ANIKA THERAPEUTICS INC
Form 10-Q
August 14, 2003

# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION

**WASHINGTON, D.C. 20549**

# FORM 10-Q

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

**For the quarterly period ended June 30, 2003**

o **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 000-21326**

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# Anika Therapeutics, Inc.

(Exact Name of Registrant as Specified in Its Charter)

| | |
|---|---|
| **Massachusetts** | **04-3145961** |
| (State or Other Jurisdiction of Incorporation or Organization) | (I.R.S. Employer Identification No.) |
| **160 New Boston Street, Woburn, Massachusetts** | **01801** |
| (Address of Principal Executive Offices) | (Zip Code) |

Registrant s Telephone Number, Including Area Code: **(781) 932-6616**

Former Name, Former Address and Former Fiscal Year, if Changed Since Last Report.

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 last 90 days. Yes ý No o

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

Indicate the number of shares outstanding of each of the issuer s classes of common stock, as of the last practicable date. At August 5, 2003 there were 9,959,780 outstanding shares of Common Stock, par value $.01 per share.

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**PART I: FINANCIAL INFORMATION**

**ITEM 1: FINANCIAL STATEMENTS**

**Anika Therapeutics, Inc. and Subsidiaries**

**Consolidated Balance Sheets**
**(Unaudited)**

| | June 30, 2003 | December 31, 2002 |
|---|---|---|
| **ASSETS** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 11,453,000 | $ 11,002,000 |
| Marketable securities | | 2,500,000 |
| Accounts receivable, net of reserves of $29,000 and $35,000 at June 30, 2003 and December 31, 2002, respectively | 2,105,000 | 1,198,000 |
| Inventories | 3,228,000 | 2,924,000 |
| Prepaid expenses and other current assets | 249,000 | 320,000 |
| Total current assets | 17,035,000 | 17,944,000 |
| Property and equipment, at cost | 9,752,000 | 9,619,000 |
| Less: accumulated depreciation | (8,175,000) | (7,679,000) |
| | 1,577,000 | 1,940,000 |
| Long-term deposits | 143,000 | 143,000 |
| Notes receivable from officer | 59,000 | 59,000 |
| Total assets | $ 18,814,000 | $ 20,086,000 |
| | | |
| **LIABILITIES AND STOCKHOLDERS EQUITY** | | |
| Current liabilities: | | |
| Accounts payable | $ 406,000 | $ 845,000 |
| Accrued expenses | 1,003,000 | 1,703,000 |
| Customer Deposit | | 327,000 |
| Deferred revenue | 726,000 | 147,000 |
| Total current liabilities | 2,135,000 | 3,022,000 |
| | | |
| Stockholders equity: | | |
| Preferred stock, $.01 par value; 1,250,000 shares authorized, no shares issued and outstanding at June 30, 2003 and December 31, 2002 | | |
| Common stock, $.01 par value; 30,000,000 shares authorized, 9,991,943 shares issued June 30, 2003 and December 31, 2002 | 100,000 | 100,000 |
| Additional paid-in capital | 31,613,000 | 31,640,000 |
| Treasury stock, at cost, 50,163 shares at June 30, 2003 and 57,663 shares at December 31, 2002 | (244,000) | (280,000) |
| Accumulated deficit | (14,790,000) | (14,396,000) |
| Total stockholders equity | 16,679,000 | 17,064,000 |
| Total liabilities and stockholders equity | $ 18,814,000 | $ 20,086,000 |

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

**Anika Therapeutics, Inc. and Subsidiaries**
**Consolidated Statements of Operations**
**(Unaudited)**

| | Quarter Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2003 | 2002 | 2003 | 2002 |
| Product revenue | $ 3,303,000 | $ 3,416,000 | $ 6,673,000 | $ 5,801,000 |
| License revenue | 15,000 | 5,000 | 29,000 | 10,000 |
| Total revenue | 3,318,000 | 3,421,000 | 6,702,000 | 5,811,000 |
| Cost of product revenue | 1,846,000 | 2,202,000 | 3,815,000 | 4,289,000 |
| Gross profit | 1,472,000 | 1,219,000 | 2,887,000 | 1,522,000 |
| Operating expenses: | | | | |
| Research and development | 648,000 | 1,050,000 | 1,457,000 | 2,140,000 |
| Selling, general and administrative | 945,000 | 1,388,000 | 2,060,000 | 2,468,000 |
| Total operating expenses | 1,593,000 | 2,438,000 | 3,517,000 | 4,608,000 |
| Loss from operations | (121,000) | (1,219,000) | (630,000) | (3,086,000) |
| Interest income | 40,000 | 62,000 | 82,000 | 125,000 |
| Loss before income tax benefit | (81,000) | (1,157,000) | (548,000) | (2,961,000) |
| Income tax benefit | | | 154,000 | |
| Net loss | $ (81,000) | $ (1,157,000) | $ (394,000) | $ (2,961,000) |
| | | | | |
| Basic and diluted net loss per common share | $ (0.01) | $ (0.12) | $ (0.04) | $ (0.30) |
| Shares used to calculate basic and diluted net loss per common share | 9,941,121 | 9,934,280 | 9,937,719 | 9,934,280 |

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

**Anika Therapeutics, Inc. and Subsidiaries**

**Consolidated Statements of Cash Flows**
**For the Six Months Ended**
**(Unaudited)**

| | June 30, 2003 | June 30, 2002 |
|---|---|---|
| | | |
| Cash flows from operating activities: | | |
| Net loss | $ (394,000) | $ (2,961,000) |
| Adjustments to reconcile net loss to net cash used by operations: | | |
| Depreciation | 496,000 | 544,000 |
| Changes in operating assets and liabilities: | | |
| Accounts receivable | (907,000) | 12,000 |
| Inventories | (304,000) | 940,000 |
| Prepaid expenses and other current assets | 71,000 | 85,000 |
| Accounts payable | (439,000) | (189,000) |
| Accrued expenses | (700,000) | (101,000) |
| Customer deposit | (327,000) | |
| Deferred revenue | 579,000 | 551,000 |
| Net cash used in operating activities | (1,925,000) | (1,119,000) |
| | | |
| Cash flows from investing activities | | |
| Proceeds from sale of marketable securities | 2,500,000 | 1,994,000 |
| Purchase of marketable securities | | (2,500,000) |
| Purchase of property and equipment | (133,000) | (42,000) |
| Note receivable from officer | | 75,000 |
| Deposits | | 5,000 |
| Net cash provided by (used in) investing activities | 2,367,000 | (468,000) |
| | | |
| Cash flows from financing activities | | |
| Proceeds from exercise of stock options | 9,000 | |
| | | |
| Net cash provided by financing activities | 9,000 | |
| | | |
| Increase (decrease) in cash and cash equivalents | 451,000 | (1,587,000) |
| Cash and cash equivalents at beginning of period | 11,002,000 | 9,065,000 |
| Cash and cash equivalents at end of period | $ 11,453,000 | $ 7,478,000 |

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

**ANIKA THERAPEUTICS, INC.**

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

## 1. Nature of Business

Anika Therapeutics, Inc. ( Anika or the Company ) develops, manufactures and commercializes therapeutic products and devices intended to promote the protection and healing of bone, cartilage and soft tissue. These products are based on hyaluronic acid (HA), a naturally occurring, biocompatible polymer found throughout the body. Due to its unique biophysical and biochemical properties, HA plays an important role in a number of physiological functions such as the protection and lubrication of soft tissues and joints, the maintenance of the structural integrity of tissues, and the transport of molecules to and within cells. The Company s currently marketed products consist of ORTHOVISC®, which is an HA product used in the treatment of some forms of osteoarthritis in humans, CoEase™, STAARVISC -II, and ShellGel™, each an injectable ophthalmic viscoelastic HA product, and HYVISC®, which is an HA product used in the treatment of equine osteoarthritis. ORTHOVISC is currently approved for sale and is being marketed in Canada, parts of Europe, Turkey, and Israel. In the U.S., ORTHOVISC is currently limited to investigational use. The Company manufactures AMVISC® and AMVISC® Plus for Bausch & Lomb, which are HA products used as viscoelastic supplements in ophthalmic surgery.

The Company is subject to risks common to companies in the biotechnology and medical device industries including, but not limited to, development by the Company or its competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, commercialization of existing and new products, and compliance with FDA government regulations and approval requirements as well as the ability to grow the Company s business.

## 2. Basis of Presentation

The accompanying consolidated financial statements have been prepared by the Company without audit, pursuant to the rules and regulations of the Securities and Exchange Commission and in accordance with accounting principles generally accepted in the United States. In the opinion of management, these consolidated financial statements contain all adjustments (consisting only of normal recurring adjustments) necessary to fairly state the financial position of the Company as of June 30, 2003 and the results of its operations for the quarter and six months ended June 30, 2003 and 2002 and its cash flows for the six months ended June 30, 2003 and 2002.

The accompanying consolidated financial statements and related notes should be read in conjunction with the Company s annual financial statements filed with the Annual Report on Form 10-K for the year ended December 31, 2002. The results of operations for the quarter and six months ended June 30, 2003 are not necessarily indicative of the results to be expected for the year ending December 31, 2003 or any future periods. See Risk Factors and Certain Factors Affecting Future Operating Results.

## 3. Summary of Significant Accounting Policies

***Use of Estimates***

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

*Principles of Consolidation*

The accompanying consolidated financial statements include the accounts of Anika Therapeutics, Inc. and its wholly owned subsidiary, Anika Securities, Inc. All intercompany transactions and balances have been eliminated in consolidation.

*Cash and Cash Equivalents*

Cash and cash equivalents consists of cash and highly liquid investments with original maturities of 90 days or less.

*Marketable Securities*

The Company follows the provisions of Statement of Financial Accounting Standards ( SFAS ) No. 115, Accounting for Certain Investments in Debt and Equity Securities . Marketable securities consists of municipal bonds and commercial paper with initial maturities of twelve months or less from the date of issuance. The Company has the positive intent and ability to hold these marketable securities to maturity and, accordingly, classifies these marketable securities as held-to-maturity. Marketable securities are carried at amortized cost.

The Company has no marketable securities at June 30, 2003. At December 31, 2002 marketable securities classified as hold-to-maturity consists of the following:

| | Amortized Cost | Gross Unrealized Holding Gains | Fair Value |
|---|---|---|---|
| | | | |
| Municipal bond (due in one year or less) | $ 2,500,000 | $ 2,000 | $ 2,502,000 |

***Revenue Recognition***

Product revenue is recognized upon confirmation of regulatory compliance and shipment to the customer as long as there is (1) persuasive evidence of an arrangement, (2) delivery has occurred and risk of loss has passed, (3) the sales price is fixed or determinable and (4) collection of the related receivable is probable. Amounts billed or collected prior to recognition of revenue are classified as deferred revenue. When determining whether risk of loss has transferred to customers on product sales or if the sales price is fixed or determinable the Company evaluates both the contractual terms and conditions of its distribution and supply agreements as well as its business practices. Under our agreement with Bausch and Lomb, the price for units sold in a calendar year is dependent on total unit volume of sales of certain ophthalmic products to all of our customers during the year. Accordingly, unit prices for sales occurring in interim quarters are subject to possible retroactive price adjustments when the actual annual unit volume for the year becomes known. In accordance with the Company s revenue recognition policy, the amount of revenue subject to the potential contracted price adjustment is recorded as deferred revenue until the annual unit volume becomes known and the sales price becomes fixed. ORTHOVISC has been sold through several distribution arrangements as well as outsource order-processing arrangements ( logistic agents ). Sales of product through third party logistics agents in certain markets are recognized as revenue upon shipment by the logistics agent to the customer. The Company recognizes non-refundable upfront or milestone payments received as part of supply, distribution, and marketing arrangements, ratably over the terms of the arrangements to which the payments apply.

***Stock-Based Compensation***

SFAS No. 123, Accounting for Stock-Based Compensation, requires that companies either recognize compensation expense for grants of stock options and other equity instruments based on fair value, or provide pro forma disclosure of net income (loss) and net income (loss) per share in the notes to the financial statements. At June 30, 2003, the Company had stock options outstanding pursuant to three stock-based compensation plans. The Company accounts for the awards granted pursuant to the plans under

the recognition and measurement principles of Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees, and related interpretations. Accordingly, no compensation cost has been recognized under SFAS 123 for the awards granted under the Company s employee stock option plans. Had compensation cost for the awards under those plans been determined based on the grant date fair values, consistent with the method required under SFAS 123, the Company s net loss and net loss per share would have been increased to the pro forma amounts indicated below:

| | Quarter Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | **2003** | **2002** | **2003** | **2002** |
| Net loss | | | | |
| As reported | $ (81,000) | $ (1,157,000) | $ (394,000) | $ (2,961,000) |
| Deduct: Total stock-based employee compensation under the fair-value-based method for all awards | (26,000) | (158,000) | (198,000) | (278,000) |
| Pro forma net loss | $ (107,000) | $ (1,315,000) | $ (592,000) | $ (3,239,000) |
| Basic and diluted net loss per share | | | | |
| As reported | $ (0.01) | $ (0.12) | $ (0.04) | $ (0.30) |
| Proforma | $ (0.01) | $ (0.13) | $ (0.06) | $ (0.33) |

***Comprehensive Income***

SFAS No. 130, Reporting Comprehensive Income establishes standards for reporting and display of comprehensive income and its components in the financial statements. Comprehensive income is the total of net income and all other non-owner changes in equity including such items as unrealized holding gains/losses on securities, foreign currency translation adjustments and minimum pension liability adjustments. The Company had no such other items of comprehensive income (loss) for the quarter and six months ended June 30, 2003 and 2002 and as a result, comprehensive income (loss) is the same as reported net income (loss) for all periods presented.

***Disclosures About Segments of an Enterprise and Related Information***

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision maker, or decision-making group, in making decisions regarding how to allocate resources and assess performance. The Company s chief decision-making group consists of the chief executive officer, the chief financial officer and other officers of the Company. Based on the criteria established by SFAS No. 131, Disclosures about Segments of an Enterprise and Related Information , the Company has one reportable operating segment, the results of which are disclosed in the accompanying consolidated financial statements. Substantially all of the operations and assets of the Company have been derived from and are located in the United States.

Revenues by geographic location in total and as a percentage of total revenues are as follows for the quarter and six months ended June 30, 2003 and 2002, respectively:

| | Quarter Ended June 30, | | | |
|---|---|---|---|---|
| | 2003 | | 2002 | |
| | Revenue | Percent of Revenue | Revenue | Percent of Revenue |
| United States | $ 2,488,000 | 75.0% | $ 2,688,000 | 78.6% |
| Europe/Other | 830,000 | 25.0 | 733,000 | 21.4 |
| Total | $ 3,318,000 | 100.0% | $ 3,421,000 | 100.0% |

| | Six Months Ended June 30, | | | |
|---|---|---|---|---|
| | 2003 | | 2002 | |
| | Revenue | Percent of Revenue | Revenue | Percent of Revenue |
| United States | $ 5,342,000 | 79.7% | $ 4,551,000 | 78.3% |
| Europe/Other | 1,360,000 | 20.3 | 1,260,000 | 21.7 |
| Total | $ 6,702,000 | 100.0% | $ 5,811,000 | 100.0% |

Product revenue by significant customers as a percent of total revenues is as follows:

| | Quarter Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2003 | 2002 | 2003 | 2002 |
| Bausch & Lomb | 49.9% | 42.2% | 43.8% | 47.1% |
| Boehringer Ingelheim | 8.1% | 16.6% | 16.9% | 15.1% |
| Advanced Medical Optics | 14.4% | 4.7% | 14.9% | 2.8% |
| Pharmaren AG | 17.7% | 11.6% | 14.9% | 8.9% |
| | 90.1% | 75.1% | 90.5% | 73.9% |

## 4. Earnings Per Share

The Company reports earnings per share in accordance with SFAS No. 128, Earnings per Share , which establishes standards for computing and presenting earnings (loss) per share. Basic earnings per share is computed by dividing net income (loss) by the weighted average number of common shares outstanding during the period. Diluted earnings per share is computed by dividing net income (loss) by the weighted average number of common shares outstanding and the number of dilutive potential common share equivalents during the period. Under the treasury stock method, unexercised in-the-money stock options are assumed to be exercised at the beginning of the period or at issuance, if later. The assumed proceeds are then used to purchase common shares at the average market price during the period. For periods where the Company has incurred a loss, dilutive net loss per share is equal to basic net loss per share. Accordingly, outstanding options of 324,086 and 126,875, at June 30, 2003 and 2002, respectively, are excluded from the calculation of diluted weighted average shares outstanding because to include them would have been antidilutive for those periods presented.

## 5. Inventories

Inventories consist of the following:

| | June 30, 2003 | December 31, 2002 |
|---|---|---|
| Raw materials | $ 1,221,000 | $ 1,239,000 |
| Work-in-process | 1,362,000 | 1,354,000 |
| Finished goods | 645,000 | 331,000 |
| Total | $ 3,228,000 | $ 2,924,000 |

Inventories are stated at the lower of cost or market, with cost being determined using the first-in, first-out (FIFO) method. Work-in-process and finished goods inventories include materials, labor, and manufacturing overhead.

## 6. Notes Receivable from Officers

Notes receivable from officers of $59,000 at June 30, 2003 and December 31, 2002, consists of a loan made to one officer. The note receivable from the officer accrues interest at 6.22%. The note receivable was repaid in July 2003.

## 7. Licensing and Distribution Agreements

In July 2000, the Company entered into a seven-year supply agreement (the B&L Agreement ) with Bausch & Lomb Surgical, a unit of Bausch & Lomb, which was subsequently merged into Bausch & Lomb Incorporated. Under the terms of the B&L Agreement the price for units sold in a calendar year is dependent on total unit volume of sales of certain ophthalmic products to all customers during the year. Accordingly, unit prices for sales occurring in interim quarters are subject to possible retroactive price adjustments when the actual annual unit volume for the year becomes known. In accordance with the Company s revenue recognition policy, the amount of revenue subject to the price adjustment is recorded as deferred revenue until the annual unit volume becomes known and the sales price becomes fixed. At June 30, 2003 and 2002, the deferred revenue under the B&L Agreement amounted to approximately $645,000 and $488,000, respectively.

## 8. Legal Matters

*Securities and Exchange Commission Investigation.* In May 2000, the Securities and Exchange Commission (SEC) issued a formal order of investigation in connection with certain revenue recognition matters. On January 13, 2003 the Company announced that it had entered into a settlement with the SEC concluding and resolving this investigation, which pertained to the company s historical accounting for and disclosures concerning sales of ORTHOVISC under a long-term supply and distribution agreement with Zimmer, Inc. To conclude this matter, the Company consented to the entry of an order to comply with sections 13(a), 13(b)(2)(A) and 13(b)(2)(B) of the Securities Exchange Act of 1934 and rules 12b-20, 13a-1 and 13a-13 promulgated thereunder. The settlement did not impose any monetary sanctions against the Company, and it is not expected to affect its results of operations or financial condition. The Company neither admitted nor denied the findings in the SEC s administrative cease and desist order resolving the matter.

## 9. Guarantor Arrangements

In November of 2002, the FASB issued FIN No 45 Guarantor s Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others an interpretation of FASB Statements No. 5, 57 and 107 and rescission of FASB Interpretation No. 34. The Interpretation requires that a guarantor recognize, at the inception of a guarantee, a liability for the fair value of the obligation undertaken by the issuing the guarantee. The interpretation also requires additional disclosures to be made by a guarantor in its interim and annual financial statements about its obligations under certain guarantees it has issued. The accounting requirements for the initial recognition of guarantees are applicable on prospective basis for guarantees issued or modified after December 31,2002. The disclosure requirements are effective for all guarantees outstanding, regardless of when they were issued or modified, during the first quarter of fiscal 2003. The adoption of FIN No. 45 did not have a material effect consolidated financial statements of the Company. The following is a summary of agreements that the Company has determined are within the scope of FIN No. 45.

As permitted under Massachusetts law, the Company s Amended and Restated Certificate of Incorporation provides that the Company will indemnify its officers and Directors for certain claims asserted against them in connection with their service as an officer or Director of the Company. No indemnification shall be provided, however, for any person with respect to any matter as to which such person shall have be adjudicated in any proceeding not to have acted in good faith in the reasonable belief that his action was in the best interest of the Company. Such indemnification may include payment by the Company of expenses incurred in defending a civil or criminal action or proceeding in advance of the final disposition of such action or proceeding, including person to be indemnified that are no longer officers or directors of the Company, upon receipt of an undertaking by the person indemnified to repay such payment if such person shall be adjudicated to be not entitled to indemnification. The maximum potential amount of future payments that the Company could be required to make under these indemnification provisions is unlimited. However, the Company has purchased certain Directors and

Officers insurance policies that reduce its monetary exposure and enable it to recover a portion of any future amounts paid. As a result of the Company s insurance coverage, the Company believes the estimated fair value of these indemnification arrangements is minimal.

## 10. New Accounting Pronouncements

In January 2003, the FASB issued FIN No. 46, Consolidation of Variable Interest Entities, an Interpretation of ARB 51. The primary objectives of FIN No. 46 are to provide guidance on the identification of entities for which control is achieved through means other than through voting rights (variable interest entities or VIEs) and how to determine when and which business enterprise should consolidate the VIE. This new model for consolidation applies to an entity for which either: (a) the equity investors (if any) do not have a controlling financial interest; or (b) the equity investment at risk is insufficient to finance that entity s activities without receiving additional subordinated financial support from other parties. In addition, FIN No. 46 requires that both the primary beneficiary and all other enterprises with a significant variable interest in a VIE make additional disclosures. The Company does not maintain any VIEs.

In May 2003, the FASB issued SFAS 150, Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity. SFAS 150 establishes standards for how an issuer classifies and measures certain financial instruments with characteristics of both liabilities and equity. It requires that an issuer classify a financial instrument that is within its scope as a liability (or an asset in some circumstances). Many of those instruments were previously classified as equity. This Statement is effective for financial instruments entered into or modified after May 31, 2003, and otherwise is effective at the beginning of the first interim period beginning after June 15, 2003. The adoption of SFAS 150 is not expected to have a material effect on the Company s financial statements.

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

*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, including statements regarding:*

our future sales and product revenues, including possible retroactive price adjustments, anticipated adjustments to deferred revenue, expectations regarding unit volumes or other offsets to price reductions;

our efforts to increase sales of ophthalmic viscoelastic products;

our manufacturing capacity and work-in-process manufacturing;

the timing, scope, and rates of patient enrollment in clinical trials and related costs;

FDA or other regulatory approvals and/or reimbursement approvals of new or potential products;

the development of possible new products;

negotiations with potential and existing customers, including our performance under any of our distribution or supply agreements or our expectations with respect to sales pursuant such agreements;

the rate at which we use cash and the amounts used;

possible negotiations or renegotiations with existing or new distribution and collaboration partners.

*Statements identified by words such as will, likely, may, believe, expect, anticipate, intend, seek, designed, develop, would, future, can, could and other expressions that are predictions of or indicate future events and trends and which do not relate to historical matters, also identify forward-looking statements. Such forward looking statements involve known and unknown risks, uncertainties and other factors, some of which are beyond our control, including those factors described in the section titled Risk Factors and Certain Factors Affecting Future Operating Results in this Quarterly Report on Form 10-Q. Our actual results, performance or achievement could differ materially from anticipated results, performance or achievement, expressed or implied in such forward-looking statements. Such forward looking statements are based upon the current assumptions and beliefs of management and are only expectations of future results. Additional factors that might cause such a difference are set forth herein and in the Management s Discussions and Analysis of Financial Condition and Results of Operations beginning on page 11 of this Quarterly Report on form 10-Q, as well as the risk factors described in our Annual Report on Form 10-K for the year ended December 31, 2002 and in our press releases and other filings with the Securities and Exchange Commission. We undertake no obligation to publicly update or revise any forward-looking statement whether as a result of new information, future events or otherwise.*

***Restatement of Results on January 28, 2003***

On January 28, 2003, we announced a restatement of our previously-reported results for the three- and nine-month periods ended September 30, 2002. The restatement involved revenue recognized for the sale in the third quarter of 2002 of certain units of HYVISC®. A new clean room at our facility that at the time did not have a required regulatory approval for the manufacture of HYVISC from the Food and Drug Administration (FDA) was used in the production of these units. Because the product was shipped in the absence of this regulatory approval, we determined, and our independent accountants concurred, that revenue from that sale should not have been recognized. As a result of the restatement, revenue for the three and nine months ended September 30, 2002 was reduced by $326,000 and the net loss for those periods increased by $170,000, or $0.02 per share. Total HYVISC

inventory at September 30, 2002, was $173,000, which included $157,000 in HYVISC inventory from the restated transaction, and $17,000 in HYVISC

inventory produced in the new clean room which was previously included in our pre-restatement inventory. Included in our inventory at December 31, 2002 was $293,000 in HYVISC inventory produced in the new clean room.

In June 2003, we received regulatory approval to use the new clean room for the manufacture of HYVISC. In addition, we received regulatory approval for the re-release of the HYVISC inventory manufactured using the new clean room prior to receipt of the regulatory approval. The re-release of the HYVISC inventory was subject to certain conditions, including testing of the material and maintenance of certain records, which conditions were met. In June we began shipping the re-released HYVISC inventory. At June 30, 2003, $196,000 of the re-released HYVISC inventory remained in our total inventory valued at $3,228,000.

We had previously obtained all required regulatory approvals for the use of the new clean room in the manufacture of our products designed for human use: ORTHOVISC® (not approved for sale in the U.S.), AMVISC®, AMVISC® Plus, STAARVISC -II, Shellgel , and CoEase .

***Results of Operations***

*Product revenue.* Product revenue for the quarter ended June 30, 2003 was $3,303,000, a decrease of $113,000, or 3.3%, compared to $3,416,000 for the quarter ended June 30, 2002. Product revenue for the six months ended June 30, 2003 was $6,673,000, an increase of $872,000, or 15%, compared to $5,801,000 for the six months ended June 30, 2002. We derive a substantial portion of our revenue from the sale of AMVISC and AMVISC Plus to Bausch & Lomb Surgical. For the quarter ended June 30, 2003 and 2002, AMVISC product sales accounted for 49.9% and 42.2% of product revenue, respectively. For the six months ended June 30, 2003 and 2002, AMVISC product sales accounted for 43.8% and 47.1% of product revenue, respectively.

| | Quarter ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2003 | 2002 | 2003 | 2002 |
| Ophthalmic Products | $ 2,203,000 | $ 2,115,000 | $ 4,178,000 | $ 3,664,000 |
| ORTHOVISC® | 831,000 | 732,000 | 1,361,000 | 1,259,000 |
| HYVISC® | 269,000 | 569,000 | 1,134,000 | 878,000 |
| | $ 3,303,000 | $ 3,416,000 | $ 6,673,000 | $ 5,801,000 |

Ophthalmic product sales increased $88,000 and $514,000 for the quarter and six months ended June 30, 2003, respectively, compared to the same periods last year. The increases are attributable to higher sales to Bausch & Lomb combined with a new distributor added during the second quarter of 2002. ORTHOVISC sales increased $99,000 and $102,000 for the quarter and six months ended June 30, 2003 compared to the same periods last year primarily due to increased sales to our Turkish distributor offset principally by lower sales in Europe. Sales of HYVISC decreased $300,000 for the second quarter of 2003 compared to the second quarter of 2002. Sales of HYVISC increased $256,000 for the six months ended June 30, 2003 compared to the same period last year. Sales of HYVISC were made to a single customer under an exclusive agreement. The decrease in sales of HYVISC for the second quarter of 2003 are attributable to the timing of orders from our customer with higher shipments in the first quarter of 2003 compared to the first quarter of 2002 based on our customer s orders and higher shipments in the second quarter of 2002 compared to second quarter of 2003 based on our customer s orders. The increase in sales of HYVISC for the six months ended June 30, 2003 includes additional shipments made during the first quarter to replace units shipped in the third quarter of 2002 which units we had subsequently voluntarily withdrawn from the market pending receipt of regulatory approval. See the section captioned Restatement of Results on January 28 discussed above. Sales of HYVISC are expected to be lower for the remainder of 2003 compared to the first six months as a result of the additional units shipped during the first quarter of 2003 for distributor inventory replenishment necessary because of the withdrawal of the previously shipped units.

*Licensing revenue.* Licensing revenue for the quarter ended June 30, 2003 was $15,000, an increase of $10,000 compared to $5,000 for the same period last year. Licensing revenue for the six months ended June 30, 2003 was $29,000 an increase of $19,000 compared to $10,000 for the same period last year. Licensing revenue includes the ratable recognition of up-front and maintenance payments on certain supply agreements with distributors of our ophthalmic products over the related terms of the applicable agreements.

*Gross profit*. Gross profit for the quarter ended June 30, 2003 was $1,472,000, or 44.4% of revenue, an increase of $253,000, or 20.8%, from gross profit of $1,219,000, or 35.6% of revenue, for the quarter ended June 30, 2002. Gross profit for the six months ended June 30, 2003 was $2,887,000, or 43.1% of revenue, an increase of $1,365,000, or 89.7%, from gross profit of $1,522,000, or 26.2% of revenue, for the six months ended June 30, 2002. Gross profit for the quarter and six months ended June 30, 2003, as compared with same periods last year, benefited from improved manufacturing cost performance as a result of expense control and process improvement initiatives during 2002 combined with overall increased sales volumes and resulting manufacturing efficiencies.

*Research & development*. Research and development expenses for the quarter ended June 30, 2003 was $648,000, a decrease of $402,000, or 38.3%, compared to $1,050,000 for the quarter ended June 30, 2002. Research and development expenses for the six months ended June 30, 2003 was $1,457,000, a decrease of $683,000, or 31.9%, compared to $2,140,000 for the six months ended June 30, 2002. Research and development expenses include those costs associated with our in-house research and development efforts for the development of new medical applications for our HA-based technology, the management of clinical trials, and the preparation and processing of applications for regulatory approvals at all relevant stages of development. The decrease in research and development expenses during the quarter and six months ended June 30, 2003 is primarily attributable to a decrease in costs associated with the completion of our Phase III clinical trial for ORTHOVISC of $394,000 and $708,000, respectively. In late May 2003 we completed compilation of the clinical data and submitted a PMA application to the FDA as a requirement for seeking U.S. market approval.

*Selling, general & administrative*. Selling, general and administrative expenses for the quarter ended June 30, 2003 was $945,000, a decrease of $443,000, or 31.9%, compared to $1,388,000 for the same period last year. The decrease is attributable to a decrease in professional service fees of $316,000 primarily due to lower legal costs and a decrease in personnel-related costs of $143,000. Selling, general and administrative expenses for the six months ended June 30, 2003 was $2,060,000, a decrease of $408,000, or 16.5%, compared to $2,468,000 for the same period last year. The decrease is attributable to a decrease in professional service fees of $140,000 primarily attributable to lower legal costs, a decrease in personnel-related costs of $115,000, and a decrease in other outside services of $149,000.

*Interest income*. Interest income for the quarter ended June 30, 2003 was $40,000, a decrease of $22,000 from $62,000 for the same period last year. Interest income for the six months ended June 30, 2003 was $82,000, a decrease of $43,000 from $125,000 for the same period last year. The decreases for the quarter and six months are primarily attributable to lower interest rates.

*Income taxes.* In 2002 federal tax law changed to allow for a five year carryback period and a suspension of certain limitations on the use of alternative minimum tax losses. We filed an income tax carryback claim to carry our 2001 tax loss back to prior tax years. As a result of the carryback claim, in the first quarter of 2003, we received a refund of approximately $154,000 of taxes paid in prior years.

**LIQUIDITY AND CAPITAL RESOURCES**

We require cash to fund our operating expenses and to make capital expenditures. We expect that our requirement for cash to fund these uses will increase as the scope of our operations expand. Historically we have funded our cash requirements from available cash

and investments on hand. At June 30, 2003, cash, cash equivalents and marketable securities totaled $11.5 million compared to cash, cash equivalents

and marketable securities of $13.5 million at December 31, 2002.

Cash used in operating activities was $1,925,000 for the six months ended June 30, 2003 compared with cash used in operating activities of $1,119,000 for the six months ended June 30, 2002. Cash used in operating activities in the first six months of 2003 resulted primarily from our net loss of $394,000, increases in accounts receivable of $907,000 and inventories of $304,000 and decreases in customer deposit of $327,000 and other current liabilities of $1,139,000 and was partially offset by depreciation and amortization of $496,000 and an increase in deferred revenue of $579,000. The increase in deferred revenue largely relates to unit pricing provisions under our supply agreement with Bausch & Lomb Surgical. The increase in accounts receivable was primarily due to increased sales combined with the timing of collecting on certain payments from a customer which amounts were subsequently collected. The increase in inventories includes the remaining re-released HYVISC inventory that was not sold combined with an increase in finished goods. The customer deposit of $327,000 related to the payment from a customer for a sale in the third quarter of 2002 of certain units of HYVISC which was applied to new shipments of product during the first quarter of 2003. In connection with our restatement of results for the three- and nine-month periods ended September 30, 2002, we determined that revenue from a certain third quarter 2002 sale should not have been recognized and as of December 31, 2002 recorded the payment related to the sale as a customer deposit to be applied against subsequent shipments to the customer. See the section captioned Restatement of Results on January 28, 2003 discussed above.

Cash provided by investing activities was $2,367,000 for the six months ended June 30, 2003 reflecting proceeds from the maturity of marketable securities partially offset by capital expenditures of $133,000 primarily for manufacturing equipment. Cash used in investing activities of $468,000 for the six months ended June 30, 2002, primarily reflects the purchase of marketable securities, net of proceeds from the maturity of marketable securities, and capital expenditures of $42,000 primarily for manufacturing equipment, partially offset by the repayment of a note receivable from officer for $75,000.

Under the terms of our agreement with Bausch & Lomb, the price for units sold in a calendar year is dependent on the total unit volume of sales of certain ophthalmic products during the year. In accordance with our revenue recognition policy, revenue is not recognized if the sale price is not fixed or determinable, and any amounts received in excess of revenue recognized is recorded as deferred revenue. During the fourth quarter the actual annual unit volume becomes fixed or determinable. In the fourth quarter of 2002 we recognized $839,000 of deferred revenue related to sales to Bausch & Lomb during the first three quarters of 2002. For the six months ended June 30, 2003, we have deferred revenue of $645,000 related to sales to Bausch & Lomb which are subject to possible retroactive price adjustments when actual unit volume for the year becomes known. If the total unit volume of sales of certain ophthalmic products for the year meets or exceeds levels fixed under our agreement with Bausch & Lomb we will be required to rebate to Bausch & Lomb, in the form of a cash payment, the amount deferred during the year.

*Contractual Obligations and Other Commercial Commitments*

We do not use special purpose entities or other off-balance sheet financing techniques except for operating leases. We have no material commitments for purchases of inventories or property and equipment. We expect to incur additional investments in our operations through increased inventory levels and higher balances in accounts receivable for the remainder of 2003 compared to 2002 in addition to further capital expenditures in 2003 for small equipment, computers and software, and furniture and fixtures associated with our business operations. To the extent that funds generated from our operations, together with our existing capital resources, are insufficient to meet future requirements, we will be required to obtain additional funds through equity or debt financings, strategic alliances with corporate partners and others, or through other sources. Any additional financing may not be made available to us or may not be available on acceptable terms should such a need arise.

Our future capital requirements and the adequacy of available funds will depend, on numerous

factors, including:

- market acceptance of our existing and future products;
- the successful commercialization of products in development;
- progress in our product development efforts;
- the magnitude and scope of such efforts;
- progress with pre-clinical studies, clinical trials and product clearances by the FDA and other agencies;
- the cost of maintaining adequate manufacturing capabilities;
- the cost of filing, prosecuting, defending and enforcing patent claims and other intellectual property rights;
- competing technological and market developments;
- the development of strategic alliances for the marketing of certain of our products; and
- the cost of maintaining adequate inventory levels to meet current and future product demands.

We cannot assure you that we will record profits in future periods. However, we believe that our cash and investments on hand will be sufficient to meet our cash requirements through at least the next twelve months. See the section captioned *Risk Factors and Certain Other Factors Affecting Future Operating Results History of Losses; Uncertainty of Future Profitability.*

The terms of any future equity financings may be dilutive to our stockholders and the terms of any debt financings may contain restrictive covenants, which could limit our ability to pursue certain courses of action. Our ability to obtain financing is dependent on the status of our future business prospects as well as conditions prevailing in the relevant capital markets. We cannot assure you that any additional financing may be made available to us or may be available on acceptable terms should such a need arise.

The table below summarizes our contractual obligations of non-cancelable operating leases at June 30, 2003:

| | Amount |
|---|---|
| 2003 | $ 326,000 |
| 2004 | 99,000 |
| 2005 | 3,000 |
| Total | $ 428,000 |

**New Accounting Pronouncements**

In January 2003, the FASB issued FIN No. 46, Consolidation of Variable Interest Entities, an Interpretation of ARB 51. The primary objectives of FIN No. 46 are to provide guidance on the identification of entities for which control is achieved through means other than through voting rights ( variable interest entities or VIEs ) and how to determine when and which business enterprise should consolidate the VIE. This new model for consolidation applies to an entity for which either: (a) the equity investors (if any) do not have a controlling financial interest; or (b) the equity investment at risk is insufficient to finance that entity s activities without receiving additional subordinated financial support from other parties. In addition, FIN No. 46 requires that both the primary beneficiary and all other enterprises with a significant variable interest in a VIE make additional disclosures. We do not maintain any VIEs.

In May 2003, the FASB issued SFAS 150, Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity. SFAS 150 establishes standards for how an issuer classifies and measures certain financial instruments with characteristics of both liabilities and equity. It requires that an issuer classify a financial instrument that is within its scope as a liability (or an asset in some circumstances). Many of those instruments were previously classified as equity. This Statement is effective for financial instruments entered into or modified after May 31, 2003, and otherwise is effective at the beginning of the first interim period beginning after June 15, 2003. The adoption of SFAS 150 is not

expected to have a material effect on our financial statements.

**RISK FACTORS AND CERTAIN FACTORS AFFECTING FUTURE OPERATING RESULTS**

***Our business is subject to comprehensive and varied government regulation and, as a result, failure to obtain FDA or other governmental approvals for our products may materially adversely affect our business, results of operations and financial condition.***

Product development and approval within the FDA framework takes a number of years and involves the expenditure of substantial resources. We cannot assure you that the FDA will grant approval for our new products on a timely basis if at all, or that FDA review will not involve delays that will adversely affect our ability to commercialize additional products or expand permitted uses of existing products, or that the regulatory framework will not change, or that additional regulation will not arise at any stage of our product development process which may adversely affect approval of or delay an application or require additional expenditures by us. In the event our future products are regulated as human drugs or biologics, the FDA s review process of such products typically would be substantially longer and more expensive than the review process to which they are currently subject as devices.

In order to sell ORTHOVISC in the U.S., we will have to meet regulatory requirements for a Class III device as determined by the FDA. Class III devices are those that generally must receive pre-market approval from the FDA (e.g. life-sustaining, life-supporting and implantable or new devices which have not been found to be substantially equivalent to legally marketed devices) and require clinical testing to ensure safety and effectiveness and FDA approval prior to marketing and distribution. In order for us to commercially distribute ORTHOVISC in the U.S., we must obtain a Pre-Market Approval (PMA). The PMA process can be expensive, uncertain and lengthy. A number of devices for which PMAs have been sought have never been approved for marketing. The review of an application often occurs over a protracted time period, potentially taking two years or more from the filing date to complete. We submitted a PMA application for ORTHOVISC in December 1997. In October 1998, we were notified by the FDA that our PMA application for ORTHOVISC was not approvable and that additional clinical data would be required to demonstrate the effectiveness of ORTHOVISC. We submitted an Investigational Device Exemption (IDE) to the FDA in February 1999 and received approval in late March 1999 to commence a second Phase III clinical study. We received initial results from the Phase III clinical trial in late May 2000 that we determined did not show sufficient efficacy to support the filing of a PMA application. In February 2001, we commenced another Phase III clinical trial of ORTHOVISC. We completed patient enrollment in May 2002, which included 373 patients in 24 centers in the U.S. and Canada and, in accordance with trial protocol, took six months to complete the follow-up on the final patients. All of the patients completed the study in 2002. We compiled the data and submitted a PMA application to the FDA in late May 2003 as a requirement for seeking U.S. market approval. We cannot assure you that:

- any additional clinical data will support the efficacy of ORTHOVISC;
- we will complete any additional required clinical trials of ORTHOVISC;
- we will be able to successfully complete the FDA approval process;
- additional required clinical trials will support a PMA application and/or FDA approval in a timely manner or at all.

We also cannot assure you that any delay in receiving FDA approvals will not continue to adversely affect our competitive position. Furthermore, even if we were to receive a PMA approval:

the approval may include significant limitations on the indications and other claims sought for use for which the product may be marketed;

the approval may include other significant conditions to approval such as post-market testing, tracking, or surveillance requirements;

we may not be able to achieve meaningful sales of ORTHOVISC in the U.S.

Our HA products under development, including a product for cosmetic tissue augmentation and INCERT®, a product designed to prevent surgical adhesions, have not obtained regulatory approval in the U.S. for commercial marketing and sale. We believe that these products will be regulated as Class III medical devices and will require a PMA prior to marketing. We cannot assure you that:

- we will begin or successfully complete clinical trials for these products;
- the clinical data will support the efficacy of these products;
- we will be able to successfully complete the FDA approval process;
- additional clinical trials will support a PMA application and/or FDA approval in a timely manner or at all.

We also cannot assure you that any delay in receiving FDA approvals will not adversely affect our competitive position. Furthermore, even if we do receive FDA approval:

- the approval may include significant limitations on the indications and other claims sought for use for which the products may be marketed;
- the approval may include other significant conditions of approval such as post-market testing, tracking, or surveillance requirements;
- meaningful sales may never be achieved.

Once obtained, marketing approval can be withdrawn by the FDA for a number of reasons, including, among other things, the failure to comply with regulatory standards, or the occurrence of unforeseen problems following initial approval. We may be required to make further filings with the FDA under certain circumstances. The FDA s regulations require a PMA supplement for certain changes if they affect the safety and effectiveness of an approved device, including, but not limited to, new indications for use, labeling changes, the use of a different facility to manufacture, process or package the device, and changes in performance or design specifications. Changes in manufacturing procedures or methods of manufacturing that may affect safety and effectiveness may be deemed approved after a 30-day notice unless the FDA requests a 135-day supplement. Our failure to receive approval of a PMA supplement regarding the use of a different manufacturing facility or any other change affecting the safety or effectiveness of an approved device on a timely basis, or at all, may have a material adverse effect on our business, financial condition, and results of operations. The FDA could also limit or prevent the manufacture or distribution of our products and has the power to require the recall of such products. Significant delay or cost in obtaining, or failure to obtain FDA approval to market products, any FDA limitations on the use of our products, or any withdrawal or suspension of approval or rescission of approval by the FDA could have a material adverse effect on our business, financial condition, and results of operations.

In addition, all FDA approved or cleared products manufactured by us must be manufactured in compliance with the FDA s Good Manufacturing Practices (GMP) regulations and, for medical devices, the FDA s Quality System Regulations (QSR). Ongoing compliance with QSR and other applicable regulatory requirements is enforced through periodic inspection by state and federal agencies, including the FDA. The FDA may inspect us and our facilities from time to time to determine whether we are in compliance with regulations relating to medical device and manufacturing companies, including regulations concerning manufacturing, testing, quality control and product labeling practices. We cannot assure you that we will be able to comply with current or future FDA requirements applicable to the manufacture of products.

FDA regulations depend heavily on administrative interpretation and we cannot assure you that the future interpretations made by the FDA or other regulatory bodies, with possible retroactive effect, will not adversely affect us. In addition, changes in the existing regulations or adoption of new governmental regulations or policies could prevent or delay regulatory approval of our products.

Failure to comply with applicable regulatory requirements could result in, among other things, warning letters, fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of

production, refusal of the FDA to grant pre-market clearance or pre-market approval for devices, withdrawal of approvals and criminal prosecution.

In addition to regulations enforced by the FDA, we are subject to other existing and future federal, state, local and foreign regulations. International regulatory bodies often establish regulations governing product standards, packing requirements, labeling requirements, import restrictions, tariff regulations, duties and tax requirements. We cannot assure you that we will be able to achieve and/or maintain compliance required for Conformité Européenne marking (CE marking) or other foreign regulatory approvals for any or all of our products or that we will be able to produce our products in a timely and profitable manner while complying with applicable requirements. Federal, state, local and foreign regulations regarding the manufacture and sale of medical products are subject to change. We cannot predict what impact, if any, such changes might have on our business.

The process of obtaining approvals from the FDA and other regulatory authorities can be costly, time consuming, and subject to unanticipated delays. We cannot assure you that approvals or clearances of our products will be granted or that we will have the necessary funds to develop certain of our products. Any failure to obtain, or delay in obtaining such approvals or clearances, could adversely affect our ability to market our products.

***We have historically incurred operating losses and we cannot make any assurances about our future profitability.***

From our inception through December 31, 1996 and 1999 through June 30, 2003 we have incurred annual operating losses. As of June 30, 2003, we had an accumulated deficit of approximately $14.8 million. The continued development of our products will require the commitment of substantial resources to conduct research and preclinical and clinical development programs, and to establish sales and marketing capabilities or distribution arrangements. Our ability to reach profitability is highly uncertain. To achieve profitability, we must, among other things, successfully complete development of certain of our products, obtain regulatory approvals and establish sales and marketing capabilities or distribution arrangements for certain of our products.

***Substantial competition could materially affect our financial performance.***

We compete with many companies, including, among others, large pharmaceutical companies and specialized medical products companies. Many of these companies have substantially greater financial and other resources, larger research and development staffs, more extensive marketing and manufacturing organizations and more experience in the regulatory process than us. We also compete with academic institutions, governmental agencies and other research organizations that may be involved in research, development and commercialization of products. Because a number of companies are developing or have developed HA products for similar applications, the successful commercialization of a particular product will depend in part upon our ability to complete clinical studies and obtain FDA marketing and foreign regulatory approvals prior to our competitors, or, if regulatory approval is not obtained prior to competitors, to identify markets for our products that may be sufficient to permit meaningful sales of our products. For example, several of our competitors have already obtained FDA and foreign regulatory approvals for marketing HA products with applications similar to that of ORTHOVISC. Thus, the successful commercialization of ORTHOVISC will depend in part on our ability to effectively market ORTHOVISC against more established products with a longer sales history. We cannot assure you that we will be able to compete against current or future competitors or that competition will not have a material adverse effect on our business, financial condition and results of operations. We are currently experiencing volatility in our international sales of ORTHOVISC including ongoing competitive factors as well as economic issues, and potential regional conflict and political uncertainties. As a result, we are uncertain of the extent of our future sales in these markets.

***We are uncertain regarding the success of our clinical trials.***

Several of our products, including ORTHOVISC, will require clinical trials to determine their safety and efficacy for U.S. and international marketing approval by regulatory bodies, including the FDA. In late May 2000, our initial analysis of the results of our second Phase III clinical trial of ORTHOVISC did not show sufficient efficacy to support the filing of a PMA application to obtain FDA approval. However, our analysis of our third Phase III clinical trial of ORTHOVISC included data we believe is worthy for FDA approval, and accordingly, we filed a PMA submission in late May 2003. We cannot assure you that:

- any additional clinical data will support the efficacy of ORTHOVISC,
- we will begin or complete clinical trials of our HA products under development or complete any additional clinical trials of ORTHOVISC,
- we will be able to successfully complete the FDA approval process for either ORTHOVISC our HA products under development,
- additional ORTHOVISC clinical trials or clinical trials for our HA products under development will support a PMA application and/or FDA approval in a timely manner, or at all.

We cannot assure you that we will not encounter additional problems that will cause us to delay, suspend or terminate the clinical trials. In addition, we cannot make any assurance that such clinical trials, if completed, will ultimately demonstrate these products to be safe and efficacious.

***We are dependent upon marketing and distribution partners and the failure to maintain strategic alliances on acceptable terms will have a material adverse effect on our business, financial condition and results of operations.***

Our success will be dependent, in part, upon the efforts of our marketing partners and the terms and conditions of our relationships with such marketing partners.

We cannot assure you that such marketing partners will not seek to renegotiate their current agreements on terms less favorable to us. Under the terms of the B&L Agreement, effective January 1, 2001, we became Bausch & Lomb s exclusive provider of AMVISC and AMVISC Plus ophthalmic viscoelastic products, in the U.S. and international markets. The B&L Agreement expires December 31, 2007, and superceded an existing supply contract with Bausch & Lomb that was set to expire December 31, 2001. The B&L Agreement is subject to early termination and/or reversion to a non-exclusive basis under certain circumstances. The B&L Agreement lifted contractual restrictions on our ability to sell certain ophthalmic products to other companies, subject to our payment of royalties. In exchange, we agreed to a reduction in unit selling prices retroactively effective to April 1, 2000 and the elimination of minimum unit purchase obligations by Bausch & Lomb.

We have not yet achieved incremental sales of our ophthalmic products to Bausch & Lomb and/or other companies sufficient to offset the effects of the price reduction and royalties to Bausch & Lomb and we cannot assure you that we will be able to do so in the future. The reduction in unit prices resulted in a decrease in our revenue and gross profit from Bausch & Lomb. Under the terms of the B&L Agreement, the price for units sold in a calendar year is dependent on the total unit volume of sales of certain ophthalmic products during the year. Accordingly, unit prices for sales occurring in the six months ended June 30, 2003 are subject to possible retroactive

price adjustments when the actual annual unit volume becomes known. In accordance with our revenue recognition policy, revenue is not recognized if the sale price is not fixed or determinable, and any amounts received in excess of revenue recognized is recorded as deferred revenue. In the fourth quarter of 2002 product revenue included the recognition of $839,000 of revenue related to sales of AMVISC to Bausch & Lomb, which had been previously deferred during the first three quarters of the year. During the fourth quarter the actual annual unit volume becomes fixed or determinable. For the first half of 2003 we have deferred revenue of $645,000 related to sales of AMVISC to Bausch & Lomb. Based on current forecasts of the relevant ophthalmic products provided to us, recognition of this deferred revenue in the fourth quarter of 2003 and consequently expected total revenue from sales to B&L for 2003 is indeterminable. In addition, under certain circumstances, Bausch & Lomb has the right to terminate the agreement, and/or the agreement may revert to a non-exclusive basis; in each case, we cannot make any

assurances that such circumstances will not occur. For the six months ended June 30, 2003 and 2002, sales of AMVISC products to Bausch & Lomb accounted for 43.8% and 47.1% of our overall product revenues, respectively. Although we intend to continue to seek new ophthalmic product customers, there can be no assurances that we will be successful in obtaining new customers or to achieve meaningful sales to such new customers.

We have established marketing and distribution relationships for ORTHOVISC in Canada, Turkey and other Middle-Eastern countries as well as certain European countries. We are continuing to seek to establish long-term distribution relationships in those other regions not currently covered, but can give no assurances that we will be successful in doing so. We filed a PMA submission with the FDA for ORTHOVSIC in late May 2003 and are currently focusing on establishing a relationship with a U.S. distribution or collaboration partner. We cannot assure you that we will be able to identify or engage appropriate partners in the U.S., should we receive marketing approval for ORTHOVISC, or elsewhere in the world or effectively transition to any such partners. We cannot assure you that we will obtain European or other reimbursement approvals or, if such approvals are obtained, they will be obtained on a timely basis or at a satisfactory level of reimbursement.

We will need to obtain the assistance of additional marketing partners to bring new and existing products to market. The failure to establish strategic partnerships for the marketing and distribution of our products on acceptable terms will have a material adverse effect on our business, financial condition, and results of operations.

***Our future success depends upon market acceptance of our existing and future products.***

Our success will depend in part upon the acceptance of our existing and future products by the medical community, hospitals and physicians and other health care providers, and third-party payers. Such acceptance may depend upon the extent to which the medical community perceives our products as safer, more effective or cost-competitive than other similar products. Ultimately, for our new products to gain general market acceptance, it will also be necessary for us to develop marketing partners for the distribution of our products. We cannot assure you that our new products will achieve significant market acceptance on a timely basis, or at all. Failure of some or all of our future products to achieve significant market acceptance could have a material adverse effect on our business, financial condition, and results of operations.

***We may be unable to adequately protect our intellectual property rights.***

Our success will depend, in part, on our ability to obtain and enforce patents, protect trade secrets, obtain licenses to technology owned by third parties when necessary, and conduct our business without infringing on the proprietary rights of others. The patent positions of pharmaceutical, medical products and biotechnology firms, including ours, can be uncertain and involve complex legal and factual questions. We cannot assure you that any patent applications will result in the issuance of patents or, if any patents are issued, whether they will provide significant proprietary protection or commercial advantage, or will not be circumvented by others. In the event a third party has also filed one or more patent applications for any of its inventions, we may have to participate in interference proceedings declared by the United States Patent and Trademark Office (PTO) to determine priority of invention, which could result in failure to obtain, or the loss of, patent protection for the inventions and the loss of any right to use the inventions. Even if the eventual outcome is favorable to us, such interference proceedings could result in substantial cost to us, and diversion of management s attention away from our operations. Filing and prosecution of patent applications, litigation to establish the validity and scope of patents, assertion of patent infringement claims against others and the defense of patent infringement claims by others can be expensive and time consuming. We cannot assure you that in the event that any claims with respect to any of our patents, if issued, are challenged by one or more third parties, that any court or patent authority ruling on such challenge will determine that such patent claims are valid and enforceable. An adverse outcome in such litigation could cause us to lose exclusivity covered by the disputed rights. If a third party is found to have

rights covering products or processes used by us, we could be forced to cease using the technologies or marketing the products covered by such rights, could be subject to significant liabilities to such third party, and could be required to license technologies from such third party. Furthermore, even if our patents are determined to be valid, enforceable, and broad in scope, we cannot assure you that competitors will not be able to design around such patents and compete with us using the resulting alternative technology.

We have a policy of seeking patent protection for patentable aspects of our proprietary technology. We intend to seek patent protection with respect to products and processes developed in the course of our activities when we believe such protection is in our best interest and when the cost of seeking such protection is not inordinate. However, we cannot assure you that any patent application will be filed, that any filed applications will result in issued patents or that any issued patents will provide us with a competitive advantage or will not be successfully challenged by third parties. The protections afforded by patents will depend upon their scope and validity, and others may be able to design around our patents.

Other entities have filed patent applications for or have been issued patents concerning various aspects of HA-related products or processes. We cannot assure you that the products or processes developed by us will not infringe on the patent rights of others in the future. Any such infringement may have a material adverse effect on our business, financial condition, and results of operations. In particular, we received notice from the PTO in 1995 that a third party was attempting to provoke a patent interference with respect to one of our co-owned patents covering the use of INCERT for post-surgical adhesion prevention. It is unclear whether an interference will be declared. If an interference is declared it is not possible at this time to determine the merits of the interference or the effect, if any, the interference will have on our marketing of INCERT for this use. We cannot assure you that we would be successful in any such interference proceeding. If the third-party interference were to be decided adversely to us, involved claims of our patent would be cancelled, our marketing of the INCERT product may be materially and adversely affected and the third party may enforce patent rights against us which could prohibit the sale and use of INCERT products, which could have a material adverse effect on our future operating results.

We also rely upon trade secrets and proprietary know-how for certain non-patented aspects of our technology. To protect such information, we require all employees, consultants and licensees to enter into confidentiality agreements limiting the disclosure and use of such information. We cannot assure you that these agreements provide meaningful protection or that they will not be breached, that we would have adequate remedies for any such breach, or that our trade secrets, proprietary know-how, and our technological advances will not otherwise become known to others. In addition, we cannot assure you that, despite precautions taken by us, others have not and will not obtain access to our proprietary technology. Further, we cannot assure you that third parties will not independently develop substantially equivalent or better technology.

Pursuant to the B&L Agreement, we have agreed to transfer to Bausch & Lomb, upon expiration of the term of the B&L agreement on December 31, 2007, or in connection with earlier termination in certain circumstances, our manufacturing process, know-how and technical information, which relate only to AMVISC products. Upon expiration of the B&L Agreement, we cannot assure you that Bausch & Lomb will continue to use us to manufacture AMVISC and AMVISC Plus. If Bausch & Lomb discontinues the use of us as a manufacturer after such time, our business, financial condition, and results of operations would likely be materially and adversely affected.

***Our manufacturing processes involve inherent risks and disruption could materially adversely affect our business, financial condition and results of operations.***

Our results of operations are dependent upon the continued operation of our manufacturing facility in Woburn, Massachusetts. The operation of biomedical manufacturing plants involves many risks, including the risks of breakdown, failure or substandard performance of equipment, the occurrence of natural and other disasters, and the need to comply with the requirements of directives of government agencies, including the FDA. In addition, we rely on a single supplier for syringes and a small number of

suppliers for a number of other materials required for the manufacturing and delivery of our HA products. Furthermore, our manufacturing processes and research and development efforts involve animals and products derived from animals. We procure our animal-derived raw materials from qualified vendors, control for contamination and have processes that effectively inactivate infectious agents; however, we cannot assure you that we can completely eliminate the risk of transmission of infectious agents and in the future regulatory authorities could impose restrictions on the use of animal-derived raw materials that could impact our business.

The utilization of animals in research and development and product commercialization is subject to increasing focus by animal rights activists. The activities of animal rights groups and other organizations that have protested animal based research and development programs or boycotted the products resulting from such programs could cause an interruption in our manufacturing processes and research and development efforts. The occurrence of material operational problems, including but not limited to the events described above, could have a material adverse effect on our business, financial condition, and results of operations during the period of such operational difficulties.

***Our financial performance depends on the continued growth and demand for our products and we may not be able to successfully manage the expansion of our operations***

Our future success depends on substantial growth in product sales. We cannot assure you that such growth can be achieved or, if achieved, can be sustained. We cannot assure you that even if substantial growth in product sales and the demand for our products is achieved, we will be able to:

- develop the necessary manufacturing capabilities;
- obtain the assistance of additional marketing partners;
- attract, retain and integrate the required key personnel;
- implement the financial, accounting and management systems needed to manage growing demand for our products.

Our failure to successfully manage future growth could have a material adverse effect on our business, financial condition, and results of operations.

***Sales of our products are largely dependent upon third party reimbursement and our performance may be harmed by health care cost containment initiatives.***

In the U.S. and foreign markets, health care providers, such as hospitals and physicians, that purchase health care products, such as our products, generally rely on third party payers, including Medicare, Medicaid and other health insurance and managed care plans, to reimburse all or part of the cost of the health care product. We depend upon the distributors for our products to secure reimbursement and reimbursement approvals. Reimbursement by third party payers may depend on a number of factors, including the payer s determination that the use of our products is clinically useful and cost-effective, medically necessary and not experimental or investigational. Since reimbursement approval is required from each payer individually, seeking such approvals can be a time consuming and costly process which, in the future, could require us or our marketing partners to provide supporting scientific, clinical and cost-effectiveness data for the use of our products to each payer separately. Significant uncertainty exists as to the reimbursement status of newly approved health care products, and third party payers are increasingly attempting to contain the costs of health care products and services by limiting both coverage and the level of reimbursement for new therapeutic products and by refusing in some

cases to provide coverage for uses of approved products for disease indications for which the FDA has not granted marketing approval. In addition, Congress and certain state legislatures have considered reforms that may affect current reimbursement practices, including controls on health care spending through limitations on the growth of Medicare and Medicaid spending. We cannot assure you that third party reimbursement coverage will be available or adequate for any products or services developed by us. Outside the U.S., the success of our products is also dependent in part upon the availability of reimbursement and health care payment systems.

Lack of adequate coverage and reimbursement provided by governments and other third party payers for our products and services could have a material adverse effect on our business, financial condition, and results of operations.

***We may seek financing in the future, which could be difficult to obtain and which could dilute your ownership interest or the value of your shares.***

We had cash, cash equivalents and marketable securities of approximately $11.5 million as of June 30, 2003. Our future capital requirements and the adequacy of available funds will depend, however, on numerous factors, including:

- market acceptance of our existing and future products;
- the successful commercialization of products in development;
- progress in our product development efforts;
- the magnitude and scope of such product development efforts,
- progress with preclinical studies, clinical trials and product clearances by the FDA and other agencies;
- the cost and timing of our efforts to manage our manufacturing capabilities and related costs;
- the cost of filing, prosecuting, defending and enforcing patent claims and other intellectual property rights;
- competing technological and market developments;
- the development of strategic alliances for the marketing of certain of our products; and
- the cost of maintaining adequate inventory levels to meet current and future product demands.

To the extent that funds generated from our operations, together with our existing capital resources are insufficient to meet future requirements, we will be required to obtain additional funds through equity or debt financings, strategic alliances with corporate partners and others, or through other sources. The terms of any future equity financings may be dilutive to you and the terms of any debt financings may contain restrictive covenants, which limit our ability to pursue certain courses of action. Our ability to obtain financing is dependent on the status of our future business prospects as well as conditions prevailing in the relevant capital markets. We cannot assure you that any additional financing will be made available to us or will be available on acceptable terms should such a need arise.

***We could become subject to product liability claims, which, if successful, could materially adversely affect our business, financial condition and results of operations.***

The testing, marketing and sale of human health care products entail an inherent risk of allegations of product liability, and we cannot assure you that substantial product liability claims will not be asserted against us. Although we have not received any material product liability claims to date and have an insurance policy of $5,000,000 per occurrence and $5,000,000 in the aggregate to cover such

claims should they arise, we cannot assure you that material claims will not arise in the future or that our insurance will be adequate to cover all situations. Moreover, we cannot assure you that such insurance, or additional insurance, if required, will be available in the future or, if available, will be available on commercially reasonable terms. Any product liability claim, if successful, could have a material adverse effect on our business, financial condition and results of operations.

***Our business is dependent upon hiring and retaining qualified management and scientific personnel.***

We are highly dependent on the members of our management and scientific staff, the loss of one or more of whom could have a material adverse effect on us. We experienced a number of management changes in 2001 and as of April 2, 2002, Dr. Sherwood, previously President and Chief Operating Officer was appointed our company s Chief Executive Officer. As of July 8, 2002, we appointed a new Chief Financial Officer. As of October 25, 2002, the Senior Vice President of Sales and Marketing s employment with our company was terminated and on March 17, 2003, we appointed a new Vice President of Sales and Marketing. There can be no assurances that such management changes will not adversely affect our

business. In addition, we believe that our future success will depend in large part upon our ability to attract and retain highly skilled, scientific, managerial and manufacturing personnel. We face significant competition for such personnel from other companies, research and academic institutions, government entities and other organizations. We cannot assure you that we will be successful in hiring or retaining the personnel we require. The failure to hire and retain such personnel could have a material adverse effect on our business, financial condition and results of operations.

***We are subject to environmental regulation and any failure to comply with applicable laws could subject us to significant liabilities and harm our business.***

We are subject to a variety of local, state and federal government regulations relating to the storage, discharge, handling, emission, generation, manufacture and disposal of toxic, or other hazardous substances used in the manufacture of our products. Any failure by us to control the use, disposal, removal or storage of hazardous chemicals or toxic substances could subject us to significant liabilities, which could have a material adverse effect on our business, financial condition, and results of operations.

***Our future operating results may be harmed by economic, political and other risks relating to international sales.***

During the years ended December 31, 2002 and 2001, approximately, 18% and 28%, respectively, of our product sales were sold to international distributors. During the six months ended June 30, 2003 and 2002 approximately 20% and 22%, respectively, of our product sales were sold to international distributors. Our representatives, agents and distributors who sell products in international markets are subject to the laws and regulations of the foreign jurisdictions in which they operate and in which our products are sold. A number of risks are inherent in international sales and operations. For example, the volume of international sales may be limited by the imposition of government controls, export license requirements, political and/or economic instability, trade restrictions, changes in tariffs, difficulties in managing international operations, import restrictions and fluctuations in foreign currency exchange rates. We sell our ORTHOVISC product to a European sales and marketing company for supply of the Turkish market. The Turkish economic situation has been volatile and the impacts of this volatility on future sales of ORTHOVISC are uncertain. Such changes in the volume of sales may have a material adverse effect on our business, financial condition, and results of operations.

***Our stock price has been and may remain highly volatile, and we cannot assure you that market making in our common stock will continue.***

The market price of shares of our common stock may be highly volatile. Factors such as announcements of new commercial products or technological innovations by us or our competitors, disclosure of results of clinical testing or regulatory proceedings, governmental regulation and approvals, filings with governmental agencies, developments in patent or other proprietary rights, public concern as to the safety of products developed by us and general market conditions may have a significant effect on the market price of our common stock. In particular, our stock price declined significantly in October 1998 following our announcement that the FDA had notified us that its PMA for ORTHOVISC was not approvable and that additional clinical data would be required to demonstrate the effectiveness of ORTHOVISC. The stock price declined again in May 2000 following our announcements that initial analysis of results from the Phase III clinical trial of ORTHOVISC did not show sufficient efficacy to support the filing of a PMA application to obtain FDA approval, and that the SEC had issued a formal order of investigation and required us to provide information in connection with certain revenue recognition matters. During the past six months, our stock price has increased by as much as 300% in the aggregate with relatively high trading volume. The trading price of our common stock could be subject to wide fluctuations in response to quarter-to-quarter variations in our operating results, material announcements by us or our competitors, governmental regulatory action, conditions in the health care industry generally or in the medical products industry specifically, or other events or factors, many of which are beyond our control. In addition, the stock market has experienced extreme price and volume fluctuations which have particularly

affected the market prices of many medical products companies and which often have been unrelated to the operating performance of such companies. Our operating results in future quarters may be below the expectations of equity research analysts and investors. In such event, the price of our common stock would likely decline, perhaps substantially.

No person is under any obligation to make a market in the common stock or to publish research reports on us, and any person making a market in the common stock or publishing research reports on us may discontinue market making or publishing such reports at any time without notice. We cannot assure you that an active public market in our common stock will be sustained.

***There is a risk that we may be unable to maintain our listing on the Nasdaq National Market.***

Our common stock is currently traded on the Nasdaq National Market. Under NASDAQ s listing maintenance standards, if the minimum bid price of our common stock is under $1.00 per share for 30 consecutive trading days, NASDAQ may choose to notify us that it is delisting our common stock from NASDAQ. If the minimum bid price of our common stock does not thereafter regain compliance for a minimum of 10 consecutive trading days during the 90 days following notification by NASDAQ, our common stock may be delisted from trading on NASDAQ. During periods of the last twelve months our common stock traded at or near $1.00 per share. There is a risk that our common stock will not meet NASDAQ s listing maintenance standards and fail to remain eligible for trading on the NASDAQ. If our common stock is delisted, the delisting would most likely have a material adverse effect on the price of our common stock and your ability to sell any of our common stock at all would be severely limited.

***Our charter documents contain anti-takeover provisions that may prevent or delay an acquisition of us.***

Certain provisions of our Restated Articles of Organization and Amended and Restated By-laws could have the effect of discouraging a third party from pursuing a non-negotiated takeover of us and preventing certain changes in control. These provisions include a classified Board of Directors, advance notice to the Board of Directors of stockholder proposals, limitations on the ability of stockholders to remove directors and to call stockholder meetings, the provision that vacancies on the Board of Directors be filled by a majority of the remaining directors. In addition, the Board of Directors adopted a Shareholders Rights Plan in April 1998. We are also subject to Chapter 110F of the Massachusetts General Laws which, subject to certain exceptions, prohibits a Massachusetts corporation from engaging in any of a broad range of business combinations with any interested stockholder for a period of three years following the date that such stockholder became an interested stockholder. These provisions could discourage a third party from pursuing a takeover of us at a price considered attractive by many stockholders, since such provisions could have the effect of preventing or delaying a potential acquirer from acquiring control of us and its Board of Directors.

***Our revenues are derived from a small number of customers, the loss of which could materially adversely affect our business, financial condition and results of operations.***

We have historically derived the majority of our revenues from a small number of customers, most of whom resell our products to end users and most of whom are significantly larger companies than us. For the year ended December 31, 2002, Bausch & Lomb accounted for 59% of product revenues and 67% of our accounts receivable balance and Pharmaren (an affiliate of Biomeks), our distributor in Turkey, accounted for 10% of product revenues and 0% of our accounts receivable balance. For the six months ended June 30, 2003, four customers accounted for 90.5% of product revenues and 91.4% of our accounts receivable balance. Our failure to generate as much revenue as expected from these customers or the failure of these customers to purchase our products would seriously harm our business. On March 11, 2002, Bausch & Lomb s senior debt and short-term debt ratings were downgraded. Although Bausch & Lomb emphasized at that time it was not facing any issues with respect to liquidity, any such issues that impact their ability to pay their accounts with us could adversely impact future revenues. In addition, if present and future customers terminate their purchasing arrangements with us, significantly reduce or delay their orders,

or seek to renegotiate their agreements on terms less favorable to us, our business, financial condition, and results of operations will be adversely affected. If we accept terms less favorable than the terms of the current agreement, such renegotiations may have a material adverse effect on our business, financial condition, and/or results of operations. Furthermore, we may be subject to the perceived or actual leverage the customers may have given their relative size and importance to us in any future negotiations. Any termination, change, reduction or delay in orders could seriously harm our business, financial condition, and results of operations. Accordingly, unless and until we diversify and expand our customer base, our future success will significantly depend upon the timing and size of future purchases by our largest customers and the financial and operational success of these customers. Product revenue in the future may continue to be adversely impacted by economic uncertainties associated with the Turkish market.

The loss of any one of our major customers or the delay of significant orders from such customers, even if only temporary, could reduce or delay our recognition of revenues, harm our reputation in the industry, and reduce our ability to accurately predict cash flow, and, as a consequence, could seriously harm our business, financial condition, and results of operations.

We, through our distributors, distribute ORTHOVISC in territories such as Canada, U.K., Spain, Portugal, Turkey, Israel and Greece. Marketing efforts in these countries have been and may continue to be negatively affected by the lack of pre-market approval from the FDA. We cannot assure you that past ORTHOVISC sales levels will be maintained or that sales will occur at all in these countries.

**ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

As of June 30, 2003, the Company did not participate in any derivative financial instruments or other financial and commodity instruments for which fair value disclosure would be required under SFAS No. 107. All of the Company s investments consist of money market funds and commercial paper that are carried on the Company s books at amortized cost, which approximates fair market value. Accordingly, the Company has no quantitative information concerning the market risk of participating in such investments.

***Primary Market Risk Exposures***

The Company s primary market risk exposures are in the areas of interest rate risk and foreign currency exchange rate risk. The Company s investment portfolio of cash equivalent and short-term investments is subject to interest rate fluctuations, but the Company believes this risk is immaterial due to the short-term nature of these investments. The Company s exposure to currency exchange rate fluctuations is specific to certain sales to a foreign customer and is expected to continue to be modest. The impact of currency exchange rate movements on sales to this foreign customer was immaterial for the quarter and six months ended June 30, 2003. Currently, the Company does not engage in foreign currency hedging activities.

**ITEM 4. CONTROLS AND PROCEDURES**

*Disclosure Controls and Procedures.* As required by Securities Exchange Act Rule 13a-15, the Company carried out an evaluation under the supervision and with the participation of the Company s management, including the Company s Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of the Company s disclosure controls and procedures, as of the end of the period covered by this report.

Based upon their evaluation, the Chief Executive Officer and Chief Financial Officer concluded that the Company s disclosure controls and procedures are effective to ensure that material information relating to the Company required to be included in this Quarterly Report on Form 10-Q is made known to them by others within the Company on a timely basis.

The Company is currently are in the process of further reviewing and documenting its disclosure controls and procedures and may from time to time make changes aimed at enhancing their effectiveness and to ensure that its systems evolve with its business.

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

**PART II: OTHER INFORMATION**

**Item 1. Legal Proceedings**

See Note 8, Legal Matters of the consolidated financial statements. The description of such matters is incorporated herein by reference to such financial statements.

**Item 4. Submission of Matters to a Vote of Security Holders**

On June 4, 2003, we held our 2003 Annual Meeting of Stockholders. At our annual meeting, stockholders were asked to consider two proposals:

1. to elect two (2) Class I Directors, each to serve until the 2006 Annual Meeting of Stockholders and until their respective successors are duly elected and qualified; and

2. to approve the Anika Therapeutics, Inc. 2003 Stock Option and Incentive Plan authorizing the issuance of up to 1,500,000 shares of Common stock.

With respect to proposal 1, Joseph L. Bower and Eugene A. Davidson, Ph.D., were nominated as Class I Directors of Anika. Drs. Bower and Davidson each received 9,410,540 shares voted in favor of his election and 180,323 votes were withheld. Drs. Bower and Davidson were therefore elected as Class I Directors. Samuel F. McKay and Harvey S. Sadow, Ph.D. (Class II Directors), and Steven E. Wheeler and Charles H. Sherwood, Ph.D. (Class III Directors) continued to serve their respective terms after the Annual Meeting.

With respect to proposal 2, the Board of Directors adopted the 2003 Stock Option and Incentive Plan for officers, employees, independent directors and other key person of Anika and its subsidiaries, subject to the approval of the 2003 Stock Option and Incentive Plan by our stockholders. The 2003 Stock Option and Incentive Plan received 3,519,291 shares voted in favor of the proposal, 1,320,972 shares voted against the proposal and 39,699 shares abstained. The Stock Option and Incentive Plan was therefore approved by our shareholders.

**Item 6.** **Exhibits and Reports on Form 8-K**

(a)

| Exhibit No. | Description |
|---|---|
| (3) | Articles of Incorporation and Bylaws: |
| 3.1 | Amended and Restated Articles of Organization of the Company, (incorporated herein by reference to Exhibit 3.1 to the Company s Registration Statement on Form 10 (File no. 000-21326), filed with the Securities and Exchange Commission on March 5, 1993). |
| 3.2 | Certificate of Vote of Directors Establishing a Series of Convertible Preferred Stock, (incorporated herein by reference to Exhibits to the Company s Registration Statement on Form 10 (File no. 000-21326), filed with the Securities and Exchange Commission on March 5, 1993). |
| 3.3 | Amendment to the Amended and Restated Articles of Organization of the Company, (incorporated herein by reference to Exhibit 3.1 to the Company s quarterly report on Form 10-QSB for the period ended November 30, 1996, (File no. 000-21326), filed with the Securities and Exchange Commission on January 14, 1997). |
| 3.4 | Certificate of Vote of Directors Establishing a Series of a Class of Stock, (incorporated herein by reference to Exhibit 3.1 of the Company s Registration Statement on Form 8-AB12 (File no. 001-14027), filed with the Securities and Exchange Commission on April 7, 1998). |
| 3.5 | Amendment to the Amended and Restated Articles of Organization of the Company, (incorporated herein by reference to Exhibit 3.1 to the Company s quarterly report on Form 10-QSB for the quarterly period ending June 30, 1998 (File no. 001-14027), filed with the Securities and Exchange Commission on August 14, 1998). |
| 3.6 | Amendment to the Amended and Restated Articles of Organization of the Company, (incorporated herein by reference to Exhibit 3.3 of the Company s quarterly report on Form 10-Q for the quarterly period ending June 30, 2002 (File no. 000-21326), filed with the Securities and Exchange Commission on August 14, 2002). |
| 3.7 | Amended and Restated Bylaws of the Company, (incorporated herein by reference to Exhibit 3.6 to the Company s quarterly report on Form 10-Q for the quarterly period ended June 30, 2002 (File no. 000-21326), filed with the Securities and Exchange Commission on August 14, 2002). |
| (4) | Instruments Defining the Rights of Security Holders |
| 4.1 | Shareholder Rights Agreement dated as of April 6, 1998 between the Company and Firstar Trust Company, (incorporated herein by reference to Exhibit 4.1 to the Company s Registration Statement on Form 8-A12B (File no. 001-14027), filed with the Securities and Exchange Commission on April 7, 1998). |
| 4.2 | Amendment to Shareholder Rights Agreement dated as of November 5, 2002 between the Company and American Stock Transfer and Trust Company, as successor to Firstar Trust Company, (incorporated herein by reference to Exhibit 4.2 to the Company s quarterly report on Form 10-Q for the quarterly period ended September 30, 2002 (File no. 000-21326), filed with the Securities and Exchange Commission on November 13, 2002). |

| | | |
|---|---|---|
| | (10) | Material Contracts |
| * 10.35 | | Change in Control, Bonus and Severance Agreement dated June 9, 2003 by and between the Company and Francesco (Frank) J. Luppino. |
| | (11) | Statement Regarding the Computation of Per Share Earnings |
| 11.1 | | See Note 4 to the Financial Statements included herewith. |
| | (31) | Rule 13a-14(a)/15d-14(a) Certifications |
| * 31.1 | | Certification of Charles H. Sherwood, Ph.D. |
| * 31.2 | | Certification of William J. Knight |
| | (32) | Section 1350 Certifications |
| ** 32.1 | | Section 1350 Certification of Charles H. Sherwood, Ph.D. and William J. Knight |

* Filed herewith

** Furnished herewith

(b) Reports on Form 8-K:

The Registrant filed the following Current Report on Form 8-K during the quarter ended June 30, 2003:

1. Current Report on Form 8-K filed May 6, 2003, attaching a press release announcing financial results for the first quarter of 2003 pursuant to Item 12 - Results of Operations and Financial Conditions in accordance with the interim guidance provided by the SEC pursuant to SEC Release No. 33-8216 and 34-47583.

**SIGNATURES**

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

ANIKA THERAPEUTICS, INC.

August 14, 2003

By: /s/ William J. Knight
William J. Knight
*Chief Financial Officer and Treasurer*
(Principal Financial Officer and Accounting Officer)