necessary for us to provide reliable financial reports and help prevent fraud. We are continuously evaluating and working to improve our internal controls. Our evaluation may conclude that enhancements, modifications or changes to our internal controls are necessary to satisfy the requirements of Sarbanes-Oxley Act of 2002. We cannot be certain that the measures we implement will ensure that we maintain adequate controls over our financial processes and reporting in the future. Any failure to implement required new or improved controls, or difficulties encountered in their implementation, could harm our operating results or cause us to fail to meet our financial reporting obligations. Any failure to maintain the adequacy of our internal controls and provide accurate financial reports could subject us to costly litigation, could make it difficult to attract and retain quality management personnel and could have a negative effect on the market price of our stock.

We have limited product offerings, and if demand for Invisalign declines or fails to develop as we expect or if dental professionals or consumers do not adopt Invisalign in sufficient numbers or as rapidly as we anticipate, or if orthodontists and GP dentists do not collaborate 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 by both dental professionals and consumers is critical to our future success. If orthodontists and dentists experience a reduction in consumer demand for orthodontic services or consumers prove unwilling to adopt Invisalign as rapidly as we anticipate or in the volume that we anticipate, or if orthodontists and GP dentists do not collaborate as we expect, our operating results could be harmed. Factors that could cause Invisalign not achieve market acceptance at the rate at which we expect, or at all are described more fully below.

- *Dental professionals may not adopt Invisalign in sufficient numbers or as rapidly as we anticipate.*

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 only since July 1999, dental professionals may be reluctant to adopt it until more historical clinical results are available. Also, increasing adoption and cumulative use 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, reduced acceptance by dental professionals. If Invisalign does not achieve growing acceptance in the orthodontic and dental communities, our operating results will be harmed.

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- *Consumers may not adopt Invisalign in sufficient numbers or as rapidly as we anticipate.*

Our success depends upon the acceptance of Invisalign by a substantially larger number of dental professionals as well as potential patients to whom we are now actively marketing. 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 for Invisalign, which could compromise the effectiveness of their treatment. We have generally received positive feedback from both dental professionals and patients regarding Invisalign as both an alternative to braces and as a clinical method for treatment of malocclusion, but a number of dental professionals believe that Invisalign is appropriate for only a limited percentage of their patients. 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, including the economic downturn and increased unemployment levels in the United States of America, levels of consumer confidence and consumer spending, all of which fluctuate and could be affected by unstable global economic, political or other conditions.

- *The orthodontist and GP dentist may choose not to collaborate and referrals between orthodontists and GPs may not increase at the rate that we anticipate or at all.*

Our success depends in part upon improving the collaboration and referral relationships between orthodontists and GP dentists. Although orthodontists have historically generated a majority of our revenues, there exists a significantly greater number of general practitioners in North America than orthodontists. As the primary care dental provider, GPs have access to a greater number of patients than orthodontists, possess a unique opportunity to educate these patients and introduce them to Invisalign, have the ability to refer appropriate cases to orthodontists and, in certain instances, may choose to treat less complex cases themselves. We are committed to improving the collaboration and referral relationships between orthodontists and GPs. We believe that improved collaboration is beneficial to the orthodontist and the GP and will accelerate growth in Invisalign cases and consequently increase our revenues. If, however, this improved collaboration and increase in referrals does not occur or occurs more slowly than we anticipate, our operating results could be harmed.

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

Currently, two of our key production steps are performed in operations located outside of the U.S. At our facility in 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 electronic files form the basis of our ClinCheck™ product and are used to manufacture Aligner molds. A third party manufacturer in Mexico fabricates Aligners and ships the completed products to our customers. Our costs associated with these operations are denominated in Costa Rican colons, Mexican pesos and U.S. dollars.

Our reliance on international operations exposes us to risks and uncertainties that may affect our business or results of operation, including:

- political, social and economic instability;
- acts of terrorism and acts of war;
- difficulties in staffing and managing international operations;
- controlling quality of the manufacturing process;
- 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;

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- import and export license requirements and restrictions;
- fluctuations in currency exchange rates; and
- potential adverse tax consequences.

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

Our success depends in part on our proprietary technology and if we are unable to successfully enforce our intellectual property rights, our competitive position may be harmed.

Our success will depend in part on our ability to maintain existing intellectual property and to obtain and maintain further intellectual property protection for our products, both in the U.S. and in other countries. Our inability to do so could harm our competitive position. We believe our intellectual property position represents a substantial business advantage. As of June 30, 2004, we had 50 issued U.S. patents, 84 pending U.S. patent applications, and numerous foreign issued patents, as well as 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, any protection afforded by foreign patents may be more limited than that provided under U.S. patents and intellectual property laws. We also rely on protection of our copyrights, trade secrets, know-how and proprietary information. We generally enter into confidentiality agreements with our employees, consultants and our collaborative partners upon commencement of a relationship with us. However, these agreements may not provide meaningful protection against the unauthorized use or disclosure of our trade secrets or other confidential information, and adequate remedies may not exist if unauthorized use or disclosure were to occur. Our inability to maintain the proprietary nature of our technology through patents, copyrights or trade secrets would impair our competitive advantages and could have a material adverse effect on our operating results, financial condition and future growth prospects. In particular, a failure 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 or are subject to a patent infringement claim, 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 third party's patents in the past and, while these actions have been dismissed, we may be the subject of patent or other litigation in the future.

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

See Part II Item 1 of this Form 10-Q for a summary of our material pending legal proceedings.

Pending or future litigation could have a material adverse impact on our results of operation and financial condition.

We are currently a party to various legal proceedings and claims. Management does not believe that the ultimate outcome of these legal proceedings and claims will have a material adverse effect on our financial position or results of operations. However, there is no assurance that the court's decision in the Ormco litigation will not be overturned on appeal. In addition, litigation is subject to inherent uncertainties and unfavorable rulings could occur. An unfavorable ruling could include monetary damages or, in cases where injunctive relief is sought, an injunction prohibiting us from selling our products. If an unfavorable ruling were to occur in any specific period, there exists the possibility of a material adverse impact on the results of operations of that period or future periods.

See Part II Item 1 of this Form 10-Q for a summary of our material pending legal proceedings.

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We currently rely on third parties to provide key inputs to our manufacturing process, and if our access to these inputs is diminished, our business may be harmed.

We currently outsource key portions of our manufacturing process. We rely on a third party manufacturer in Mexico to fabricate Aligners and to ship the completed product to customers. As a result, if this third party manufacturer fails to deliver its components or if we lose its services, we may be unable to deliver our products in a timely manner and our business may be harmed. Any difficulties encountered by the third party manufacturer with respect to hiring personnel, and maintaining acceptable manufacturing standards, controls, procedures and policies could disrupt our ability to deliver our products in a timely manner. Finding a substitute manufacturer may be expensive, time-consuming or impossible.

In addition, we are highly dependent on manufacturers of specialized scanning equipment, rapid prototyping machines, resin and other advanced materials. We maintain single supply relationships for many of these machines and materials technologies. Our growth may exceed the capacity of one or more of these manufacturers to produce the needed equipment and materials in sufficient quantities to support our growth. In the event of delivery delays or shortages of these items, our business and growth prospects may be harmed.

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

We have expanded rapidly since we commenced commercial sales in 1999. Our headcount increased from approximately 50 employees as of September 30, 1999 to approximately 886 employees as of June 30, 2004. 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. Our inability to effectively manage this level of growth could 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, technology development 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. If we are unable to attract and retain key personnel, our business could be materially harmed.

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

Currently, our Invisalign product competes directly against a product called Red, White and Blue, which is manufactured and distributed by Ormco, a subsidiary of Sybron Dental Specialties. In addition, manufacturers of traditional braces, such as 3M Company, Sybron Dental Specialties and Dentsply International 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 product companies may also enter the orthodontic supply market. Furthermore, we may face competition in the future from new companies that may introduce new technologies. We may be unable to compete with these competitors and one or more of these competitors may render our technology obsolete or economically unattractive. If we are unable to compete effectively with existing products or respond effectively to any products developed by our competitors, our business could be harmed.

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

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

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

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

- Warning letters, fines, injunctions, consent decrees and civil penalties;
- Repair, replacement, refunds, recall or seizure of our products;
- Operating restrictions or partial suspension or total shutdown of production;
- Refusing our requests for 510(k) clearance or premarket approval of new products, new intended uses, or modifications to existing products;
- Withdrawing clearance or premarket approvals that have already been granted; and
- Criminal prosecution.

If any of these events were to occur, they could harm our business.

We must comply with facility registration and product listing requirements of the FDA and adhere to applicable Quality System regulations. The FDA enforces its Quality System regulations through periodic unannounced inspections. We have not yet been subject to an FDA inspection, and we cannot assure you we will successfully pass such an inspection in the future. Our failure to take satisfactory corrective action in response to an adverse inspection or our failure to comply with applicable manufacturing regulations could result in enforcement action, and we may be required to find alternative manufacturers, which could be a long and costly process.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

In fiscal 2003 and the first and second quarter of fiscal 2004, the market price for our common stock was volatile.

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

- quarterly variations in our results of operations and liquidity;
- changes in recommendations by the investment community or in their estimates of our revenues or operating results;
- speculation in the press or investment community concerning our business and results of operations;
- strategic actions by our competitors, such as product announcements or acquisitions;
- announcements of technological innovations or new products by us, our customers or competitors; and
- general 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, class action litigation has often been brought against the issuing company following periods of volatility in the market price of a company's securities. If a securities class action suit is filed against us in the future, 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.

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

A large percentage of our outstanding common stock is currently owned by a small number of significant stockholders. These stockholders have sold in the past, and may sell in the future, large amounts of common stock over relatively short periods of time. Sales of substantial amounts of our common stock in the public market by our existing stockholders may adversely affect the market price of our common stock. Such sales could create public perception of difficulties or problems with our business. In addition, certain of our current stockholders have registration rights in connection with a private placement sale of approximately 9.6 million shares of our common stock that occurred in November 2002. As a result of these registration rights, we were required to file a registration statement under the Securities Act at our expense to register the securities sold in the November 2002 private placement. We filed this registration statement with the SEC on October 17, 2003 and it was declared effective by the SEC on November 20, 2003. Our stock price could fluctuate significantly if the holders of these shares sell them or are perceived by the market as intending to sell them. These sales may also make it more difficult for us to sell securities in the future at a time and at a price we deem appropriate.

If we account for employee stock options using the fair value method, it could significantly reduce our net profit.

There has been ongoing public debate whether stock options granted to employees should be treated as a compensation expense and, if so, how to properly value such charges. On March 31, 2004, the Financial Accounting Standard Board (FASB) issued an Exposure Draft, Share-Based Payment: an amendment of FASB statements No. 123 and 95, which would require a company to recognize, as an expense, the fair value of stock options and other stock-based compensation to employees beginning in 2005 and subsequent reporting periods. If we elect or are required to record an expense for our stock-based compensation plans using the fair value method as described in the Exposure Draft, we could have significant and ongoing accounting charges, which could significantly reduce our net profit.

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

The interests of our management could conflict with those of our other stockholders. As of June 30, 2004, our executive officers, directors and principal stockholders beneficially owned an aggregate of approximately 29% 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 us, which in turn could reduce the market price of our stock.

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.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Quantitative Disclosures

For quantitative and qualitative disclosures about market risk affecting us, see Item 7A, "Quantitative and Qualitative Disclosures About Market Risk," of our Annual Report on Form 10-K for the fiscal year ended December 31, 2003, which is incorporated herein by reference. Our exposure to market risk has not changed materially since December 31, 2003.

ITEM 4. CONTROLS AND PROCEDURES

(a) Evaluation of disclosure controls and procedures.

Our management evaluated, under the supervision and with the participation of our Chief Executive Officer and our Chief Financial Officer, the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of the end of the period covered by this Quarterly Report on Form 10-Q. Based upon that evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that our disclosure controls and procedures are effective as of June 30, 2004 to provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission rules and forms.

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(b) Changes in internal controls over financial reporting.

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

PART II—OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

On January 6, 2003, Ormco Corporation (“Ormco”) filed suit against us in the United States District Court for the Central District, Orange County Division, asserting infringement of U.S. Patent Nos. 5,447,432, 5,683,243 and 6,244,861. The complaint seeks unspecified monetary damages and injunctive relief. On February 18, 2003, we answered the complaint and asserted counterclaims seeking a declaration by the Court of invalidity and non-infringement of the asserted patents. In addition, we counterclaimed for infringement of our U.S. Patent No. 6,398,548, seeking unspecified monetary damages and injunctive relief. Ormco filed a reply to our counterclaims on March 10, 2003 and asserted counterclaims against us seeking a declaration by the Court of invalidity and non-infringement of U.S. Patent No. 6,398,548. We responded to Ormco’s counterclaims on April 2, 2003. We amended our counterclaim to add Allesee Orthodontic Appliances, Inc. (“AOA”), a wholly-owned subsidiary of Ormco, as a counterdefendant in regard to our counterclaim of infringement of U.S. Patent No. 6,398,548. The Court then permitted Ormco to amend its Complaint and permitted us to amend our counterclaim to add an additional patent each. Ormco filed a first amended complaint for infringement of U.S. Patent No. 6,616,444 on October 15, 2003. On October 27, 2003, we filed an answer to Ormco’s first amended complaint and a counterclaim for invalidity and non-infringement of U.S. Patent No. 6,616,444 and for infringement of U.S. Patent No. 6,554,611.

At a Scheduling Conference held on November 24, 2003, the Court set a June 10, 2004 discovery cutoff (later moved to June 28, 2004), a September 10, 2004 Pretrial Conference, and an October 2004 trial date.

We filed a motion for summary judgment of non-infringement of each of Ormco’s asserted patents earlier this year. On May 14, 2004, the Court granted our motion for summary judgment of non-infringement as to each of Ormco’s patents. Accordingly, we have been found not to infringe Ormco’s U.S. Patent Nos. 5,477,432, 5,683,243, 6,244,861 and 6,616,444. Ormco has indicated that it intends to appeal this decision following final judgment in this case. On July 2, 2004, the Court ruled that Align will be permitted to pursue its counterclaim that Ormco’s patents are invalid.

On April 26, 2004, Align filed a motion for summary judgment that Ormco and AOA’s Red, White and Blue system of appliances infringe Align’s U.S. Patent Nos. 6,398,548 and 6,554,611, which relate to methods and systems for incrementally moving teeth using a series of appliances designed to be placed successively on the patient’s teeth. On May 14, 2004, AOA and Ormco filed a motion for summary judgment of non-infringement. The Court consolidated the motions for hearing on June 28, 2004. On July 2, 2004, the Court granted our motion for summary judgment, finding that Ormco’s and AOA’s Red, White and Blue product infringes our two patents noted above (U.S. Patent No. 6,398,548 and 6,554,611). Claims found to be infringed upon by Ormco and AOA are claims 1-3 and 11-13 of U.S. Patent No. 6,398,548, which require that the appliances are marked to indicate their order of use and claims 1-3, 7 and 17 of U.S. Patent No. 6,554,611 which require that the appliances are provided in a single package to the patient.

From time to time, we have received and may in the future receive letters from third parties drawing our attention to their patent rights. While we do not believe that we infringe upon any valid and enforceable rights that have been brought to our attention, there may be other more pertinent rights of which we are presently unaware. The defense and prosecution of intellectual property suits, interference proceedings and related legal and administrative proceedings could result in substantial expense to us and significant diversion of effort by our technical and management personnel. In the event the court’s decision in the Ormco litigation discussed above is overturned on appeal, or if we are subject to an adverse determination in a patent suit by Ormco or in any other litigation or interference proceeding to which we may become a party, we could be subject 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 are 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 our financial condition, results of operations or cash flows.

ITEM 2. CHANGES IN SECURITIES, USE OF PROCEEDS AND ISSUER PURCHASES OF EQUITY SECURITIES

Not applicable.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

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

On May 19, 2004, we held our Annual Meeting of Stockholders (the “Annual Meeting”).

At the Annual Meeting, our stockholders elected the following individuals to the Board of Directors for the succeeding year or until their successors are duly qualified and elected:

| <u>NOMINEE</u> | <u>VOTES IN FAVOR</u> | <u>VOTES WITHHELD</u> |
|------------------------|-----------------------|-----------------------|
| H. Kent Bowen | 50,106,183 | 1,324,015 |
| David E. Collins | 50,103,284 | 1,326,914 |
| Brian Dovey | 50,098,876 | 1,331,322 |
| Joseph Jacob | 51,329,983 | 100,215 |
| Thomas M. Prescott | 51,315,884 | 114,314 |
| Greg J. Santora | 51,044,418 | 385,780 |
| Kelsey Wirth | 51,327,124 | 103,074 |
| C. Raymond Larkin, Jr. | 51,323,226 | 106,972 |

At the Annual Meeting, our stockholders voted on the following proposal:

1. To ratify the appointment of PricewaterhouseCoopers LLP as our independent auditors for the fiscal year ending December 31, 2004.

| <u>FOR</u> | <u>AGAINST</u> | <u>ABSTAIN</u> | <u>BROKER NON-VOTE</u> |
|------------|----------------|----------------|------------------------|
| 50,996,551 | 408,568 | 25,079 | 0 |

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K

- (a) Exhibits:

| <u>Exhibit Number</u> | <u>Description</u> |
|-----------------------|--|
| 10.41 | Lease Agreement between Schootsepoort Onroerendgoed Beheer, for Stichting Philips Pensioenfonds and Align Technology, Inc. (with English summary attached). |
| 10.42 | Terms of employment between Align Technology, Inc. and Bob Mitchell dated June 15, 2004. |
| 10.43 | Lease Agreement No. Am-1 dated April 15, 2004 between Align Technology Research and Development Inc. and OAO MZHM “Iskra”. |
| 31.1 | Certifications pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. |
| 32.1 | Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. |

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(b)

On June 7, 2004, Align filed a report on Form 8-K reporting under Item 5 the appointment of Warren S. Thaler to the Board of Directors of Align.

On May 17, 2004, Align filed a report on Form 8-K reporting under Item 5 that on May 13, 2004, the United States District Court for the Central District, Southern Division, granted Align's motion for summary judgment of non-infringement of Ormco Corporation's ("Ormco") Patent Nos. 5,447,432, 5,683,243, 6,244,861 and 6,616,444 in the patent infringement case brought against Align by Ormco in January 2003.

On April 28, 2004, Align furnished under Item 12 a transcript of its conference call held on April 22, 2004 to discuss its financial results for its first quarter ended March 31, 2004.

On April 22, 2004, Align filed a report on Form 8-K reporting under Item 5 the announcement of its financial results for its first quarter ended March 31, 2004. Under Form 8-K, Align furnished under Item 12 the press release relating to its financial results for its first quarter ended March 31, 2004.

SIGNATURES

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

Date: August 5, 2004

ALIGN TECHNOLOGY, INC.

By: /s/ THOMAS M. PRESCOTT

Thomas M. Prescott
President and Chief Executive Officer

By: /s/ ELDON M. BULLINGTON

Eldon M. Bullington
Vice President of Finance and Chief Financial Officer

EXHIBIT INDEX

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| 32.1 | Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. |

Summary

By courtesy we enclose this translation as an explanation of the Dutch version. The Dutch version is legally valid.

Lessor

Schootsepoort Onroerend Goed Beheer, representing Stichting Philips Pensioenfonds established in Eindhoven, Beukenlaan 143.

Lessee

Align Technology Inc. USA. *Lessor requests a subcontract of registration Chamber Of Commerce with the authorized person(s) to sign the lease.*

Property to be leased

Approx. 1,066 sqm. Lettable Floor Area (LFA) situated on the ground and first floor (including a share in common space) in building A (solitary building) of the new office development 'Telespy' at the Tempelhofstraat, Amsterdam.

Lessee can lease parking spaces in the parking garage. According to the parking ratio (1:107) 10 spaces are available.

Lessee has the possibility to lease additional 67 – 140 m² archive space in the basement.

Lease term

5 years with contiguous extension periods of 5 years. First extension period is tenants option only.

Commencement date of the lease

July 1, 2004.

Notice period

12 months.

Rent

Office **EUR 160.00** per sqm. per annum, excluding service charges and VAT;

Archive **EUR 70.00** per sqm. per annum, excluding service charges and VAT;

Parking **EUR 1,500.00** per space per annum, excluding VAT.

| | |
|-----------------------|--|
| Designated use: | Approximately 30% of the leased area is technical space in which an X-ray machine is operating. All governmental permits will be shown to lessor, the other approx. 70% will be used as office space. |
| Payment: | Rent and service charges plus VAT, to be paid quarterly in advance. First payment of rent will take place on March 1 2005. Service charge are to be paid as of date of commencement. |
| Security: | A bank quarantine of 3 months rent, including service charges with VAT. |
| Level of outfitting: | <p>Lessor will deliver the rented space including:</p> <ul style="list-style-type: none"> - Windows can be opened so sunblinds will still be operable inside. - Stairs with carpeting. - Ceiling height 2750 mm, ceiling height external wall 3150 mm, ceilings with light fittings, air inlet grids, etc. - Climate installation, adjustable per 25 square meters. - Luxury lavatories per floor and a disabled lavatory. - Cable ducts above ceiling. - Service panel in central entry hall. - Doorbell, fire detection. - Connection point for pantry, provisional sum of € 5000, ex. VAT for a pantry. - Parking garage has a roller door and intercom installation with connection to both rented floors so garage door and doors can be opened automatically. - Main entry door with automatic door opener and letterbox. - Internal and external signs, as well as in elevators with lessee's name. - Receptions desk, provisional sum € 5000,— excluding VAT. - Lessor creates a good entrance at the rear side of the building so a separate entrance is there for euro pallets. Lessee will give details. - Air-conditioning in all rooms, in both floors. We would like to know how many W/m² the topcooling system is right now. |
| Fit out contribution: | The lessor should calculate with 6% instead of 7% interest and the penalty should be adjusted. Please give us an other calculation with amounts. |
| Lease contract: | ROZ-model July 2003, subject to lessee's approval. |

Rent adjustment

Increased annually, for the first time on July 1, 2005, on the basis of the change in the monthly index in accordance with the consumer price index (CPI), series CPI All Households (2000 = 100), as published by the Central Bureau of Statistics (CBS).

Service/service charges

The service charges amount to **EUR 22.00** per sqm. per annum plus BTW. (The service charges must be paid in advance. Settlement will take place annually on the basis of the actual costs.) Overview of the services: See lease proposal – Dutch version.

Payment

Rent and service charges plus BTW, to be paid quarterly in advance. First rent payment will take place on March 1, 2005. Service charges are to be paid as of date of commencement.

Security

Bank guarantee or deposit amounting to 3 months' rent, including service charges and BTW.

If a subsidiary of Align Technology Inc. USA will be assigned as lessee, lessor requests additional security by a corporate guarantee provided by the parent company (Align Technology Inc. USA).

Use

To be used as office space with technical space (for X-Ray scan) and parking. Lessor emphasises that the current designated use is office. Lessee is responsible for holding the necessary permits for the intended use.

Level of outfitting

See lease proposal – Dutch version

Special features

- Rent free period
Lessee receives a rent free period of **8 months**; first rent payment on January 2005. Service charges are to be paid as of date of commencement.
- Fit out contribution
Lessor is prepared to contribute a fit out allowance of **EUR 300.00** per sqm. LFA (f.e. to be used for purchase of partitioning, carpeting, cabling and/or furniture).

For compensation lessee will pay an additional rent of **EUR 39.00** per sqm. LFA. Lessee provides an additional bank-or corporate guarantee for the total amount of the investment.

This contribution is based on a 10 years annuity; 6% interest. If lessee does not use her right to extend the lease, lessee should pay a one-time penalty of EUR 170.00 per sqm. LFA.

- Goods entrance
Lessor creates a goods entrance at the rear side of the building including reinforcing the outside floor grid. Point of departure is a separate entrance for shipping by euro-pallet.
- Kitchenette and reception desk
Lessor contributes a provisional sum with a maximum of **EUR 10,000.00** excl. BTW for a kitchenette in the leased space and a reception desk. Execution in consultation with lessor.
- Cooling
The building is fitted with mechanical ventilation system with peak cooling. Cooling capacity is **35 W/sqm**. If required additional cooling capacity can be created in technical space (X-Ray scan and computer room). Lessor requests lessee to provide details regarding the required cooling capacity.
- Floor load
Lessor guarantees that the technical equipment can be put on the ground floor according to the specifications of the architect (details have already been send to you).
- Market rent review
Both parties have the right to adjust the rent to the market after every lease term (for the first time on July 1, 2009). Review exercised according to the ROZ standard.
- Name sign
Lessee has the right to put up a name sign -advertising sign on the facade of the building A after approval of lessor and local authorities. Lessee will show an example to owner before putting up the sign for approval. Lessor will not disapprove on unreasonable grounds. Lessee can use one flagpole.
- Right to sublease/ substitution
Lessee has the right to sublease the whole or a part of rented area or the right of substitution, after written approval of the lessor who will not disapprove on unreasonable grounds.

- Miscellaneous items
 - Lessor arranges electricity meters and intercom/ opener per floor;
 - Lessee is free to place the reception desk;
 - Lessor arranges name signs in the building.

Miscellaneous

Lessee has the right to dissolve the lease agreement if the required permit(s) for the use of the X-Ray scan and/or a general occupancy permit is not issued by local government. The dissolved can only be called in by letter together with the rejection letter and at latest on Friday September 10, 2004. When the right is exercised, lessee will credit all incentives given by – and compensate investments made by – lessor within 10 working days, including 7% interest over the period from provision to date of dissolution.

Until the lease agreement is irrevocable, lessor will not start with adjustments to the leased space or apply for a building permit for the goods entrance.

Van Dijk en Ten Cate Vastgoed Adviseurs
T.a.v. de heer R.J.F. ten Cate
De Boelelaan 7
1083 HJ AMSTERDAM

Betreft
Telespy, Tempelhofstraat
Telefoon
020 5711431

Onze referentie
Fab/Qbu/A5
Contactpersoon
ing. Erik O. Tijsma

Datum
13 mei 2004
E-mail
etijsma@dtz.nl

Geachte heer Ten Cate,

Naar aanleiding van uw schriftelijke reactie van 6 mei 2004 op ons huurvoorstel van 20 april 2004 ten behoeve van uw cliënt **Align Technology**, is het ons een genoegen u hierbij ons aangepaste huurvoorstel te doen op basis van navolgende uitgangspunten en voorwaarden.

Verhuurder

Schootsepoort Onroerend Goed Beheer, namens Stichting Philips Pensioenfonds gevestigd te Eindhoven aan de Beukenlaan 143.

Huurder

Align Technology Inc. USA. *Graag ontvangen wij een uittreksel KVK waarop vermeld de tekeningsbevoegde perso(o)n(en).*

Te huren

Circa **1.066 m²** v.v.o. kantoorruimte gelegen op de begane grond en 1e verdieping (inclusief een aandeel in de algemene ruimten) in het bouwdeel A (vrijstaande gebouw) van de kantoorontwikkeling Telespy, gelegen aan de Tempelhofstraat te Amsterdam.

Bij het gehuurde zijn parkeerplaatsen aanwezig in ondergelegen parkeerkelder. Conform de vigerende norm (1:107) zijn 10 plaatsen beschikbaar. De plaatsen zijn gesitueerd nabij de ingang van bouwdeel A.

Huurder heeft de mogelijkheid tot de huur van circa 67 -140 m² v.v.o. archiefruimte in de kelder.

Huurtermijn

5 jaar met aansluitende perioden van telkens 5 jaar (eerste verlengingsperiode is huurdersoptie).

Huuringangsdatum

1 juli 2004.

Opzegtermijn

12 maanden.

Huurprijs

Kantoorruimte **EUR 160,00** per m² v.v.o. per jaar, te vermeerderen met servicekosten en BTW

Archief **EUR 70,00** per m² v.v.o. per jaar, te vermeerderen met servicekosten en BTW

Parkeren **EUR 1.450,00** per plaats per jaar, te vermeerderen met BTW.

Huurprijsaanpassing

Jaarlijkse verhoging, voor het eerst één jaar na huuringangsdatum, op basis van de wijziging van het maandprijnsindexcijfer volgens de consumentenprijsindex (CPI) reeks CPI Alle Huishoudens (2000 = 100), gepubliceerd door het Centraal Bureau voor de Statistiek (CBS).

Service/servicekosten

Onderstaande leveringen en diensten zijn inde servicekosten opgenomen:

- gas, c.q. olieverbruik inclusief vastrecht;
- elektriciteitsverbruik inclusief vastrecht ten behoeve van de installaties en de verlichting van de gemeenschappelijke ruimten;
- waterverbruik inclusief vastrecht;
- onderhoud en periodieke controle van verwarmings-en/of luchtbehandelingsinstallatie(s);
- idem van liftinstallatie(s), met uitzondering van de minder validenlift;
- idem van hydrofoorinstallatie;
- idem van glazenwasinstallatie;
- idem van brandmelder-, gebouwbewakings-, storingsmelder-en nood-stroominstallatie(s);
- schoonmaakkosten van de gemeenschappelijke ruimten, liften, beglazing buitenzijde, beglazing gemeenschappelijke ruimten, terrassen, parkeerkelder en/of terrein;
- verzorging huisvuil, containerhuur e.d.;
- assurantiepremie buitenbeglazing;
- administratiekosten ad 5% over de hierboven genoemde leveringen en diensten.

De servicekosten bedragen **EUR 22,00** per m² v.v.o. per jaar, te vermeerderen met BTW. De servicekosten dienen op voorschotbasis te worden voldaan. Verrekening vindt jaarlijks plaats op basis van de werkelijke kosten.

Betalingsverplichting

Huur en servicekosten per kwartaal vooruit, inclusief de daarover verschuldigde BTW. Eerste huurbetaling vindt plaats voor het eerst op 1 maart 2005. Servicekosten worden per datum van huuringang in rekening gebracht.

Zekerheidstelling

Bankgarantie of waarborgsom ter grootte van 3 maanden huur inclusief de servicekosten en de BTW.

Indien een dochter van Align Technology Inc. USA de hurende partij is, dan verstrekt Align Technology Inc. USA een additionele concerngarantie.

Gebruik

Te gebruiken als kantoorruimte voorzien van technische werk-/ kantoorruimte (onder andere een röntgenscan) met parkeervoorziening. Verhuurder meldt nadrukkelijk dat

conform het vigerende bestemmingsplan het gehuurde een kantoorbestemming heeft. Huurder dient zelf zorg te dragen voor het verkrijgen van (eventueel) benodigde vergunningen en/of ontheffingen ten behoeve van het beoogde gebruik.

Opleveringsniveau

Het geheel wordt eenmalig opgeleverd door verhuurder inclusief o.a.:

- representatieve entree;
- isolerend zonwerend glas;
- te openen ramen;
- natuursteen in de centrale hal;
- trappen en bordes voorzien van vloerbedekking;
- plafondhoogte 2750 mm, plafondhoogte gevelzone 3150 mm, systeemplafond voorzien van verlichtingsarmaturen, luchttoevoerroosters etc.
- klimaat behandelingsinstallatie als een constant volumesysteem met na(lucht)-verwarming individueel regelbaar per vertrek van minimaal 25 m²;
- indeelbaarheid per 1.80 m;
- luxe toiletgroepen per etage en een extra mindervalide toilet op de begane grond;
- in de muur geïntegreerde wandgoten;
- kabelgoten en ladders boven de verlaagde plafonds;
- bedienings-en signaleringspaneel in centrale hal;
- deurbelinstallatie en brandmeldinstallatie;
- aansluitvoorziening ten behoeve van pantry;
- de parkeergarage is voorzien van roldeur en intercominstallatie.

De ruimte wordt eenmalig schoon en ontruimd opgeleverd inclusief het reinigen van beglazing aan binnen en buitenzijde.

Bijzonderheden

- Huurvrije periode
Huurder verkrijgt een huurvrije periode van **8 maanden** (van 1 juli 2004 tot en met 28 februari 2005). In deze periode is huurder alleen servicekosten verschuldigd.
- Inrichtingsbijdrage
Verhuurder is bereid een inrichtingsbijdrage ter beschikking te stellen van **EUR 300,00** per gehuurde m² v.v.o ten behoeve van inrichting van het gehuurde (bijvoorbeeld voor wanden, vloerbedekking, bekabeling en/of meubilair). Als compensatie hiervoor wordt de huurprijs van de kantoorruimte verhoogd met **EUR 39,00** per m² v.v.o. Huurder verstrekt een additionele bankgarantie/ concerngarantie ter grootte van de totale investering. *Uitgangspunt hierbij is een tienjarige annuïteit op*

basis van 6%. Indien huurder geen gebruik maakt de eerste verlengingsperiode, dan zal zij een eenmalige vergoeding betalen aan verhuurder (voor de resterende waarde van de investering) ter grootte van EUR 170,00 per gehuurde m² v.v.o

- Goedereningang
Verhuurder verzorgt de aanpassingen in de achtergevel van de begane grond ten behoeve van een goedereningang alsmede het aanpassen van het vloerrooster. Uitgangspunt is een toegangsdeur waardoor een pallet het gebouw binnengebracht kan worden.
- Pantry en receptie voorzieningen
Verhuurder stelt eenmalig een stelpost van maximaal **EUR 10.000,00** excl. BTW ter beschikking voor een pantry in de gehuurde ruimte en een receptiebalie. Uitvoering in overleg met verhuurder.
- Koeling
Het gebouw beschikt over mechanische ventilatie met top-koeling. Koelcapaciteit is **35 W/m²**. Indien nodig kan de bedrijfsruimte (X-Ray scan en computerruimte) voorzien worden van additionele koeling. Verhuurder verzoekt huurder om aanvullende gegevens omtrent wamtelasten.
- Vloerbelasting
Verhuurder garandeert dat de technische apparatuur op de begane grond van het gehuurde geplaatst kan worden. De plaats hiervoor is bepaald door de constructeur en gegevens hiervan zijn reeds aan u verstrekt.
- Markthuurprijsherziening
Partijen hebben het recht tot een markthuurprijsherziening aan het einde van iedere huurtermijn (voor het eerst op 1 juli 2009) conform het standaardmodel ROZ.
- Toegang
Huurder heeft 24 uur, 7 dagen per week toegang tot het gehuurde.
- Naamsaanduiding
Huurder heeft het recht na toestemming verhuurder en goedkeuring gemeente een naamsaanduiding aan te brengen op de gevel. Huurder zal hiervoor een voorstel doen. Verhuurder zal haar toestemming niet op onredelijke gronden weigeren. Huurder heeft het recht één vlaggenmast te gebruiken.
- Recht van onderverhuur/ contractsovername
Huurder heeft het recht (een deel van) de gehuurde ruimte onder te verhuren dan wel het contract aan een derde partij over te dragen (contractsovername), na schriftelijke toestemming van verhuurder welke hij niet op onredelijke gronden zal weigeren.
- Overige bijzonderheden
 - verhuurder verzorgt elektrameters per verdieping;
 - verhuurder verzorgt een intercom/opener per verdieping;

- huurder is vrij de locatie van de receptiebalie te bepalen;
- verhuurder verzorgt bewegwijzeringen in het complex.

Overige

Voor het overige zullen de bij huur en verhuur van soortgelijke ruimten gebruikelijke bepalingen van toepassing zijn met dien verstande dat voor de verdere vastlegging gebruik gemaakt zal worden van het standaardmodel van de Raad voor Onroerende Zaken (ROZ).

De huurovereenkomst zal in de Nederlandse taal worden opgesteld en deze wordt door partijen ondertekend. Ter informatie zal een vertaling in het Engels worden bijgevoegd. Aan deze vertaling kunnen geen rechten worden ontleend.

Huurder heeft het recht de huurovereenkomst te ontbinden indien er geen vergunning voor het gebruik van de X-Ray scan en/of algemene gebruiksvergunning wordt verstrekt. Deze ontbinding is alleen schriftelijk in te roepen waarbij de stukken welke de afwijzing bevestigen worden bijgevoegd. Huurder kan uiterlijk op vrijdag 10 september 2004 een beroep doen op de ontbindende voorwaarde. Bij ontbinding zal huurder alle bijdragen van en investeringen door -verhuurder binnen 10 werkdagen crediteren aan verhuurder, verhoogd met 7% rente gerekend over de periode van verstrekking door verhuurder tot datum ontbinding.

Verhuurder zal niet eerder dan dat de huurovereenkomst onherroepelijk is geworden, aanvangen met bouwkundige/ installatietechnische aanpassingen aan het gehuurde alsmede de aanvraag voor een bouwvergunning ten behoeve van de goedereningang.

Bovenstaand huurvoorstel doen wij u gestand tot vrijdag 14 mei 2004, 12:00 uur. Indien wij voordien geen schriftelijke reactie van u hebben ontvangen acht verhuurder zich vrij met derden een overeenkomst te sluiten.

Wij vertrouwen erop u hiermede een passend voorstel te hebben gedaan en zien gaarne uw bevestiging tegemoet.

Met vriendelijke groet,
DTZ Zadelhoff v.o.f.,
namens deze,

ing. Erik O. Tijmsma

Align Technology,
namens deze,

/s/ ROGER E. GEORGE

Roger E. George, General Counsel
Plaats: Align Technology

Datum: 13 mei 2004

c.c. verhuurder

June 21, 2004

PERSONAL AND CONFIDENTIAL

Robert D. Mitchell
4800 Inverness Woods Road
Bloomington, Indiana 47401

Re: Employment Terms

Dear Bob:

Align Technology, Inc. (the "Company") is pleased to offer you the position of Vice President of Worldwide Sales.

Your anticipated start date is July 12 (the "Effective Date"), and you will attend new hire orientation from 9:00 a.m. to 4:00 p.m. Your rate of pay will be a bi-weekly salary of \$8653.85, which equals an annual salary of \$225,000, less payroll deductions and all required withholdings. In addition, you will be eligible for a discretionary annual target bonus of 60% of your base salary, which bonus is based on your meeting agreed-upon performance objectives established between you and me. We will discuss these objectives in more detail shortly after you start. You will be guaranteed the bonus for FY2004 of 60% of \$225,000, payable in early 2005 according to the Company's standard practice, prorated for the number of days that you are employed during 2004.

Recognizing that you will incur additional costs such as M.B.A. tuition, acquiring an automobile and higher taxes and living expenses, you will also receive a cost of living supplement to your monthly salary, less payroll deductions and all required withholdings, as follows:

1. for the remainder of 2004 and 2005, \$6,000
2. for 2006, \$4,800
3. for 2007, \$4,200
4. for 2008, \$3,000.

You will receive a signing bonus in the amount of \$100,000.00, subject to all taxes and withholdings (the "Signing Bonus"). Should your employment with the Company be terminated within the first year of your employment, the Signing Bonus must be reimbursed to the Company based on the attached reimbursement agreement (See "Attachment A"). In addition, if you purchase a home in the Bay Area during the first twelve months of your employment, upon the execution of a binding purchase contract for such home, you will be entitled to receive the amount of \$400,000.00, subject to all taxes and withholdings (the "Offer Letter Bonus"). Should your employment with the Company be terminated within the first three years of your employment, the Offer Letter Bonus must be reimbursed to the Company based on the attached reimbursement agreement (See "Attachment A").

Align will cover the normal, reasonable costs associated with your relocation from Bloomington, Indiana to the Bay Area as set forth in the attached relocation agreement (See "Attachment B"). Should your employment with the Company be terminated voluntarily within the first three years of your employment, your relocation costs must be reimbursed to the Company based on attached relocation agreement.

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

Subject to the approval of the Board of Directors, Align Technology will grant you the option to purchase 215,000 shares of Align Technology common stock which shall vest as to 25% of the shares on the first anniversary of your employment and as to 1/48th of the shares at the end of each month thereafter, for full vesting after 4 years. The exercise price shall be 100% of the fair market value of the stock on the date of grant, which shall be the later of your employment date or the date the grant is approved by the board.

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

Your place of work will be at the offices of Align Technology, 881 Martin Ave, Santa Clara, CA 95050. Of course, Align Technology may change your position, duties, and work location from time to time as it deems necessary.

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

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

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

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

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

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

It is anticipated that Align Technology and you will enter into the Company's standard form of Executive Employment Agreement. Included in that agreement will be provisions to address the implications of a change of control on your stock option grant, as well as the terms of your relocation allowance, and termination.

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

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

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

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

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

Sincerely,

Thomas M. Prescott, President & CEO

ACCEPTED:

/s/ Robert D. Mitchell

Robert D. Mitchell

6-21-04

Date

**Agreement No. AM-1
on the Lease of the Non-Residential Premises**

City of Moscow

15 April 2004

OAo MZHM "Iskra," registration number 023356, hereinafter referred to as the "Lessor" represented by General Director Petrov K.A. acting pursuant to the Charter, from the one part, and Align Technology Research and Development, a company, organized and existing pursuant to its Articles of Association under the laws of the State of Delaware, hereinafter referred to as the "Lessee," represented by Roger E. George, the President and Chief Executive Officer of Align Technology Research & Development, Inc. acting on the basis of the Unanimous Written Consent of the Board of Directors of Align Technology Research & Development, Inc., from the other part, collectively the "Parties," had entered into this agreement on the following:

1. General

1.1 On the ground of ownership (Certificate of Title No. 77 AB 337931, dated 21 August 2003, issued by Moscow City Committee on the Registration of Titles), the Lessor hereby leases out and the Lessee hereby accepts for lease, under a bilateral act, the non-residential premises with a total area of 591 sq.m located on the second floor of the building located at: 27/29, Pavlovskaya street, block 1, Moscow, cadastre number 239475, hereinafter the "Premises," to use the same as office. The Premises are indicated on the floor plan of the Building. Schedule No. 1.

1.2 The lease of the Premises shall not entail transfer of the title thereto.

1.3 A transfer of the title to the leased Premises to another party shall not be a ground to amend or terminate this Agreement.

1.4 The inseparable improvements made by the Lessee to the leased Premises shall be its property. The Parties undertake to sign the list of inseparable improvements within 10 calendar days of receipt by the Lessor of the Lessee's notice of completion of the repair works.

1.5 The inseparable improvements made by the Lessee to the leased Premises shall be property of the Lessor. The Lessee shall not be entitled to require reimbursement from the Lessor for the cost of the inseparable improvements made to the Premises.

1.6 The lease term is established until 10 April 2005.

1.7 Upon expiration of the Lease Agreement the Lessee, performing its obligations duly, shall have a preemptive right to enter into the Lease Agreement for a new term. At that, the amount of payment shall be adjusted for the rate of inflation. The other terms and conditions of the Agreement may be changed upon mutual agreement between the parties.

1.8 This Agreement is allowed to be terminated unilaterally:

1.8.1. by the Lessor:

- 1.8.1.1 if the full, or any part of the, lease payment shall not have been made by Lessee within thirty (30) days after the due payment date;
or
- 1.8.1.2 in case of the Lessee's material default on any of its obligations under this Agreement and its failure to cure such default within ten (10) days after receipt of a relevant written notice from the Lessor.

1.8.2. By the Lessee:

- 1.8.2.1. if the building or the Premises become unsuitable for use by the Lessee for their designated purpose including for the reason of the Lessor's failure to perform its obligations in accordance with clauses 2.1.2.-2.1.7 hereof and the Lessor's failure to remove the cause of such unsuitability within thirty (30) days.

2. Obligations of the Parties

2.1. The Lessor undertakes:

- 2.1.1. Within two (2) days of the date of signing of this Agreement to transfer the Premises to the Lessee under a transfer and acceptance act.
- 2.1.2. To procure that the Premises during the Lease Term be connected to the systems of sewage, heat, water and power supply provided the Lessee shall have obtained a permit for connection from power supply authorities.
- 2.1.3. To provide the Lessee, at its request and for a separate fee, with outgoing and incoming fiber-optic communication and with access to the Internet.
- 2.1.4. In case of a failure occurred through no fault of the Lessee, the Lessor shall undertake all necessary measures to repair such a failure.
- 2.1.5. To maintain due order in public spaces and keep engineering services of the buildings in good order.
- 2.1.6. To grant employees and visitors of the Lessee access to the Leased Premises.
- 2.1.7. To allocate to the Lessee three (3) spaces for parking cars, the cost of which spaces shall be included into the cost of the lease. Up to 12 optional parking spaces at a price of USD50 (VAT excluded) per month for each parking space shall also be available for the Lessee.
- 2.1.8. The Lessor undertakes to grant employees and/or visitors of the Lessee access to the Premises on weekdays from Monday through Friday from 8 a.m. to 10 p.m. Work during week-ends from 8.00 a.m. to 10 p.m. shall be

permitted as per the lists prepared and signed by managers of the Lessee. A permit to work on holidays and after 10 p.m. on week-days shall be executed by the General Director of the plant and, in the event of his absence, by the Chief Engineer of the plant. The executed lists shall be delivered to the security office.

During other hours and during the weekends and holidays the Lessor undertakes to grant employees and/or visitors of the Lessee access to the Premises provided the Lessor shall have been notified by the Lessee in advance. A notification requesting access for employees and/or visitors of the Lessee to the Premises on weekends and holidays shall be sent to the Lessor on a business day preceding the relevant weekend or holiday.

2.2. The Lessee undertakes:

2.2.1. To accept the Premises for lease with the outlook and in the condition thereof which exist as of the moment of execution of this Agreement.

2.2.2. To use the Premises for the designated purposes thereof in accordance with Clause 1.1. hereof.

2.2.3. To be fully responsible for compliance with the rules of fire safety, environmental and sanitary standards, standards of labor safety of the Lessee's employees and clients on the area occupied by the Lessee, and with other rules regulating the procedure for using non-residential premises, service lines and equipment installed therein, which rules are determined by laws of the Russian Federation.

2.2.4. To perform routine repair of the Premises at its own cost.

2.2.5. Not to sublease the Premises, in full or in part, without a written permit by the Lessor.

2.2.6. To notify the Lessor in writing on a forthcoming vacation of the Premises not later than one (1) month prior thereto for the reason of both expiration of the lease term and early termination thereof and to deliver the Premises, together with all inseparable improvements made thereto, to the Lessor under a transfer and acceptance act, in good order and with performed cosmetic repairs of the Premises.

2.2.7. To make the lease payment *within* the periods established by this Agreement.

2.2.8. Not to make a replanning of the Premises, service lines without a written permit by the Lessor.

2.2.9. To comply with the access rules established by the Lessor.

2.2.10. To grant the Lessor's representatives free access to the Premises in order to examine the Premises from time to time to ascertain that the same are used *in accordance with this Agreement* and applicable law.

3. Payments and Settlements under the Agreement

3.1. During the first six (6 months), commencing from 15 April 2004, the Lessee shall pay the Lessor the lease payment for the Premises in the amount of eleven thousand four hundred ninety-one US Dollars and 67 cents (US\$11,491.67) per month including 18% VAT in the amount of one thousand seven hundred fifty-two US Dollars and 97 cents (US\$1,752.97). Since 15 October 2004, the lease payment shall be seventeen thousand two hundred thirty-seven US Dollars 50 cents (US\$17,237.50) per month including 18% VAT in the amount of two thousand six hundred twenty-nine US Dollars and 45 cents (US\$2,629.45).

3.2. The payment shall be made in advance on a monthly basis prior to the fifth (5th) day of the month subject to be paid for.

3.3. The Lessee shall on a monthly basis reimburse the Lessor for the cost of electric power consumed, as per the reading of an electric meter, at official tariffs of Mosenergo, against invoices from the Lessor, within five (5) banking days of the moment such invoices received.

3.4. The Lessee shall on a monthly basis reimburse for the Lessor's costs of the provision of telephone communication and access to the Internet and, on a quarterly basis, for the costs of garbage removal, against issued invoices, in accordance with document supported costs and expenses incurred by the Lessor, within five (5) business days of the moment of receipt of such invoices.

3.5. The Lessee shall commence paying for the lease of the Premises since the moment Clause 2.1.1. is fulfilled by the Lessor.

4. Liability of the Parties

4.1. In the event that the Lessee fails to make the payment when due as specified in Clause 3.2 hereof the Lessee shall pay the Lessor an interest of 0.1% of the overdue amount for each day of the delay.

4.2. The payment of interest shall not relive the Parties from the performance of their obligations hereunder.

4.3. In the event that this Agreement is terminated upon the Lessor's initiative, the Lessor undertakes, provided the Lessee duly performs its obligations, to reimburse the Lessee for the total amount of costs incurred by the Lessee for the repair of the Premises, and to compensate for the Lessee's losses arising out of the unscheduled vacation of the leased Premises, in the amount of one month lease payment.

5. Relationship between the Parties

5.1 This Agreement is allowed to be amended upon agreement between the Parties executed in writing.

5.2. The Parties shall undertake all efforts to settle all disputable matters by bilateral negotiations. If the Parties fail to agree, the disputes shall be referred to arbitrazh court of the city of Moscow.

6. Force-Majeure

6.1. The Parties shall not be liable for a failure to perform their obligations hereunder in part or in full if such failure is a result of force majeure circumstance and such circumstances have directly affected the performance of this Agreement. Force-majeure circumstances shall be understood as circumstances which arise after the execution of this Agreement as a result of events unforeseen and unpreventable by the Parties, such as: Acts of God (fire, flooding, etc.); acts of war conducted in the area of the Premises location, state of emergency announced by competent authorities, as well as other decisions impeding performance of this Agreement. At that, the deadline of the obligations performance shall be extended for as long as the circumstances will continue in effect.

7. Miscellaneous

7.1. All amendments, attachments and supplements to this Agreement shall be valid if only executed in writing and signed by both Parties and shall make integral part to this Agreement.

7.2. Neither Party is entitled to transfer its rights and obligations hereunder without written consent of the other Party.

7.3. All the matters not covered by the Agreement shall be treated in accordance with applicable laws of the Russian Federation.

7.4. This Agreement is made in two (2) original copies in two-column format in the English and Russian languages, one copy for each Party, both copy having equal legal force. In the event of discrepancies between the copies in different languages the Russian version shall prevail.

7.5. This Agreement shall take effect as of the moment of its signing by the Parties and shall continue in force till the Parties perform their obligations in full.

8. Legal Addresses and Bank Details of the Parties

8.1. The Lessor:

OAO MZHM "ISKRA"

Legal address: 27/29, ul. Pavlovskaya, Moscow 115093, Russian Federation
TIN 7725040638, KPP 772501001,

Forex transit account: 40702840900001001265 at AB "BPF" (ZAO)

Beneficiary's bank: PROJECT FINANCING BANK Zemlyanoi Val, 34A
105064, Moscow, Russia

Beneficiary's bank account at the agency bank: 04416812

Agency Bank: DEUTSCHE BANK TRUST COMPANY AMERICAS

130 Liberty street, MS 2214, NY 10006, USA

SWIFT: BKTRUS33, TELEX: 420066 BANTR US

8.2. The Lessee:

Align Technology Research & Development, Inc

Legal address: 881 Martin Avenue, Santa Clara, California, USA.

Bank of America, Bay Area Commercial Banking, CA3-103-01-03,
125 South Market Street, San Jose, CA 95113-2250
Account number: 14993-11585

In witness whereof the Parties have caused their duly authorized representatives to sign this Agreement in their names on the date first written above.

The Lessor

The Lessee

OA0 MZHM "ISKRA"

Align Technology Research & Development, Inc.

/s/ K.A. Petrov

/s/ Roger E. George

General Director

President and Chief Executive Officer

K.A. Petrov

Roger E. George

Помещение срубленного в аренду
в здании в здании
2 этаж стр. №1

План

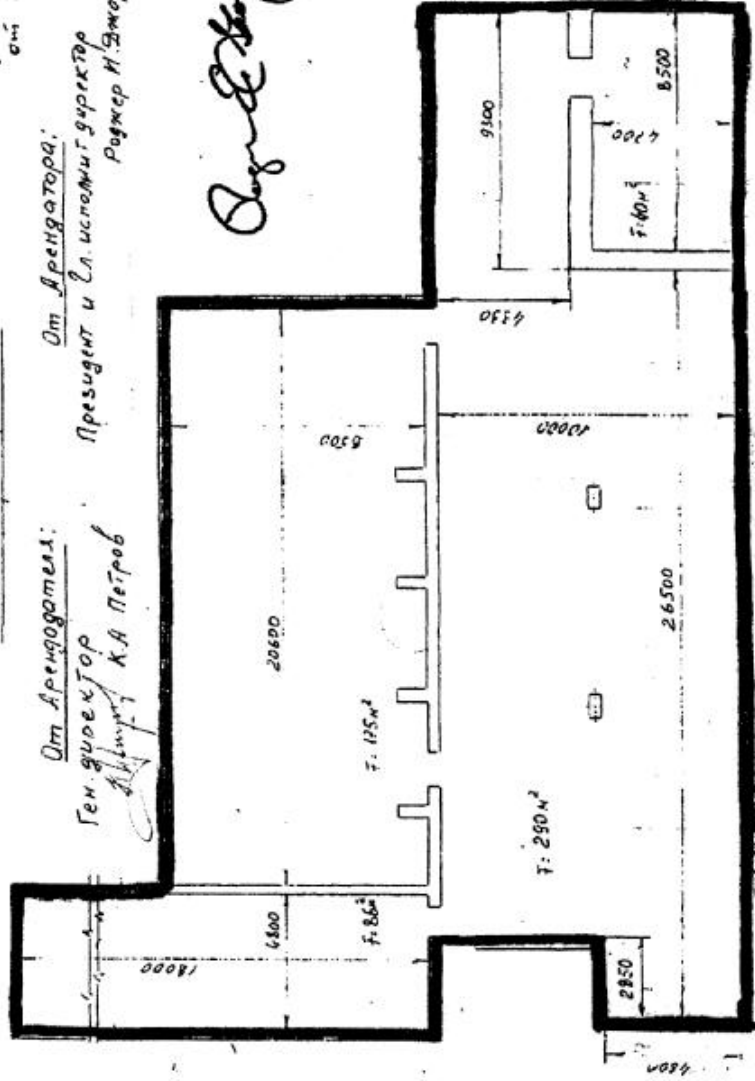
Получение №1
к 302. М.В.М.-1
от 15.04.04

От арендодателя:

Ген директор
Иванов К.А. Петров

От арендатора:

Президент и вл. компания директор
Роджер Н. Джордан



[Handwritten signature]

CERTIFICATION

I, Thomas M. Prescott, certify that:

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

Date: August 5, 2004

/s/ THOMAS M. PRESCOTT

Thomas M. Prescott
President and Chief Executive Officer

I, Eldon M. Bullington, certify that:

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

Date: August 5, 2004

/s/ ELDON M. BULLINGTON

Eldon M. Bullington
Vice President of Finance and Chief Financial Officer

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

I, Thomas M. Prescott, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Quarterly Report of Align Technology, Inc. on Form 10-Q for the quarter ended June 30, 2004 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in such Quarterly Report on Form 10-Q fairly presents in all material respects the financial condition and results of operations of Align Technology, Inc.

By: /s/ THOMAS M. PRESCOTT

Date: August 5, 2004

Name: Thomas M. Prescott
Title: President and Chief Executive Officer

I, Eldon M. Bullington, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Quarterly Report of Align Technology, Inc. on Form 10-Q for the quarter ended June 30, 2004 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in such Quarterly Report on Form 10-Q fairly presents in all material respects the financial condition and results of operations of Align Technology, Inc.

By: /s/ ELDON M. BULLINGTON

Date: August 5, 2004

Name: Eldon M. Bullington
Title: Vice President of Finance and Chief Financial Officer